

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

Improved Access. Improved Services.
Better Health Outcomes.



Annual Report: Program Year 2

October 2012–September 2013



USAID
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SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

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About SIAPS

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

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ACRONYMS AND ABBREVIATIONS

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

MOF	Ministry of Finance
MoH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare
MOHSS	Ministry of Health and Social Service
MRA	Medicines Regulatory Authority
NDP	National Drug Policy
NDRA	National Drug Regulatory Authority
NHTC	National Health Training Center
NMCP	National Malaria Control Program
NMRC	Namibia Medicines Regulatory Council
NTP	National Tuberculosis Program
PEPFAR	President's Emergency Plan for AIDS Relief
PMDT	programmatic management of drug-resistant TB
PMI	President's Malaria Initiative
PMTCT	prevention of mother to child transmission
PR	primary recipient
PTC	Pharmaceutical and Therapeutics Committee
RDT	rapid diagnostic test
RH	reproductive health
SACU	South African Customs Union
SADC	South African Development Community
SCM	supply chain management
SCMP	Supply Chain Management Portal
SIAPS	Systems for Improving Access to Pharmaceuticals and Services [Program]
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems [Program]
TB	tuberculosis
TDF	Tropical Disease Foundation
TOR	terms of reference
TOT	training of trainers
VPP	Voluntary Pooled Procurement
WHO	World Health Organization
XDR	extensively drug-resistant tuberculosis
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis
TIPC	Therapeutics Information and Pharmacovigilance Center
TOR	terms of reference
TOT	training of trainers
VPP	Voluntary Pooled Procurement
XDR-TB	extremely drug resistant tuberculosis

INTRODUCTION



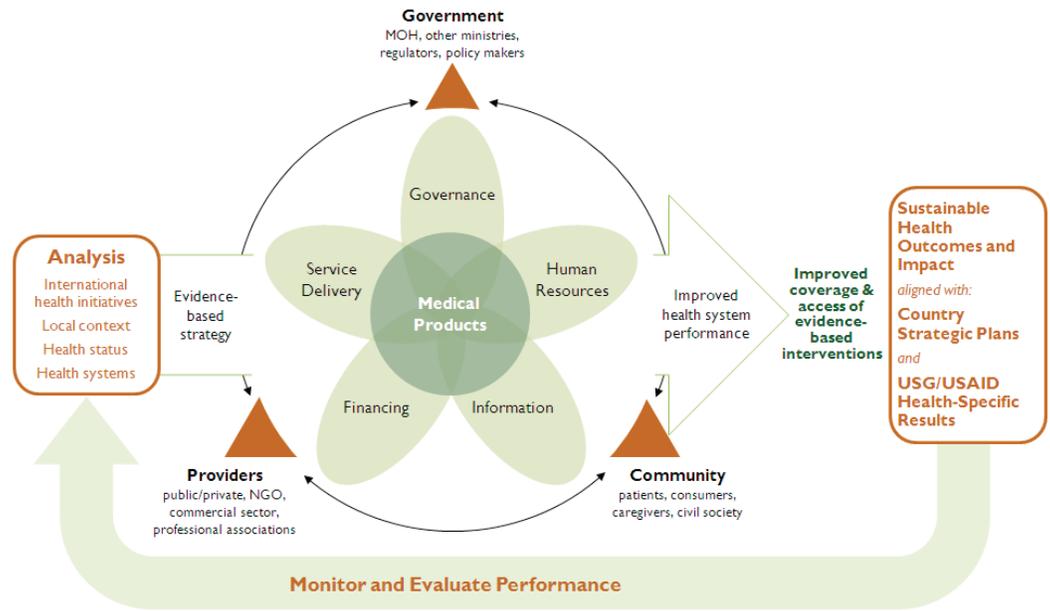
The **SIAPS GOAL** is to assure the *availability of quality* pharmaceutical products and *effective* pharmaceutical services to achieve desired health *outcomes*.

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

The availability of pharmaceuticals at reduced prices does not automatically lead to access to medicines. Even when medicines are available, they are not always prescribed, dispensed, or used appropriately. To ensure good health worldwide, governments must create sound, efficient health systems that can provide effective disease prevention and treatment for all. 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 takes a holistic approach that looks beyond product availability to include other essential

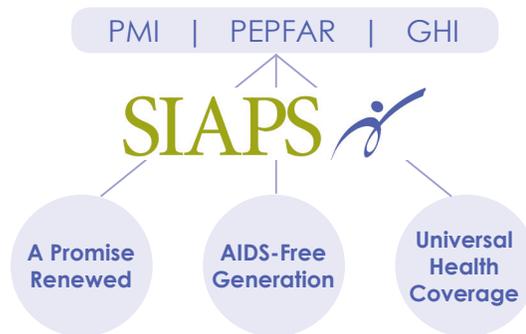
access components such as the availability of quality pharmaceutical services, ensuring rational use for improved health outcomes, and the ability of the patient to access both products and services.

SIAPS Pharmaceutical System Strengthening Framework



SIAPS provides next generation technical leadership and assistance to developing countries in pharmaceutical system strengthening with a deliberate focus on patient-centered services and health outcomes for health areas including HIV and AIDS, malaria, maternal and child health (MCH), tuberculosis (TB) and neglected tropical diseases (NTDs). The SIAPS technical approach emphasizes Global Health Initiative (GHI) principles, especially country ownership, health system strengthening, capacitating local governments and organizations, sustainability, and improving metrics and monitoring and evaluation (M&E). Toward this end, the SIAPS framework and result areas reflect the dynamic relationships among five health systems building blocks: governance, human resources, information, financing, and service delivery, with a pharmaceutical product overlay that guides technical content.

As a strategic partner to the US Government’s commitments to “A Promise



Renewed,” an AIDS-free generation, and universal health coverage, SIAPS uses platforms presented by funding through the President’s Malaria Initiative (PMI), the President’s Emergency Plan for AIDS Relief (PEPFAR), and other USAID streams to accelerate the advancement of these goals.

SIAPS works with partners globally and nationally to improve access to and use of life-saving medicines for all, including women and children. SIAPS’ efforts address increasing capacity for pharmaceutical management for integrated management of childhood illness at facility and community levels. SIAPS works with international organizations and participates in partner working groups to ensure that pharmaceutical care is included in international guidance on best practices, provide guidance

on regulatory and policy issues, increase global awareness of the barriers to essential MCH medicines and supplies, and assist national stakeholders in developing innovative approaches to addressing these barriers in their countries. These activities help accelerate the decline in child and maternal mortality and contribute to the 3.5 million children's lives that must be saved between 2013 and 2015 in order to meet Millennium Development Goal 4¹.

Working towards an AIDS-free generation, SIAPS helps countries expand access to HIV diagnosis, care, and treatment by helping develop efficient procurement, quantification, distribution, and prescribing and dispensing practices for antiretrovirals (ARVs), HIV test kits, and other HIV and AIDS-related essential medicines and supplies. SIAPS helps countries update policies and supports regulatory authorities to ensure that ARVs and diagnostics are properly registered and meet efficacy, quality, and safety standards. SIAPS designs interventions to specifically help scale up antiretroviral treatment (ART) programs, which in turn will strengthen the pharmaceutical management system for all medicines and supplies and support integration of supply and patient services.

SIAPS' work underscores the importance of equitable access to medicines and pharmaceutical services which supports the goal of attaining universal health coverage. Many SIAPS country programs have participated in local and cross-country dialogues about gaps in pharmacy benefits management and the role medicine benefits would have as part of universal health coverage. As SIAPS moves forward in the upcoming program years, it will remain firmly committed to doing its part toward the goal of universal and equitable health care for all.

SIAPS generates measurable results that demonstrate improved cost-efficiencies and contributions to sustainable health systems strengthening that are clearly linked to health outcomes. This is attained through the following IRs:

- Intermediate Result 1: Pharmaceutical Sector Governance Strengthened
- Intermediate Result 2: Capacity for Pharmaceutical Management and Services Increased and Enhanced
- Intermediate Result 3: Information for Decision-Making Challenges in the Pharmaceutical Sector Addressed
- Intermediate Result 4: Financing Mechanisms Strengthened to Improve Access to Medicines
- Intermediate Result 5: Pharmaceutical Products and Services Improved to Achieve Health Outcomes

SIAPS achieves these through its network of staff in the United States and country offices, as well as its core and resource partners. SIAPS is currently operational in 21 countries. Its country teams work directly with Missions and local partners to deliver results that are locally appropriate and sustainable. They are supported by a country program team at headquarters that ensures that quality work plans and reports are delivered on time, mobilizes technical and other resources, and

1 Committing to Child Survival: A Promise Renewed Progress Report 2013, New York, United Nations Children's Fund (UNICEF), September 2013, p. 3.

liaises with USAID/Washington, other MSH technical units, and other partners. The SIAPS core technical team provides cross-cutting and specialized technical support to all country and health-element portfolios that assure the program-wide application of best practices and lessons learned. They also focus on operational research and comparative analysis that contributes to the body of knowledge and enhances technical leadership. Our health-element focal persons and their staff liaise directly with the health-element leads for malaria, TB, MCH, and reproductive health (RH) and family planning 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, pharmacoconomics and epidemiology, laboratory strengthening, mission sector coordination, research and evaluation, operations research, and management information systems.

YEAR 2 HIGHLIGHTS



In fiscal year (FY) 2013, SIAPS continued to advance its goal of assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. The program worked with local counterparts and partners in 21 countries, including 2 regional programs in the Latin American states. SIAPS welcomed 3 new countries—Ukraine, Uzbekistan, and Turkmenistan—and closed out Brazil and Liberia. This year, we focused on intensifying advocacy efforts to advance the global agenda in key areas of health and pharmaceutical services; applying our technical leadership to create replicative solutions through research, technical services, documentation, and information sharing; intensifying data analyses and use for advocacy and decision making; optimizing integration across tools and systems; strengthening country supply chains to respond to immediate and long-term needs for access to medicines; and strengthening our support to field missions by consolidating and refining systems for program management, including M&E.

A Promise Renewed

SIAPS has contributed to efforts to reduce childhood mortality by two-thirds by 2015 by improving access to affordable, high-quality oral rehydration salts and zinc products for diarrhea, access to and rational use of amoxicillin for pneumonia, and access to treatment for malaria. At the global level, SIAPS actively participated in

the Pneumonia and Diarrhea Working Group, formed to support the UN Commission on Life-Saving Commodities for Women and Children, as well as in other initiatives such as the Community Case Management Task Force, whose objective is to increase access to life-saving interventions for children. SIAPS also supported governments and other key stakeholders to implement community case management (CCM), including assisting in budgeting and planning for implementation, training and supervision of providers, and strengthening pharmaceutical management for CCM. In Bangladesh, Burundi, Democratic Republic of Congo (DRC), Guinea, and Mali, SIAPS works to support procurement of essential medicines, integrated management of childhood illnesses, and health worker capacity building (especially in community case management and introduction of new MCH technologies); to help improve access to and use of life-saving medicines for women and children; and to accelerate the decline in child and maternal mortality.

Creating an AIDS-Free Generation

With PEPFAR funds in ten countries and TB funds in nine countries, SIAPS made significant contributions toward creating an AIDS-free generation. SIAPS support to TB and HIV and AIDS commodities quantification strengthened PEPFAR supply chains in South Sudan, Cameroon, Swaziland, and Tajikistan, and averted major stock-out of TB drugs in the Philippines. Through pharmacovigilance activities in Namibia, Swaziland, and Ukraine, SIAPS contributed to improvements in patient safety and reductions in HIV/TB co-morbidity and mortality. In South Africa, SIAPS interventions have not only helped scale up ART programs, but have strengthened the pharmaceutical management system for a wider range of medicines and supplies and supported integration of supply and patient services. The pharmaceutical leadership development program (PLDP) has contributed to results as systemic as increased adverse drug events (ADEs) reporting in certain districts, improved compliance with National Core Standards for many pharmacies at primary health care facilities, fewer chronic repeat prescriptions containing inappropriately prescribed medicine, less expired stock in numerous clinics, and projected cost savings of 680,561.65 US dollars (USD) per 100,000 patients per year on an angiotensin-converting enzyme (ACE) inhibitor. At the same time, SIAPS continued to provide leadership in global TB initiatives by working with the Stop TB Partnership, Global Drug Facility (GDF), UNITAID, and the World Health Organization (WHO); by conducting two multi-stakeholder regional TB conferences for Africa and Europe; by being named the training “partner of choice” for Stop TB and WHO; and by rolling out QuanTB, a system for early warning and stock-out detection. The tool, which has been endorsed by Stop TB for use by the GDF, allows users to modify items, such as treatment regimens, buffer stock, and lead time, to reflect the local environment and help guarantee that shelves are always stocked with quality medicines.

Technical Leadership

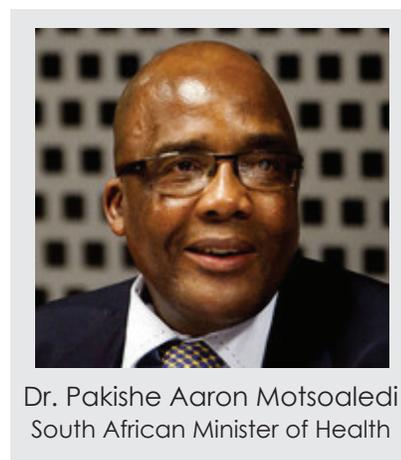
We continued to contribute to technical leadership by disseminating information at conferences and increasing the knowledge base in our key areas of expertise. We contributed to the African Medicines Regulatory Harmonization Technical Working Group; People that Deliver Initiative; Global Health Supply Chain Summit; the International Association of Public Health Logisticians Ad Hoc Workgroup on Developing a Global Regulatory Curriculum initiated by the US Food and Drug Administration (FDA) Office of Strategy, Partnerships and Analytics; the

Regulatory Affairs Professional Society with whom we held a meeting on regulatory capacity development in low- and middle-income countries. The meeting discussed the challenges and the need for development of core competencies to support regulatory systems strengthening. We conducted groundbreaking pharmacovigilance studies and developed recommendations for strengthening regulatory systems in several countries, and supported them in setting up pharmacovigilance systems. We contributed to the seminal conference on “Medicines as Part of Universal Health Coverage (UHC): Starting a Dialogue” in June 2013.

We have collaborated with WHO on key standard-setting events and documents—launch of the WHO Renewed Partnership Program for strengthening pharmaceutical systems and improving access to quality medicines in African, Caribbean, and Pacific (ACP) countries; the Technical Briefing Seminar on Pharmaceutical Policy held by WHO/Geneva in April; and the WHO/Essential Medicines Programme (EMP) global meeting for WHO country and regional advisors held in Geneva in September 2013. SIAPS wrote the supply management section of the *WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for the Treatment and Prevention of HIV Infection* launched on June 30, 2013. We launched the WHO portal for the documentation and dissemination of experiences, tools, approaches, and lessons learned in pharmaceutical management, developed with technical and financial support from SIAPS. The portal has been demonstrated at the regional WHO meetings in Geneva to begin the public rollout and the portal has been publicized on the e-Drug email list. We significantly advanced the development of the E-Learning module on good governance in pharmaceutical systems for USAID and other users with Internet access.

Tools and Guidelines

SIAPS’ publications help build capacity of facility staff, program managers, and policy makers so that systems and services for optimizing health care delivery are improved. In FY 2013, SIAPS published a nine-module document on infection control—*Infection Control (Self) Assessment Tool (ICAT) for Primary Health Care (PHC) Facilities*. The ICAT was recently endorsed by the South African Minister of Health. The endorsement signifies the National Department of Health’s (NDoH) ownership of the ICAT as a national tool to be used across all facilities. We made significant progress in developing an accreditation framework for in-service education with our partner, the Accreditation Council for Pharmacy Education (ACPE). We contributed to the development of the procurement and supply management tool-kit concept paper as a member of the elimination of mother-to-child transmission of HIV Interagency Task Team. We published and disseminated the manual *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators*. We revised and disseminated the *Preservice Curriculum to Incorporate Rational Medicine Use Topics: A Guide*. In collaboration with UNITAID, we initiated development of a framework to highlight adequate procurement practice requirements. The framework will provide guidance to UNITAID grantees, implementing partners, and other entities on how to conduct pharmaceutical procurements. We made progress in developing a framework and metrics for describing and measuring the contributions of pharmaceutical systems strengthening interventions to overall health systems strengthening. In addition, we enhanced our tools and software to facilitate their use across program elements. We strengthened management of core SIAPS software; provided enhancements to e-TB Manager for universal data exchange via an application programming interface for optimal data exchange capabilities; and initiated an upgrade of the Pharmadex registration module.



Program Management

Focus was also applied to strengthen SIAPS internal management systems to optimize results. We organized leadership development trainings for country program directors (CPDs) and their deputies to enhance their capacities to develop, implement, monitor, and report on SIAPS technical activities, and complemented this with an online learning and collaboration tool to encourage continued education and engagement of the CPDs in the field. We conducted a global meeting that enabled SIAPS global and country programs to consolidate understanding of the project, its global intermediate results, and its various country adaptations; review implementation experience since its inception; and jointly discuss strategies for advancing the program's results in the coming year and beyond. We made enhancements to the Newdea reporting tool to facilitate improved reporting, especially on indicators, and increased our utilization of SAVIOM for technical resource planning and allocation.

In August 2012, the SIAPS program website (www.siapsprogram.org) was launched. This website provides information on the broad range of SIAPS program elements, countries, approaches, tools, and implementation stories. The site is an important element in engaging our clients, recipients, and the general public with news on our work, reports on our results, and announcements of major events. SIAPS also has a Facebook page and Twitter feed to reach new audiences on these platforms on <https://www.facebook.com/SIAPSProgram> and https://twitter.com/SIAPS_Program.

SIAPS Countries and SIAPS IRs in the Year 2 Work Plan

COUNTRY	IR1	IR2	IR3	IR4	IR5
Africa					
Angola	•	•	•		•
Burundi	•	•	•		•
Cameroon	•	•	•	•	
Democratic Republic of Congo	•	•	•		•
Ethiopia	•	•	•	•	•
Guinea	•	•	•		•
Lesotho	•	•	•	•	
Liberia		•	•		•
Mali	•	•	•	•	•
Mozambique	•	•	•	•	•
Namibia	•	•	•	•	•
South Africa	•	•	•	•	•
South Sudan	•	•	•		•
Swaziland	•	•	•		•
Asia and Middle East					
Bangladesh	•	•	•		•
Philippines		•	•		•
Europe and Eurasia					
Turkmenistan and Uzbekistan			•		
Ukraine	•	•	•		•
Latin America and the Caribbean					
Dominican Republic	•	•	•		•
Amazon Malaria Initiative	•		•		•
Total Countries	17	18	20	7	17

HIGHLIGHTED ACHIEVEMENTS

IR 1: PHARMACEUTICAL SECTOR GOVERNANCE STRENGTHENED



SIAPS APPROACH: Establishing transparent management systems grounded in policies based on best practices, legislation supported by the rule of law, and regulation supported by appropriate technology and capacity.

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

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

Over the past year, a number of SIAPS country programs have made great progress in strengthening the pharmaceutical governance of their countries.

PHARMACEUTICAL REGISTRATION, LICENSING, AND MEDICINE QUALITY

National governments must effectively register and track pharmaceutical products to ensure that they are readily available and safe. When countries have weak medicine registration systems—backlogs of drug registration applications, inefficient drug testing systems, and incomplete data on suppliers and products—they can waste millions of dollars and put millions of people at risk of using unsafe and low-quality medicines. Effective drug registration and licensing depends on appropriate legislation with strong administrative structures ensuring access to effective and safe medicines. The following are examples of how SIAPS is working to strengthen pharmaceutical registration, licensing, and medicine quality.

- » In the **Democratic Republic of the Congo (DRC)**, there has been insufficient regulation in the pharmaceutical sector. This led to a large number of unregistered and substandard medications; for example, in 2010, it was estimated that 40 percent of artemisinin-based combination therapies (ACTs) for malaria treatment on the Kinshasa market were substandard. Building on the work accomplished under SPS, SIAPS has strengthened the National Drug Regulatory Authority (NDRA) and the Directorate of Pharmacy and Medicines (DPM) to improve its registration procedures, increase the rate at which medicines are registered, and automate the medicine registration process. In 2010, the medicine regulatory database contained only 200 registered products, most with incomplete information. To date, under SPS and SIAPS, 1,479 pharmaceuticals have been registered (over 120 percent of the target number to be registered for the year) and the list of registered medicines is publicly disseminated and posted to all provincial and health district pharmacist inspectors to assist them in monitoring medicines circulating in the local markets. There is no longer a backlog of applications for drug registration; the number of files processed at future sessions now depends solely on the number of new applications for registration.

SIAPS proposed, and the NDRA accepted, that membership to the registration committee is extended to individuals outside the DPM (universities, professional societies, etc.). This has improved transparency and credibility of the registration process. In the past, SIAPS has provided financial assistance to the DPM to hold the quarterly drug registration meetings. As of this program year, MoH now includes regular funding in its budget for the quarterly drug registration meetings. SIAPS support to the NDRA/DPM has graduated from full-fledged financial and technical assistance to one where SIAPS' physical presence is no longer needed at these meetings, and technical assistance is provided solely at the NDRA's request.

Country Ownership

The NDRA and Directorate of Pharmacy and Medicines have taken complete ownership and control of the drug registration process.

- » In **South Africa**, access to pharmaceutical services is limited in underserved areas. Vacancy rates for pharmaceutical personnel are generally high in most provinces, with pharmacists, doctors, and nurses categorized as scarce resources. Increasing the number of health personnel that are authorized to dispense medicines will help to increase access to pharmaceutical services for communities. SIAPS conducted an analysis of the South African legislation that governs pharmacy ownership and licensing. Based on the findings, SIAPS

provided technical assistance to the NDoH on the legislative requirements for the designation of private providers, prescribing rights of nurses and pharmacists, dispensing of nurses' prescriptions by pharmacists, supervision of nurses employed by private providers, and requirements for nurses to hold a dispensing license. With this support and following consultations with officials in the Licensing Unit of the NDoH, the approach used to award pharmacy licenses was revised to be more robust and in line with the principles of good governance. The new criteria for licensing are based on population per sub-district and support the intention of the National Drug Policy to improve access of communities to pharmaceutical services.

- » In **Namibia**, SIAPS worked with the Namibia Medicines Regulatory Council (NMRC) to develop and implement post-market surveillance as one of the key requirements of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and to strengthen in-country inspection and quality assurance functions as mandated in the Medicines and Related Substances Control Act of 2003. Post-market surveillance is crucial to quantify recognized adverse drug reactions (ADRs), identify unrecognized ADRs, and evaluate the effectiveness of medicines to decrease mortality and morbidity associated with medicine-use-related adverse events. SIAPS helped the NMRC develop a data collection and reporting system for in-country post-marketing surveillance of the quality of ARVs and other essential medicines. As a result, there is now a mechanism for health professionals to report on ADRs. The Namibian Quality Surveillance Laboratory is liaising with the WHO-accredited Center for Quality Assurance of Medicines in South Africa to test samples of suspected poor-quality medicines. This collaboration is recent, but to date, 12 samples of suspected poor-quality medicines have been sent to the laboratory for analysis, of which 3 failed quality checks. This information will strengthen the NMRC in the recall of these medicines.

STRATEGIC PLANNING

Promoting good governance in the pharmaceutical sector requires long-term strategies through which best practices and evidence-based decision making are actively integrated into pharmaceutical systems. SIAPS supports a variety of strategic planning exercises in the majority of its program countries.

- » In **Swaziland**, SIAPS supported MoH in the revision of the National Pharmaceutical Policy and the development of the Swaziland Pharmaceutical Strategic Plan (SPSP), which sets out objectives, strategies, activities, and expected results after the implementation of all identified and prioritized policy components. The strategic plan was developed through a widely consultative approach to build consensus and foster ownership among the different stakeholders. In addition, SIAPS supported the costing of the SPSP implementation plan to facilitate resource planning, allocation, and mobilization by MoH. SIAPS also provided assistance in the pharmaceutical services baseline survey that was conducted to inform and facilitate the M&E of the SPSP implementation. The SPSP provides the overall roadmap for pharmaceutical services development in the health sector and has been approved by the Cabinet.

- » The **Burundi** SIAPS team worked closely with the National Malaria Control Program (PNILP) and WHO to develop the strategic plan for 2013–2017 in line with the National Health Development Plan for 2011–2015. The strategic plan is based on preliminary results of the malaria indicator survey published in 2013, recommendations of the malaria program review held in November 2011, and findings from the formative supervision conducted in 2012. The strategic plan defines objectives, key strategic interventions, activities, indicators, means of verification, budgets, and potential funding sources for the PNILP. The strategic plan is currently being validated by all Roll Back Malaria in-country stakeholders.
- » In the **Philippines**, SIAPS collaborated with the National TB Program (NTP) and the Philippines Information Management Services (IMS) to develop the M&E tool for the Integrated TB Information System (ITIS) which is the new Department of Health TB information management system based on eTB Manager (formerly used by PMDT). SIAPS has been working in collaboration with NTP and IMS to assist in the transition from eTB Manager to ITIS, including complete data migration. In addition to the transition, SIAPS supported the NTP and IMS in the development of the strategic implementation and financial plans for the 2013–2014 system rollout. SIAPS has also supported the National TB Reference Laboratory in the development of their strategic plan, which forms part of the foundation for the new Global Fund support.
- » In **Ukraine**, SIAPS worked with the State Service to revise the National TB Program (NTB) strategy for 2012–2016, specifically in the sections relating to rational medicine use, quantification, and pharmacovigilance.

Improving M&E

SIAPS helped develop the M&E tool for the Department of Health's new national Integrated TB Information System.

POLICIES AND PROCEDURES

Making sure that quality medicines and supplies are available requires improving pharmaceutical policies, enforcing compliance with policies and procedures, and addressing the regulatory system for the public and private sectors of the health system. SIAPS supports countries to develop, revise, and adopt a wide variety of policies and procedures that promote transparency and better health practices.

- » In **Burundi**, SIAPS supported MoH in the adoption of community Integrated Management of Childhood Illnesses (c-IMCI) and intermittent prevention treatment during pregnancy (IPTp) as priority interventions. Prior to this adoption, Burundi did not have a policy on c-IMCI or IPTp, which left many pregnant women and children vulnerable. Subsequently, SIAPS worked closely with World Relief to integrate management of diarrhea into existing tools and training modules in preparation for integrated case management of malaria and diarrhea at the community level.
- » In **Mali**, based on results of a logistics management information system (LMIS) assessment, SIAPS worked with MoH on the development of SOPs for medicines management at all levels, including CCM and supported a workshop for MoH and key stakeholders (including the Department of Pharmacy and Medicine; the central medical stores; Pharmacy Populaire du

Mali; NDoH; national disease programs; regional, district, and community health teams; USAID/Mali; WHO; nongovernmental organizations; and development partners) to map out the SOPs. A major outcome of the workshop was the decision to integrate community health workers (CHWs) into Mali's essential medicine information and logistics management system and to recognize CHWs as important actors at the operational level in addition to the community health center personnel.

- » In **Guinea**, with the support of SIAPS, the National Malaria Control Program (PNLP) and the Central Pharmacy of Guinea drafted a convention between the two parties to guide the storage, management, and distribution of PMI products to the regions. This agreement reflects the need to avoid emergency distributions due to frequent stock-outs and to encourage the smooth functioning of both the supply and demand sides (as represented by good reporting and product orders from facilities).
- » For the **Amazon Malaria Initiative**, the pharmaceutical management guidelines for malaria in primary health facilities were finalized and validated in Columbia and Bolivia.

Global Health Partnership

The majority of SIAPS countries have implemented activities in coordination with other implementing partners, country donors, and health initiatives.

Examples include:

- The development of a joint annual work plan for Roll Back Malaria partners in **Burundi**
 - Facilitation of interagency coordination committee meetings for logistics in **Angola**
 - Coordinated mechanisms for quantification in **Cameroon**
 - Coordinated implementing partners for the Supply Chain Technical Working Group in **Swaziland**
 - Collaboration with other implementing partners to guarantee access to contraceptives for the population in **Mali** during the governmental crisis
-
- » The SIAPS tool *Infection Control (Self) Assessment Tool (ICAT) for Primary Health Care Facilities* was published. This tool is based largely on the hospital ICAT, which was developed under the USAID-funded Rational Pharmaceutical Management Plus Program. Nosocomial infections are a serious issue, representing one of the most significant causes of morbidity and mortality in health care systems and consuming many scarce resources, especially in developing countries. Though much has been done to reduce the risk of these infections, the problem persists. Although most primary health care facilities have few or no beds and care is ambulatory in nature, infection prevention is still important to minimize or eliminate the risks of facility-acquired infections and assure quality patient care. Health facilities

and hospitals should have written infection control procedures and guidelines in place and should also be monitoring that these procedures are adhered to in both inpatient and ambulatory care settings. The nine modules in the ICAT form part of a standardized approach that uses rapid cycles of quality improvement, where the tool is used to identify problems and then specific indicators are used to monitor interventions. The tool includes the following modules: health facility information, employee health, cleaning the health facility, hand hygiene, waste management, isolation and standard precautions, labor and delivery, sterilization and disinfection of equipment, and preparation and administration of parenteral medications.

Three particular highlights from this program year that dynamically demonstrate the SIAPS approach to strengthening pharmaceutical governance are the APTS package of interventions being implemented in Ethiopia, the development of the Pharmacy Bill and Medicines Control Bill in Swaziland and the clofazimine procurement in the Philippines. The following pages provide detail on these SIAPS achievements.

Auditable Pharmacy Transactions and Services (APTS): Good Governance and Better Service Delivery

The US Agency for International Development (USAID)-funded Systems for Increasing Access to Pharmaceuticals and Services (SIAPS) Program has partnered with the Government of Ethiopia to bring a 100-year-old pharmaceutical management system into the 21st century. The Auditable Pharmacy Transactions and Services (APTS) is a package of data-driven interventions that ultimately result in a continuous supply of essential medicines, optimal budget utilization, and improved pharmacy services. The system has worked so well that in July 2011, the Amhara Region in Ethiopia legislated the implementation of APTS in every hospital throughout the region.

Transforming Ethiopia's Public Health System through Partnerships

During the past 20 years, Ethiopia's public health system has undergone a remarkable transformation. Although physicians are in short supply, the number of other health professionals such as health officers, nurses, midwives, and health extension workers have significantly increased in the past five years. Since 2003, the number of pharmacists has increased almost tenfold—from 172 to 1,343 in 2012. The number of pharmacy technicians has doubled from 1,171 to 2,029 during the same time period. Preventive, promotive, and curative health services have improved and access to health services has increased tremendously given the country's commitment to serving Ethiopia's largely rural population. Overall coverage in 2000 was estimated to be 89.6 percent, a 25.6 percent increase from 1996.¹ Although there is

still much work to be done, Ethiopia's public health system is moving forward to meet the needs of Africa's second largest country. One reason for Ethiopia's successful transformation is the importance the Government attaches to forging successful partnerships with donors and stakeholders.

The SIAPS program, and its predecessor program, Strengthening Pharmaceutical Systems (SPS), has forged a successful partnership with the Government of Ethiopia to transform its antiquated pharmaceutical system. USAID/SIAPS not only works with the Ministry of Health at the federal level, but with the Regional Health Bureaus and the Regional Finance and Audit Bureaus as well.

Transforming Ethiopia's Pharmaceutical System and Services

One of the most important areas of collaboration between the Government and SIAPS is making pharmaceutical transactions and services transparent and accountable. Up until recently, pharmaceutical records were based on a system developed 100 years ago and did not even remotely address the needs today's pharmaceutical practices. The system was so entrenched in the pharmaceutical sector that only after years of engagement and advocacy was there a consensus for change.

A breakthrough came in 2010 when SIAPS worked with the Ministry of Health to write

"APTS and DTC are the best opportunity and initiatives to improve facility level drug management and availability"

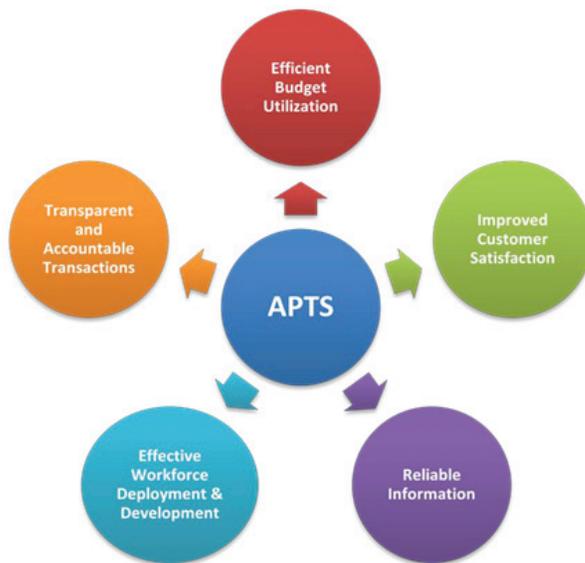
—His Excellency Dr. Kesetebirhan Admasu, Ethiopian Minister of Health

¹ WHO, Ethiopia Country Pharmaceutical Profile and NPO (2012)

the chapter on pharmacy services for the Hospital Reform Implementation Guidelines (EHRIG). To implement the new pharmacy standards laid out in EHRIG, SIAPS developed APTS—a series of interventions to modernize the way pharmacies do business. APTS ensured accountability and transparency at all points of pharmacy transactions, information management, finance, and services.

SIAPS piloted APTS at the Debre Marcos Hospital in the Amhara Region. SIAPS, in collaboration with the Amhara Regional Health Bureau, worked with pharmacy and accounting staff to completely revamp the old system through APTS to set up a comprehensive, data-driven system that links patient records, stock inventory, distribution, storage, and procurement. APTS can also be used to evaluate the services provided by the facility.

The following are some preliminary results from supervisory visits at the Debre Marcos Hospital:



- There is a new medicines list in use that takes into account the disease pattern and health needs of the catchment population.
- Implementing an ABC value analysis and identifying medicine use problems has made the procurement and use of medicines evidence-based.
- The percentage of medicines procured according to the hospital-specific medicines list increased from 35.4 percent

to 97.5 percent.

- Products both at the store and dispensary can now be physically inventoried continuously.
- Financial resources available for medicines procurement increased by 89.1 percent between June 2010/11 and June 2011/12 due to the high turnover of medicines and the substantial retention of income from medicines sales.
- Internal and external audit reports indicate that wastage of medicines due to misuse, theft, and pilferage has significantly decreased.
- Expiry of medicines was reduced dramatically. Since December 2011, expiry of medicines has consistently been below 2 percent, the most recent figure being 0.5 percent.
- The availability of indicator medicines has increased over time to 100 percent.
- A robust system that ensures transparent and accountable transactions is in place, enabling effective auditing.
- Outpatient pharmacies were reorganized and workflow and dispensing counseling services have improved.
- Improved patient satisfaction with services provided has reached 85 percent in 2012.
- Initiation of pharmaceutical care services for patients with chronic illnesses in a separate private counseling and dispensing room resulted in improved documentation and adherence to treatment.

Promoting National Ownership through Successful Partnerships

The Ethiopian Government has taken the concept of partnership to a level that promotes national ownership and, in turn, sustainability. Recognizing the power of collaborative partnerships to meet the challenges of development, the Government has structured

its Health Sector Development Program to maximize coordination with its partners and stakeholders, building on their collective strengths and resources. The Government of Ethiopia has succeeded in both driving the development of the country's health sector while embracing the assistance of the international community and domestic partners.

Today, USAID/SIAPS is scaling up the use of APTS in hospitals throughout other regions—including the Amhara, Tigray, Addis Ababa, Oromia, and the Southern Nations and Nationalities Peoples Region. It is expected that these regions will legislate APTS

implementation, following the precedent set by the Amhara Region. In 2013, the SIAPS Ethiopia team won an innovation award from Management Sciences for Health for its work in helping to transform Ethiopia's pharmacy sector.



Pharmacy accountant compiling daily summary in APTS

Regulating the Pharmaceutical Sector in Swaziland

Pharmaceutical regulatory systems ensure that medicines available for use are safe and effective. In Swaziland, the pharmaceutical sector's regulatory framework, based on antiquated legislation passed in 1929, fails to meet the needs of 21st century practice. This outdated legislation does not provide for effective regulation of the pharmacy services or for the import, export, manufacture, sale, advertising, or use of medicines in the country.

The private sector (including pharmaceutical wholesalers, retail pharmacies, private doctors, and logistics and distribution companies) imports medicines into the country from Southern African Customs Union (SACU) member countries as well as international sources. For imports from beyond the SACU region, import permits are required, which are issued by the Ministry of Finance. These medicines are not being tested for quality. The Ministry of Health does not have a list of pharmaceutical importers or a list of medicines imported into the country.

Increased Number of Counterfeit and Poor Quality Medicines

A number of recent reports indicate a wide availability of counterfeit and substandard medicines, particularly in countries in the Southern African Development Community Region, which have inadequate regulations and limited regulatory enforcement.¹ Counterfeit and substandard medicines are detrimental to the public health and result in an increased burden of disease due to therapeutic failure, exacerbation of disease, and resistance to medicines. These medicines can even lead to

death. In addition, substandard medicines erode public confidence in the health system and in health professionals.

In recent years, there has been increased incidence of counterfeit and prohibited medicines being smuggled into neighboring countries through Swaziland as noted by the MoH and the Swaziland Revenue Authority Customs. In a report on the assessment of medicines regulation in 28 sub-Saharan African Countries from 2002 to 2007, WHO emphasized the importance of reviewing and adapting the legal framework for medicines regulation in accordance with international best practices to ensure patient health and safety.

Updating the Legislative Framework

To address the gaps in the regulation of the pharmaceutical sector and control of medicines, the USAID-funded Strengthening Pharmaceutical Systems (SPS) Program supported Swaziland's MoH, collaborated with the WHO Country Office, in reviewing the National Pharmaceutical Policy. A key priority was updating the legislation regulating the pharmaceutical sector.

As a result of the review, an extensive participatory stakeholder consultation process took place to draft new legislation—the Medicines and Related Substances Control Bill, which regulates medicines, and the Pharmacy Bill, which regulates the pharmacy profession.

Following submission to the Attorney General's office, SIAPS continued the work initiated during the SPS program and provided assistance in advocating for passage of the bills. In September 2012, following the initial review, Pharmacy Bill no. 7 of 2012 and the

¹ Bulletin of the World Health Organization 84(9), 2006; Interpol Medical Products Counterfeiting and Pharmaceutical Crime, 2011

Medicines and Related Substances Control Bill no. 8 of 2012 were tabled before both Houses of Parliament.

Laying the Groundwork for Implementation

In September 2013, the Swaziland Parliament was dissolved by the King before the House or Senate could discuss the pending legislation. However, anticipating eventual passage of the legislation, SIAPS assisted in developing a Pharmaceutical Services Strategic Plan for 2012–2016. One of the strategic objectives of this plan is to prepare for establishing a Medicines Regulatory Authority (MRA) to ensure minimal delays in the enforcement of the new laws.

SIAPS worked with its Swaziland partners to begin developing a medicines listing/ registration database to register all medicines imported to and sold, and used in Swaziland.

SIAPS also participated in a joint operation between the MoH and Interpol to combat pharmaceutical crimes and ensure good pharmacy practice. The report from this operation will be used as one of the baseline tools to monitor the effectiveness of the implementation and enforcement of the legislation once enacted.

Conclusion

The process of drafting critically needed pharmaceutical legislation and shepherding the bill through the legislative process was an important learning experience for Swaziland stakeholders and partners. Although the parliament was dissolved, there is strong political will in the government to finalize passage of the legislation. SIAPS and its partners continue to take important steps to lay the groundwork for implementation of the new legislation through system strengthening and advocacy.

SUCCESS STORY

Timely Procurement of Clofazimine Prevents Stock-Outs

The Philippines is one of 27 countries worldwide that has high numbers of people with multidrug-resistant tuberculosis (MDR-TB). MDR-TB is tuberculosis that does not respond to or is resistant to the two most commonly used drugs in the current four-drug (first-line) regimen. MDR-TB is treated with second-line drugs, which are administered for two years or longer, require daily injections,

XDR-TB is resistant to first and second line drugs, so treatment options are extremely limited

and often have severe side effects. Extensively drug-resistant (XDR) TB is defined as TB that is resistant to some first-line drugs and at least

one of the three injectable second line drugs (capreomycin, kanamycin, and amikacin). With the increasing incidence of XDR-TB around the world, it is extremely important that new alternative treatment options are developed and accessible in these high burden countries.

In recent years, the Philippines National TB Program (NTP) has encountered cases of relapse during treatment with second-line TB medicines. These particular patients, who have undergone long treatment regimens with

second line anti-TB drugs, do not respond properly to the treatment, leading the NTP to believe that they have XDR-TB. To treat these patients, group of medicines with unclear efficacy to treat TB are used. These Group 5 drugs (as they are known) have not been often used to treat TB and their efficacy is unknown; many of them are expensive and access to them is limited. Among the Group 5 drugs, clofazimine, a drug that has been used to treat leprosy worldwide, has shown some positive results in several observational studies in treating MDR and XDR-TB. The Philippines NTP had limited stock of clofazimine, which they had acquired through the Tropical Disease Foundation (TDF), the previous Global Fund principal recipient.

Advocating for Clofazimine

When the Lung Center of the Philippines (LCP) took over management of the MDR and XDR programs, 78 patients were currently being treated for XDR-TB with clofazimine and 50 additional patients were waiting to be initiated on the treatment. To continue using clofazimine for XDR-TB, treatment approval from the TB Technical Working Group was needed and the LCP needed to initiate a new procurement of clofazimine from the Global Drug Facility (GDF), which they had never done.

SIAPS worked closely with LCP and all partners to present the case for continued treatment with clofazimine. Recommended dosage guidelines and methodology for use of clofazimine for MDR/XDR-TB patients were also prepared and presented. After the TB Working Group gave its approval, SIAPS supported the health care providers treating MDR and XDR-TB to meet a number of requirements for the clofazimine procurement:



A MDR/XDR-TB patient in the Philippines receives treatment

a national record of patients, national record of doctors' prescription requirements, and the submission of a signed waiver from the TB Working Group allowing the use of off-label clofazimine. These requirements had to be met and substantiation submitted to the GDF with the request that clofazimine be obtained from a sole source supplier.

After these hurdles were cleared, SIAPS followed up with the LCP and TB Working Group to expedite the clearance and release from customs of needed medications.

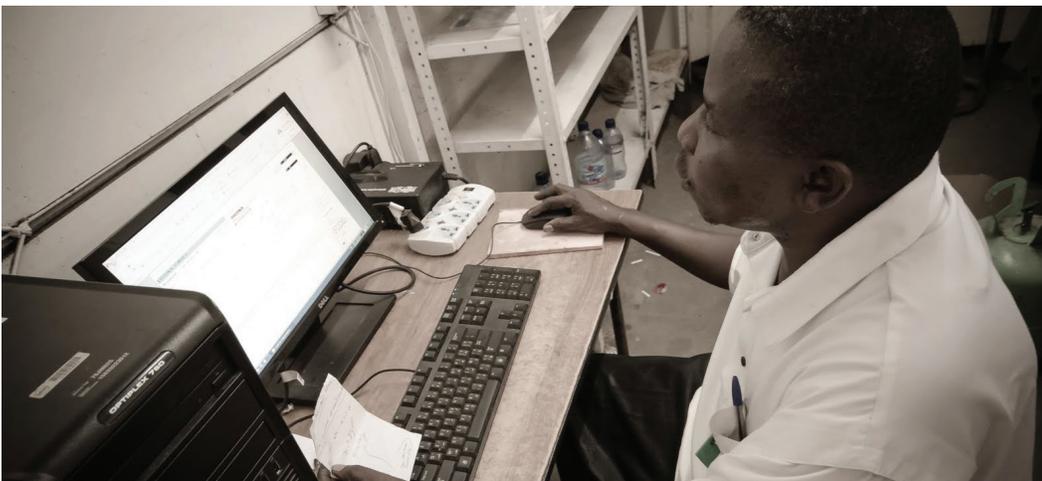
Advocacy Pays Off

In May 2013, just before the current clofazimine stocks were projected to run out, clofazimine was delivered to the Lung Center. Enough stock was received to continue the treatment of the current 78 patients as well as to initiate the additional 50 patients.

The stock-out of this important medicine was avoided by early planning and constant and regular follow up from all parties involved. Having an early alert system on the status of the medicine was crucial for the timely delivery of the drug. SIAPS played an important role in each step of the process guiding the program and ensuring that coordination was efficient to ensure uninterrupted supply of drugs.

HIGHLIGHTED ACHIEVEMENTS

IR 2: CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES INCREASED AND ENHANCED



SIAPS APPROACH: Work with stakeholders to assess the country's capacity to manage pharmaceuticals at all levels. Then, with consensus, identify areas for improvement and develop interventions to strengthen the system and build capacity.

Sustainable access to medicines and other health technologies critically relies on the availability of skilled workers to provide and manage pharmaceutical services and systems. SIAPS helps countries engage in comprehensive workforce planning to address challenges such as increasing demands, resource constraints, and health workforce policy reforms. This involves collecting and reporting data to help determine workforce needs, matching workforce and educational outcomes, and building a compelling case for funding posts in the public sector.

To increase pharmaceutical sector efficiency, SIAPS works with stakeholders to assess a country or programs capacity to manage pharmaceuticals, from the facility to the national level. Then, using a stakeholder consensus approach, we identify areas for improvement and develop long-term interventions to strengthen the system, such as building capacity among facility-level staff to track medicine consumption. Meanwhile, SIAPS provides short-term assistance when countries have immediate problems that threaten commodity security.

LEADERSHIP AND MANAGEMENT

Strong leadership, effective management, and transparent governance are the keys to country ownership and sustainability of the health and pharmaceutical systems. SIAPS works with stakeholders at every level to help them articulate a compelling vision for better pharmaceutical services and identify and remove any impediments to that vision by applying the practices of good leadership and management:

- Scanning the internal and external environment
 - Selecting and focusing on priorities
 - Aligning and mobilizing key stakeholders
 - Inspiring themselves and others to work to improve the health status of the population
- » In **South Africa**, continuing on work started under SPS, the Pharmaceutical Leadership Development Program (PLDP) is supporting numerous facilities throughout the country. Pharmacy managers in South Africa are often overwhelmed trying to address several daunting workplace challenges at once, such as making sure there is an adequate supply of pharmaceuticals, managing efficient quantification of needs, and ensuring the rational use of medicines. The PLDP presents a novel approach by combining pharmaceutical management knowledge and sound leadership practices to better equip pharmacy managers to respond to challenges in their workplace. PLDP is structured into five workshops which are held at monthly intervals. Working in teams, participants tackle one of their own workplace issues by applying the challenge model—previously developed by MSH—and other supporting tools. In working through the model, participants assess the current situation and identify opportunities; define their challenge and select priority actions; develop an action plan; implement their plan; and monitor and evaluate their progress toward achieving their desired result.

The SIAPS predecessor program, SPS, adapted the PLDP specifically for pharmacists and added sections on legislation, ethics, governance, financial management, and human resources. SIAPS has expanded the program from Gauteng Province to include pharmacists in Free State, Northern Cape, Eastern Cape, Western Cape, KwaZulu Natal, and North West. The expansion of the PLDP has resulted in several significant achievements including:

- Increased number of patients initiated on isoniazid; for example, the Dr. Ruth Mompati district team in North West worked at increasing the average number of eligible patients initiated on isoniazid preventive therapy at the Joe Morolong Memorial Hospital. The team trained health care providers on isoniazid preventive therapy guidelines and developed a patient information leaflet to facilitate patient awareness. The average number of patients initiated on isoniazid preventive therapy at the hospital increased from three to eight per month.
- Increased adverse drug events (ADE) reporting in certain districts of

Northern Cape; for example, eight months after completion of the PLDP, 45 percent of the facilities in the Frances Baard District were reporting ADEs, up from 26 percent.

- Increased access to chronic medications; for example, development of a referral system in Camdeboo Sub-District, Eastern Cape facilitated delivery of medicines supplied by Midlands Hospital to feeder clinics, thus enabling a larger number of clients easier access to medications for chronic conditions.
- Improved compliance with national core standards for many pharmacies at primary health care facilities in Free State, Western Cape, and KwaZulu Natal; for example, North West worked with 10 primary health care facilities on the development of SOPs, distribution of reference manuals, and building capacity in good pharmacy practice including medicine supply management, which increased compliance with national core standards from 33 percent to 77 percent.
- Fewer chronic repeat prescriptions containing inappropriately prescribed medicines; for example, an overall 53 percent reduction was observed at Imbalenhle Community Health Centre in KwaZulu Natal.
- Reduced expired stock in numerous clinics; for example, the value of expired stock was reduced from 3.4 percent to less than 0.5 percent of stock held in 6 of 11 clinics in Sisonke district, KwaZulu Natal.

Since inception, a total of 122 health facilities have successfully applied an approach for participatory and continuous performance improvement through the PLDP. The challenge model has been used to develop and implement 32 quality improvement initiatives with 67 percent of these attaining the desired measurable result. The PLDP has proven to be a viable option for enhancing the capacity of personnel for the provision of pharmaceutical services.

- » In the **Philippines**, inadequate capacity of NTP staff to manage pharmaceutical and laboratory services at the peripheral level continues to hamper the efficient and effective delivery of TB control services. SIAPS, in coordination with the NTP, implemented a workshop to strengthen the logistics capacity of NTP staff (nurse coordinators, laboratory coordinators, and regional supply officers) from all 17 regional offices. The workshop focused on improving management of medicines and laboratory commodities at the regional level.
- » In the **DRC**, SIAPS has been working with the provincial health authorities on the establishment of a regional distribution center (CDR) in Sud Kivu, the only province without a CDR. The CDR is the provincial-level pharmaceutical warehouse through which all health commodities purchased by PMI and other USAID funding must pass before distribution to the health facilities. The provincial government has agreed to provide land and, with SIAPS technical and financial assistance, the provincial medicines committee has finalized the TORs, organization, and functions of the board of directors and staff of the new CDR.
- » In **Ethiopia**, SIAPS supported experts at FMHACA in revising, formatting,

editing, and printing the second edition of the Ethiopian Medicines Formulary (EMF 2013 edition); 20,000 copies of EMF 2013 were printed and distributed to end users throughout the country. The formulary is expected to contribute toward improving prescribing and dispensing practices, promote the rational use of medicines, and contain antimicrobial resistance (AMR).

PRESERVICE AND IN-SERVICE TRAINING

Preservice curriculum reform and development and in-service training are cost-effective and sustainable interventions that leads to broader health system strengthening. They provide students and professionals with a critical foundation of knowledge and skills and allow them to continue to develop their competency to practice in the real world. Effective preservice training reduces the need for future large-scale and expensive in-service trainings. SIAPS works with a number of university and government training programs on the development of pharmaceutical systems strengthening curricula.

- » In **South Africa**, SIAPS works toward enhancing pharmacy human resource capacity by increasing the number of pharmacists and pharmacy support personnel. In collaboration with the Nelson Mandela Metropolitan University in Eastern Cape, SIAPS has provided a series of lectures and practical sessions on medicines supply management and pharmacy law ethics for BPharm students. In addition, SIAPS provided technical assistance in the development of curricula for the development of SOPs for pharmacy technical students; this is the first training of its kind for the new cadre of pharmacy support personnel in the country.
- » In **Namibia**, at the request of the Pharmacy Council of the Health Professions Councils of Namibia, SIAPS supported the University of Namibia (UNAM) School of Pharmacy and the National Health Training Center (NHTC) in planning and implementing its programs for BPharm students and pharmacy assistants. These programs are a prerequisite for the professional licensure and registration of pharmacists in Namibia by the Pharmacy Council. The need for improved standards and a comprehensive quality assurance framework for preservice pharmacy education became critical following the introduction of the bachelor's degree program and the recognition of the need to accredit the NHTC pharmacy assistant training program. SIAPS has provided significant contributions to the UNAM BPharm program, including the development of course modules on supply chain management. We also developed a module for the pharmacy assistant course at NHTC; preparing BPharm students for four-week rural work placements that provide students with hands-on experience; and supporting UNAM in transitioning the Department of Pharmacy to the School of Pharmacy. SIAPS has also supported staff advancement, development of teaching materials, and improvements in classroom- and workplace-based learning for the NHTC.
- » SIAPS developed a training course built on the QuanTB tool and early warning system in collaboration with the GDF. QuanTB is an electronic forecasting, quantification, and early warning tool designed to improve procurement processes, ordering, and planning for TB treatment. When used on a regular basis (e.g., monthly, quarterly), QuanTB serves as an

Additional SIAPS countries supporting preservice/in-service training

- In the **Dominican Republic**, 30 professionals completed the certified course on pharmaceutical management facilitated by SIAPS at the Santo Domingo Autonomous University.
- In **Bangladesh**, SIAPS is collaborating with the Engineering Staff College on the provision of in-service training on supply chain management for MoHFW officials.
- In **Ethiopia**, SIAPS designed and coordinated a Clinical Pharmacy/ Pharmaceutical Care course in collaboration with PFSA and Jimma University.
- In **Swaziland**, SIAPS is developing curricula for a Diploma in Pharmacy at the Southern African Nazarene University.

early warning mechanism, providing information on actual versus planned consumption, potential expiries, and stock-outs of medicines. This helps national programs plan for the phasing in and out of various medicines, reducing the risk of stock-outs, and ensuring that patients have continuous access to TB treatment. SIAPS implemented the first training in Almaty, Kazakhstan, with participants from Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, Turkmenistan, Russia, Moldova, and Azerbaijan. Participants were mainly NTP pharmacists/drug coordinators and the Global Fund principal recipient representatives in charge of quantification and supply planning.

» The SIAPS guidance document *Revising Preservice Curriculum to Incorporate Rational Medicine Use Topics: A Guide* was published. The purpose of this document is to guide stakeholders and health educators through the process of integrating rational medicine use (RMU)-related content into their preservice training curricula for medical, nursing, pharmacy, and public health students. Issues relating to RMU receive limited attention in health professionals' education curricula; for example, rational antimicrobial use, antimicrobial product quality, and infection control are often inadequately covered during both preservice and in-service training programs. The objectives of these guidelines are to:

- Promote RMU, including AMR- and pharmacovigilance-related topics, as an urgent global health issue that needs to be included in preservice training curriculum across health care disciplines
- Enable preservice health care training institutions to assess their current curriculum and identify gaps in RMU-related content
- Equip stakeholders at training institutions with the knowledge and tools necessary to successfully incorporate RMU-related content to the preservice training curricula

SIAPS and its partner ACPE finalized the accreditation credentials framework for preservice education, in-service training, and continuing education programs to support pharmaceutical systems strengthening.

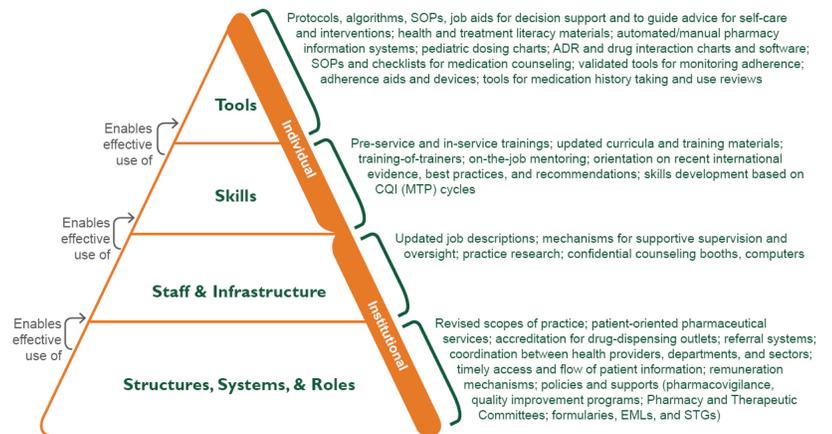
Supportive supervision is a process that promotes efficient, effective, and equitable health care through a practical system of measures that foster improvement in the procedures, personal interactions, and management of primary health care facilities and pharmacies. Supportive supervision focuses on meeting staff needs for management support, logistics, training, and continuing education. The USAID/SIAPS countries encourage and support the Government counterparts in supportive supervision of peripheral staff. Select examples of SIAPS activities involving supportive supervision are as follows:

- In **Burundi**, SIAPS supported the nationwide visits focused on supervising and monitoring distribution and consumption of ACTs, quinine, RDTs, and long-lasting insecticide treated nets (LLITNs).
- In **DRC**, SIAPS conducts supportive supervision visits to PMTCT sites to help improve pharmaceutical management.
- In **Namibia**, SIAPS helped plan and implement the Ministry of Health and Social Service (MoHSS) supportive supervisions to 11 of the country's 13 regions.
- In **Ethiopia**, SIAPS with the Food, Medicine, and Health Care Administration and Control Authority (FMHACA), conducts supportive supervision at private hospitals to assess the status of the Drug and Therapeutic Committees (DTCs).
- Also in **Ethiopia**, SIAPS is building the capacity of regional health bureaus, PFSA hubs, FMHACA branches, and regional regulatory bodies to coordinate their work and manage integrated supportive supervision.
- In **Swaziland**, SIAPS, in coordination with EGAPF, ICAP, and other implementing partners, conducts supportive supervision visits focusing on pharmaceutical services, supply chain, and information management for ART treatment facilities.

Two particular highlights from this program year that demonstrate the SIAPS approach to enhancing the capacity for pharmaceutical management and services are the success story from Tambura County (South Sudan) and the Improvement of the TB Control Program for Urban Poor (Philippines). The following pages provide information on these achievements.

Building a Public Health System One County at a Time: Tambura County, South Sudan

South Sudan, Africa's newest country, is building its public health system from the ground up—from physical infrastructure to a regulatory system. The US Agency for International Development (USAID)-funded Systems for Improved Pharmaceuticals and Services (SIAPS) Program is working with South Sudan's Ministry of Health (MoH) to meet the tremendous challenges of creating an entirely new pharmaceutical management system for a population suffering under some of the worst health care conditions in the world.



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

Challenges in South Sudan's Pharmaceutical Service System

The majority of the South Sudanese population does not have access to modern health services. It has one of the highest maternal and infant mortality rates in the world and its citizens suffer from a variety of infectious and non-communicable diseases. There is little infrastructure and few trained personnel, which is compounded by weak planning and coordinating mechanisms at the state and county levels.

In the pharmaceutical sector there are significant challenges including:

- Multiple vertical supply chains supported by different donors
- Complex pharmaceutical supply management system due to uncoordinated parallel procurement systems and/or poor donation practices
- A push system that results in over- and under-supply of some items
- Weak information management system

that does not provide timely and reliable medicine consumption/morbidity data

- Poor storage facilities and conditions
- Lack of transport and communication system
- Shortage of qualified pharmaceutical personnel at all levels
- Lack of adequate legislation and enforcement mechanism to regulate the practice of pharmacy and assure safety and effectiveness of pharmaceuticals and medical devices

Training Health Care Workers in South Sudan: The Key to Sustainability

Since 2011, SIAPS and its predecessor project have been providing critical training on pharmaceutical management to health workers in the MoH, county health departments, and health care facilities for all ten counties of South Sudan. The trainings for health workers were based on USAID-funded SIAPS's Capacity Building Pyramid, which helped identify

the training that would be the most efficient, effective, and powerful. SIAPS trained health workers to use Pharmaceutical Management Information Systems (PMIS) tools to generate, analyze, and make available information needed to make crucial decisions. Health workers were also trained in using a Logistics Management Information System (LMIS) tool, which works to ensure a continuous supply of drugs by generating reports on:

- Drugs dispensed to patients
- Drug stock balances
- Stock losses
- Stock adjustments
- Drugs received

Tambura County's Drug Supply: The Right Drugs at the Right Time

Located in Western Equatoria State, Tambura County is poor, remote, and struggling to overcome the effects of decades of civil war. Yet, finding solutions to complex problems is not new for the people of Tambura County. When it came time to fix the broken

pharmaceutical system, with the help of SIAPS, Tambura County's health authorities took the initiative to shift away from the push supply system for pharmaceuticals to a pull system.

With SIAPS's training in pharmaceutical information management tools, each county health department uses the LMIS tool to analyze the data needed to make decisions about inventory and then sends the data to the Central Medical Stores in Juba. The pull system allows Tambura County health facilities to prevent accumulation, damage, and expiry of unused medicines and other medical products. This system also helps health facilities maintain a buffer stock to mitigate the effects of delays from the Central Medical Stores. Tambura County is the only county that has switched to the pull system to date.

Investing in human resources and also building institutional capacity are key elements in building effective and efficient pharmaceutical management systems. Tambura County's health workers took the SIAPS-sponsored training to the next level of operationalization—building its public health system one county at a time.



Before



After

Grassroots Leadership Improves the TB Control Program for the Urban Poor in Quezon City, Philippines

The Philippines is one of the 22 countries worldwide with the highest tuberculosis (TB) rates and one of the 27 highest multidrug resistant tuberculosis (MDR-TB) burden countries. These countries account for more than 80 percent of the global TB and MDR-TB caseload. Several factors serve as barriers to access to TB care for the urban poor including:

- Inadequate availability of and accessibility to diagnostic facilities
- High out-of-pocket expenses for transportation
- Lack of treatment partners for community-based directly observed treatment

Case detection of TB cases is low and treatment success is poor with a high number of patients being lost during treatment.

TB prevalence in urban poor settlements, like Payatas in Quezon City, part of the metro Manila area, is almost twice that of the general population. Payatas is overcrowded and has poor access to health services, both of which are factors that contribute to this increased persistence of TB. The TB control program in Payatas is managed by the Quezon City Central and District Health Offices.

Strengthening TB Program Management at the Grassroots Level

In late 2011, Quezon City Health Department (QCHD), with the support of the US Agency for International Development (USAID)-funded Systems for Improving Access to Pharmaceuticals and Services (SIAPS) Program, took steps to strengthen TB program management at the barangay (grassroots) level.

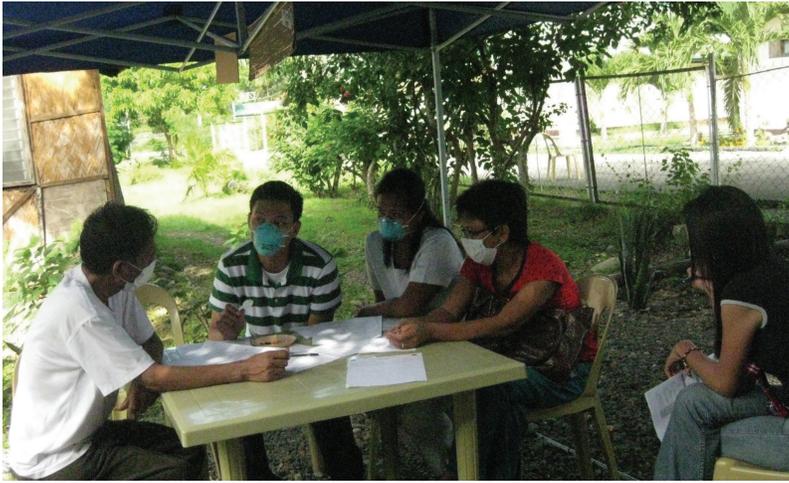
The objective was to allow the community stakeholders to participate, and take ownership, in managing the TB program in their community.

Through an existing grassroots management structure, the Barangay TB Management Council (BTBMC), SIAPS helped QCHD build program leadership and management capacity at the community level. SIAPS introduced Management Sciences for Health's (MSH) "Leading and Managing" practices to modify BTBMC's structure, roles, and processes.

SIAPS's approach is to train community leaders by providing them with the management tools that facilitate community management and participation. With an emphasis on empowerment, this approach instills community leaders with ethical values that result in effective leadership and ensures sustainability through local ownership. Local leaders can best identify the health needs of their community and the outcome is an increase in access to health care services and products.

A BTBMC core team composed of the Barangay Captain, health workers, and other stakeholders was organized to handle leadership and management tasks. The team was also tasked to plan, coordinate, monitor, and evaluate program activities so that they can identify the program's problems, and find solutions to address them. BTBMC also set up a secretariat to manage information, meetings, and coordination.

With the recently acquired leadership and management skills, the BTBMC developed and implemented action plans for their



communities. Coordination and collaboration among stakeholders increased, which led to the use of resources from other partners in the community for the TB program. The barangay, with other community partners, supported and financed advocacy and TB education meetings. A nongovernmental organization's TB Diagnostic Committee donated time and another nongovernmental organization partner supplied anti-TB medicine supplies to the local government unit health center. The BTBMC established satellite diagnostic facilities for microscopy using community resources and informal laboratory workers, which helped improve accessibility of TB microscopy services.

BTBMC organized treatment partners using volunteers in the community, and mobilized financial support from the barangay government to provide allowances to volunteer treatment partners and informal laboratory workers.

Community Participation Strengthens a TB Control Program

In 2012, the number of people with presumptive TB examined by microscopy increased by 27 percent, and TB cases that were initiated on treatment increased by 23 percent, as compared to previous years. These results suggest that strengthening program leadership and management at the grassroots level and using community resources can help reduce barriers to service delivery. Additionally, stakeholders at the grassroots level gained valuable management and leadership skills that they can use to address a variety of community level issues. The Payatas model can be applied to other health programs to improve public health services.

HIGHLIGHTED ACHIEVEMENTS

IR 3: INFORMATION FOR DECISION- MAKING CHALLENGES ADDRESSED IN THE PHARMACEUTICAL SECTOR



SIAPS APPROACH: Integrate 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.

SIAPS activities focus on capacity building for aggregation, analysis, presentation, and dissemination of information to support evidence-based decision making. Through our tools, software solutions, and pharmaceutical management information system activities, SIAPS helps ensure that quality pharmaceutical information is available to formulate pharmaceutical policy and plans and to monitor supply chain systems and pharmaceutical services.

To address these areas, SIAPS strategies include assessing and evaluating local information needs; leveraging mobile phone and other technologies in designing tools; harmonizing tools to help integrate pharmaceutical management information systems; and strengthening local organizations to customize, maintain, and take ownership of the tools and also to analyze, manage, and use the resulting data. As a result, SIAPS country partners use innovative and proven tools to generate accurate and timely information on pharmaceutical systems to improve access to products and services.

DATA UTILIZATION

SIAPS supports the development and implementation of systems for the analysis of data from a variety of information collection and management mechanisms so that health professionals can effectively plan and monitor service delivery.

- » RxSolution, developed by the MSH team in South Africa, is an integrated, computerized medicines supply system to manage procurement, inventory, distribution, dispensing, and referral activities at the facility level.
- » In **South Africa**, RxSolution is being used in 280 facilities across the country and is being piloted in two national health insurance districts in KwaZulu Natal and Eastern Cape. Use of RxSolution continues to contribute to significant improvements in medicines availability, improved inventory management, and better patient care. For example, in Free State Province, SIAPS introduced the remote demander module interface with RxSolution

RxSolution won a National Award for Innovative use of Information Technology for Effective Service Delivery. The accolade was awarded for the work at Dihlabeng Regional Hospital in Bethlehem, rural Free State, which recently moved from a paper-based system to RxSolution for dispensing prescriptions for patients on ARVs.

to facilitate the automated generation of orders based on consumption data. In Limpopo Province, SIAPS customized RxSolution to help manage direct deliveries for ARVs and oncology agents to over 40 hospitals. The software enables the procurement unit to routinely monitor supplier performance. SIAPS also helped finalize the list of products that a facility may order, based on the level of patient care it provides.

- » In **Lesotho**, ART and laboratory information system data are now routinely analyzed and presented in two-page stock status reports and technical reports that detail inventory and information management performance indicators. This information is now part of a feedback mechanism to facilities for the national ART program.
- » In **Swaziland**, RxSolution is used at national warehouses and five regional warehouses for the day-to-day management of stock, and stock status and issue reports are being generated with the tool. In addition, SIAPS is supporting PMI/Swaziland in using RxSolution at 38 of their sites.
- » In **Burundi**, analysis of data has shown that an increased number of children with confirmed positive cases of malaria are being treated with ACTs. This data is now available because of the SIAPS-supported PNILP database capturing information on CHWs (for additional information, see Burundi CCM success story under IR 5).

DATA QUALITY AND REPORTING

SIAPS works with countries to improve data quality and ensure the data is being disseminated to the appropriate stakeholders through proper reporting channels.

- » In **Guinea**, SIAPS, working with the PNLP and the National Health Information System (BSD/SNIS), took the lead in developing and launching a new monthly reporting template for malaria, with a detailed section on

pharmaceutical management including stock status and monthly consumption; and a new comprehensive product order and delivery form for antimalarials at the health district and facility levels. The reports are submitted in hard copy by the facilities to the districts, which then incorporate them into a standardized Excel template for online submission to PNLP, BSD/SNIS, and the regional level. SIAPS and PNLP have been providing customized feedback to each district on their reports. These new reports are helping to ensure that quality pharmaceutical management data is available and used for supply planning.

- » In **Ukraine**, pharmaceutical management problems, particularly in data collection, have been documented in several assessments in the last five years. The Government of Ukraine, however, has been slow to implement recommendations for various reasons, exacerbated by frequent changes in the leadership of MoH and governmental restructuring. However, based on the successful work of SPS, in October 2012, MoH issued Order No. 818 “Order on Electronic TB Registry (eTB Manager) Operations” which facilitated the adoption of e-TB Manager as the official TB register in Ukraine. As of the end of this program year, the majority of oblasts (24 of 27) are routinely entering data into eTB Manager, with over 67,000 cases entered. To improve monitoring and transparency, the Ukrainian Center for Disease Control (UCDC) has started publishing the number of TB and MDR-TB cases entered into eTB Manager on the UCDC official website. eTB Manager has been nationally recognized as a comprehensive TB case information management solution for MoH of Ukraine. SIAPS is now focusing its support to the UCDC on ensuring the quality of data entered and has developed a quality assurance protocol for standardizing procedures for data quality monitoring.
- » In **Bangladesh**, the Supply Chain Information Portal (SCIP) has been hugely successful in providing real-time procurement and logistics data on availability of RH commodities at all levels for all decision makers. Complementary to the SCIP is the Upazila Information Management System (UIMS) which enables the upazila family planning store staff to maintain stock of commodities, monitor field reporting, generate a supply plan, and automatically generate vouchers and LMIS reporting. Under SIAPS, the UIMS has been linked directly to the SCIP and has been rolled out nationally to all 488 upazilas with over 80 percent of them successfully uploading logistics data directly into the SCIP, providing real-time information on stock status.

Health Partnership

To leverage resources and facilitate implementation of eTB Manager, SIAPS Ukraine trained staff from the Chemonics STBCU project for their support to the oblasts.

INFORMATION SYSTEM DESIGN AND COLLABORATION

SIAPS helps analyze options and then designs supply chain interventions including those related to logistics information management.

- » In **Mali**, during FY12, SIAPS undertook an assessment of the LMIS and found a lack of strategic information for decision making as well as poor capacity for pharmaceutical management at the operational level. These issues constituted major obstacles to the effective functioning of Mali’s pharmaceutical supply and

Health Partnership

SIAPS worked with Mali’s Department of Pharmacy and USAID implementing partners PSI, ATN Plus, and PKCII in the redesign and implementation of the LMIS.

services. To address these obstacles, this program year, SIAPS collaborated with the key supply chain stakeholders and other implementing partners in the redesign and implementation of the LMIS, focusing on improving inventory management, recording and transmitting data, ordering and order fulfillment, reducing stock-outs, and availability of health commodities at all levels.

- » In **Swaziland**, SIAPS supported the development of a web-based commodity tracking system and manual LMIS at the regional level to track consumption of TB, HIV, malaria, RH, and laboratory commodities. This has resulted in improved ART reporting rates, and the data management unit has started capturing RH and laboratory data. The data collected through the LMIS forms is needed to inform product consumption assumptions and address confounding factors during quantification.
- » In the **Philippines**, SIAPS helped the National TB Program draft and finalize its country surveillance report (TB profile of the Philippines) that was published in the April–June 2013 issue of the *WHO Western Pacific Surveillance and Response Journal*.

eTB Manager

Managing information for adequate TB program support requires the challenging and complex integration of data processing collected from various health system elements and levels. The emergence of MDR-TB and XDR-TB is a significant health challenge in many countries, and increases the need for tools that:

- Promote effective TB case management
- Support health care provider prescription and medicines use practice
- Ensure uninterrupted availability of TB medicines
- Provide information for decision making on different aspects of TB control

eTB Manager is a health system strengthening web-based platform for managing information needed by national TB control programs. It integrates data across most aspects of TB prevention and care, including presumptive and confirmed TB/MDR-TB cases; medicines; laboratory testing; and diagnosis, treatment, monitoring and outcome; and it produces standard and customizable reports.

eTB Manager has been employed in a number of SIAPS countries: Bangladesh, Namibia, Philippines, Turkmenistan (pilot), Ukraine, and Uzbekistan (planned). The experiences of implementing this tool have shown its potential for strengthening TB programs both in-country as well as globally.

A particular highlight from this program year that demonstrates the utilization of information for decision making is the number of positive improvements in SIAPS countries that have resulted from the implementation of end use verification surveys. The following pages detail this achievement.

End Use Verification: Averting Stock-Outs by Making Commodity Information Available

Key to the success of malaria control is the availability and appropriate use of malaria commodities. The End-Use Verification (EUV) Process was developed by the President’s Malaria Initiative (PMI) in collaboration with the USAID | DELIVER Project and the US Agency for International Development (USAID) Strengthening Pharmaceutical Systems (SPS) Program. EUV is used to assess the availability of malaria commodities at the end-user level, as well as provide a snapshot of how malaria is being diagnosed and treated at a given set of health facilities.

Research Objectives and Methodology

EUV is a survey tool to assess the supply chain of malaria medicines/products and malaria case management. The EUV is designed to ask specific questions to solicit answers that will guide decision makers in strengthening malarial control programs. The questions address the following components:

- Number of facilities with stock-outs (including artemisinin-based combination therapies [ACTs], sulfadoxine-pyrimethamine, rapid diagnostic tests, medicines for treating severe malaria, the proper case management of uncomplicated malaria, and long-lasting insecticide-treated nets)
- Expiry of ACTs and other commodities currently stocked at health facilities
- Reconciliation between quantities of commodities ordered and quantities received
- Reconciliation of quantities of commodities

received and physical inventory

- Proper handling of pharmaceutical supplies, including training levels, storage conditions, and regular supervision
- Some elements of malaria case management, for example, the proportion of malaria cases treated to number of treatments dispensed within a defined time frame, stratified by the antimalarial drug used and level of care provided; and the number of patients presenting with fever that are diagnosed with malaria, broken down by age group

A total of 17 supply chain and 20 malaria case management indicators are collected during the EUV. The EUV process is designed to be implemented quarterly, with results available shortly after data collection to quickly allow corrective action to be taken.

Each country implements the EUV either quarterly or twice a year in collaboration with its national malaria control program. Supervisory visits are made to a random sampling of 60–90 facilities (20–25 facilities per survey) for countries with less than 750 facilities, or 150–200 facilities (50–75 facilities per survey) for countries with more than 750 facilities. Data is collected through interviews, records reviews, and observations using paper-based tools or mobile phones with the EpiSurveyor software.

Goal of EUV

Reduce malaria mortality and morbidity by improving the availability and use of the malaria medicines and commodities at the facility level

SIAPS EUV Results

The SIAPS countries have implemented the EUV Survey with much success—facility accountability has increased and quality data is available for making pharmaceutical supply planning decisions. Some of the recent achievements from the project year are described below.

Country	Year Started	# of EUVs Oct 2012 – Sept 2013	Frequency
Angola	2010	3	2/year
Burundi	2011	2	2/year
DRC	2012	2	2/year
Ethiopia	2009	4	4/year
Guinea	2012	2	4/year
Liberia	2011	4	4/year
Mali	2010	3	2/year

In **Angola**, survey findings were used to increase quantities of RDTs and to integrate condoms into the general distribution of other products with additional condoms included in the health kits. The national program for essential medicines is endeavoring to assure stock cards and other management tools are available and implemented in all health facilities, depots, and warehouses.

In **Guinea**, SIAPS and the Programme National de Lutte contre le Paludisme (PNLP), in coordination with Central Pharmacy (PCG), Ministry of Health, MCHIP, and Façons Ensemble, conducted EUV surveys on malaria commodity management and case management practices. This survey is the first of its kind in Guinea. The survey built capacity for the PNL, PCG, National Health Information

In a number of countries the EUV data has resulted in stock-outs being immediately corrected and patients being provided treatment

System (SNIS), national inspectors, and district pharmacists/physicians who participated as data collectors/supervisors. Recommendations from the surveys solidified the need to strengthen and automate the data

collection process and to establish a pull system for antimalarial products.

In **Liberia**, SIAPS and the NMCP have undertaken several quarterly EUV surveys which identified the poor storage conditions in a number of sites and led to the recommendation to support renovating the Nimba Medicine Depot.

Other successes in the selected countries include the following:

- Facilities that are facing the most problems will be the focus areas for next supervision (**Angola**)
- The requisition process for malaria commodities was reduced from 2 weeks to 2 days (**Burundi**)
- Supervision at the facility (for malaria) improved from 55 percent in 2012 to 83 percent in 2013 (**DRC**)
- Review meetings are held to examine the findings and address problems (**Ethiopia**)
- A new malaria reporting system was created following a baseline survey (**Guinea**)
- Trainings on malaria commodity management and case management were conducted in Grand Kru and Maryland counties (**Liberia**)
- Commodities were redistributed to avoid stock-outs and expiries (**Mali**)
- The number of children under five being treated for malaria with ACTs increased (**DRC**)

The EUV process lets policy makers and planners know how effective the health system is in making malaria commodities available to those who need them. It can be used to strengthen national malaria control programs (NMCP) and Ministry of Health (MoH) supervisory efforts, gather information to help satisfy audit requirements, verify the end use of commodities, and provide timely, actionable information for detecting and correcting program implementation problems.

HIGHLIGHTED ACHIEVEMENTS

IR 4: FINANCING STRATEGIES AND MECHANISMS STRENGTHENED TO IMPROVE ACCESS TO MEDICINES



SIAPS APPROACH:
Support analyses to inform policy decisions regarding cost containment, greater efficiency, and options for mobilizing financing.

Traditionally, pharmaceutical system financing has been perceived as funding pharmaceutical purchasing, and initiatives, such as the Global Fund, focus heavily on such funding. However, even countries that have adequate funds to procure medicines cannot always manage the flow of money and assure availability of health supplies. Financing, therefore, broadly covers resource mobilization and maximizing efficiencies, resource pooling, and payment and purchasing.

SIAPS helps countries conduct analyses to improve decisions regarding cost containment, greater efficiency, and options for mobilizing financing. Examples of this work may include evaluation of alternate supply chain systems; analysis of financial flow and sustainability; identification of options to remove roadblocks; development and implementation of systems for tracking, monitoring, and controlling pharmaceutical spending; and analysis and evaluation of pricing policy options. Our health management expertise combined with SIAPS partners' knowledge and experience in innovative financing strategies helps countries to develop systems to maximize their pharmaceutical resources.

EFFICIENT UTILIZATION

It is important for countries to establish a balance among the demand for medicines, the cost of meeting this demand, and the available resources. If this balance is not met, shortages result and quality of care declines. Pharmaceutical financing strategies allow countries to maximize their pharmaceutical resources by making better use of the funds they have available.

- » In **Ethiopia**, the APTS package of interventions has been expanded and is now implemented in 12 hospitals in Amhara, Tigray, Harari, Addis Ababa, and the Southern Nations and Nationalities Peoples Region, and has resulted in an increase in medicine costs recovered because of improved internal efficiency (bin location system, VEN analysis, minimal expiry, and selective pharmaceutical sales financial management). For example, at Debreworkos Hospital in the Amhara Region, the percentage of medicines procured from the hospital's medicines list increased from 35 percent to 98 percent. As a result of more efficient spending, 28 percent more funds became available for the medicines budget of the hospital. (For more information on APTS, see the Success Story, "Auditable Pharmacy Transactions and Services (APTS): Good Governance and Better Service Delivery" under IR 1.)
- » In the **DRC**, SIAPS led 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. This standardization is expected to increase the population's access to services in health zones where the fee charged to patients was originally higher.

TRACKING PHARMACEUTICAL SPENDING

Government financing is a major, but often insufficient, source of financing for essential pharmaceuticals. The case for public funding of pharmaceuticals can be strengthened through better quantification, per capita pharmaceutical budgets, expenditure trend analysis, and comparative expenditure analysis. SIAPS helps countries with their pharmaceutical financing strategies by strengthening the ability of the countries to track and analyze their pharmaceutical spending.

- » In **South Africa**, there is a critical need to better control pharmaceutical expenditures. To help address this need, SIAPS performed pharmacoeconomic analysis to support Provincial Pharmaceutical and Therapeutics Committees (PTC) in their selection of medicines for the provincial formularies. A number of provinces have projected significant cost savings upon revision of the formularies. In Gauteng Province, a comparison of the ABC analyses of expenditure per ATC class over the financial years 2010/11 and 2011/12 was also conducted; it revealed a large increase in percentage of expenditure year to year. It also facilitated the identification of cost drivers for the increase. The increase was driven primarily by increased use of moxifloxacin, an antibacterial agent. The percentages of EML and non-EML medicines per ATC classes were also compared. Results from these analyses were provided to district and institutional PTCs to support their roles in promoting RMU. For example, the ABC analysis helped the Sedibeng PTC in Gauteng Province target their interventions relating to the usage of psychiatric medicines in

their district. In Limpopo Province, following the comparative analysis of the cost of enalapril 10 mg versus perindopril 4 mg, the Provincial PTC decided that all new patients eligible for ACE inhibitors be initiated on enalapril. The projected savings as a result of this decision was approximately USD 480,000 per year.

- » In the **DRC**, SIAPS supported a series of National Medicine Committee meetings, and participated in the task force charged with quantifying essential medicines for 65 health zones that do not receive donor support. This activity resulted in MoH, for the first time in decades, providing more than USD 1.5 million of government funds to purchase a six-month supply of essential medicines for those health zones.

Improving Pricing Regulation in Mozambique

A recent study to investigate how medicine prices are decided in urban Mozambique found that local mark-ups are responsible for up to two-thirds of the final price of drugs. MoH's Pharmacy Department requested support from USAID/SIAPS in addressing the limitations of the current pricing regulations. To identify options for the policy and regulatory reform, SIAPS conducted a best practices review of current pricing regulation literature. Findings from the review were analyzed against the local context of Mozambique. Some of the relevant pricing regulation options include a reference pricing system, distribution chain cost controls, fixed professional fees, reducing duties and taxes on medicines, and generics substitution.

A review of the operations of the Pharmacy Department identified the following limitations: lack of capacity and resources, limited quality control system, and limited pricing information available to retailers and consumers.

Over the next project year, SIAPS will continue to work with the Pharmacy Department to update current price regulations and develop a pricing regulation guideline, strengthen the monitoring and information system for medicine price and availability, and improve the regulatory capacity for inspection and enforcement of the pricing system.

Previous efforts at enforcing pricing regulation in Mozambique have been unsuccessful. The current effort by the Pharmacy Department, with support from SIAPS, is designed to be evidence-based, transparent, and involve all stakeholders. The strategic plan that will be developed through extensive consultation will be endorsed by all stakeholders and lead to the development of action plans. The Pharmacy Department will be empowered by adequate infrastructure and resources to enable it to regulate, monitor, and enforce the new pricing system for improved access to essential medicines in Mozambique.

Two particular highlights from this program year that demonstrate the SIAPS approach to strengthening financing strategies toward improving access to medicines are the primary treatment centers in South Africa and the reevaluation of the HIV financing gap in the Dominican Republic. The following pages provide detail on these SIAPS achievements.

Evidence-Based Decisions Result in Financial Savings in South Africa

The Eastern Cape, Gauteng, and Limpopo provinces of South Africa (SA) have projected a total combined savings per 100,000 patients of 24 million SA rand (ZAR) per annum through performance of medicine use evaluations (MUEs), and the promotion of rational medicines use. This is because functional Pharmaceutical and Therapeutics Committees (PTCs) are tasked with the responsibility to oversee and ensure safe and cost effective supply and use of medicines.

The establishment of PTCs has been advocated by WHO as one of the 12 key interventions¹ to promote rational medicine use (RMU). In SA, the National Drug Policy (NDP) requires hospital PTCs to be established and strengthened in “all hospitals in South Africa (both public and private sector) to ensure the rational, efficient and cost-effective supply and use of drugs.”² Functional PTCs at provincial, district, and facility levels are a cornerstone of the SA NDP.

A PTC is a multidisciplinary forum established to promote the safe, efficacious, and cost-effective use of medicines. The PTCs members come from medical, nursing, pharmaceutical and financial backgrounds and are selected for their expertise. With support from USAID, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program actively supported the implementation and strengthening of the PTCs within the country at provincial, district, and

facility levels to promote rational medicine use and ultimately reduce expenditure.

Non-Functioning PTC Monitoring

The National Essential Medicines Lists (EMLs) serve as the basis for the development of formularies at provincial, district and hospital levels. Unfortunately, delays in the routine review of the EMLs resulted in provincial and hospital PTCs including medicines new to the market in their formularies. This was done without the needed alignment with EMLs, national contracts, and available budget.

With the PTCs not playing their monitoring role, the expenditure on non-EML medicines, as well as irrational use of EML medicines, increased.

Strengthening the PTCs

SIAPS worked to strengthen governance and sound decision making within the PTCs by developing generic terms of reference (ToRs) and other governance tools for PTCs at provincial, district, and hospital levels. Policies relating to confidentiality and conflict of interest were also addressed in light of the sensitive and confidential information dealt with by the provincial PTCs. The ToRs promote establishing subcommittees to allow the PTC to tackle various issues simultaneously, to work in synergy, and to gain the most benefit from the selected members’ expertise.

In Gauteng Province, the subcommittees strongly promoted rational medicine use. The Gauteng Provincial PTC (PPTC) developed a guidance document for the function of PTCs at all levels with an aim to optimizing available resources and rational medicines use. The

1 WHO, Medicines, The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences, http://www.who.int/medicines/areas/rational_use/en/ (accessed July 17, 2012).

2 National Department of Health. 1966. *National Drug Policy for South Africa*, section 7.5.

guidelines addressed governance structures and processes, accountability and responsibilities, functions and role of the PTC at all levels, and communication strategies. SIAPS assisted with the development, printing, and dissemination of the guidelines to ensure that the benefits gained at provincial level were cascaded down to hospital and district levels PTCs for an integrative and comprehensive approach toward an optimum use of available resources.

Cost Analyses and Medicine Utilization Evaluations

The ABC analysis (method of ranking and analyzing medicine products according to the value of products used) and formulary maintenance are among the standing items to be included on the PTC meeting agenda. Working with PPTC members, SIAPS built capacity in analysing expenditure on medicines, designing, and implementing the relevant interventions to address the identified problems. This was further reinforced by customized workshops held with PTC members at hospital and district levels where the ABC analysis of the institution was discussed and potential problems highlighted.

The Eastern Cape and Limpopo PPTCs used provincial internal memos to communicate the resolution taken with regard to use of enalapril as the angiotensin convertor enzyme (ACE) inhibitor of choice in the province. The Limpopo PPTC used a similar approach to implement the use of amlodipine as preferred calcium channel blocker of choice in the province. The Gauteng PPTC sent individualized letters to each facility listing projected savings to encourage increased use of lamotrigine versus sodium valproate in the treatment of epilepsy. Similarly, letters were sent to facilities showing their potential savings by decreasing the use of insulin pens by 50 percent.

The designed interventions involved a change in prescribing habits, and as such, will take time. For a meaningful result, the effect of these interventions will only be measured 12 months after their implementation. However, the projected savings were presented to

the members of the PPTCs and served as supportive information for decision making.

Result: Financial Savings for PTCs

Based on the ABC analysis results, the respective PPTCs developed a range of interventions to promote safe and cost effective use of medicines. These interventions have not only helped scale up ART programs, but have strengthened the pharmaceutical management system for a wider range of medicines and supplies and supported integration of supply and patient services.

Province	Intervention	Projected savings/100,000 patients/yr
Eastern Cape, Gauteng, Limpopo	Enalapril 10 mg as preferred ACE inhibitor (versus perindopril 4 mg)	ZAR 6.9 million
Gauteng, Limpopo	Amlodipine 5 mg as preferred calcium channel blocker (versus nifedipine 30 mg XL)	ZAR 10.3 million
Gauteng	Increase usage of lamotrigine to 50 percent of adult epileptic patients (versus sodium valproate)	ZAR 5.2 million
Gauteng	Decrease usage of insulin pens by 50 percent for adult diabetic patients (versus insulin vials)	ZAR 1.6 million

Challenges and Lessons Learned

Although ABC analysis was performed, it was seen by most PPTC members as an end unto itself and not as a tool to review pharmaceutical data to identify potential problems. SIAPS built capacity among PPTC members to analyse, review, and put into context the results from ABC analysis. SIAPS further supported cost analysis to calculate projected savings from the proposed interventions. This approach was used by the Gauteng PPTC to support implementing the intervention at facility level and hopefully obtain buy-in from prescribers.

To be fully functional, PTCs have to have effective governance structures and transparent, evidence-based decision-

making processes. Technical assistance in building or strengthening sound foundations for PTCs has been key factor in improving their functionality. Systematically using cost analysis as supportive evidence and bringing a more global picture to the cost implications helped get buy-in from clinicians who were at first reluctant to change prescribing habits.

SIAPS Future Plans

The next steps will be to monitor and assist with the designed intervention and then evaluate the results. SIAPS will continue to build capacity among PTC members to conduct analysis of pharmaceutical data and design corrective interventions to address identified problems. SIAPS will also continue to help revise the provincial formularies to further strengthen use of safe and cost effective medicines in the provinces.

Ensuring Access to Treatment through Better Quantification

Declining rates in HIV infection led former US Secretary of State Hilary Clinton to publically declare that the global community is on the path towards realizing an AIDS-free generation. The three pillars of an AIDS-free generation are: (1) no baby will be born with the virus; (2) there will be a lower risk of infection; and (3) people living with HIV will get treatment that keeps them healthy and prevent them from transmitting the virus to others.

The Dominican Republic (DR) has one of the highest rates of HIV/AIDS infection in the region. Until recently, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) has provided the majority of financing to purchase life-saving ARVs for the DR. However, in the last few years, Global Fund disbursements for ARVs have decreased. The government of the DR was unable to cover the gap left by the reduction of Global Fund resources. The US Agency for International Development (USAID)-funded Systems for Improving Access to Pharmaceuticals and Services (SIAPS) Program worked with the unified pharmaceutical system to document the significant stock-outs of ARVs due to the lack of national financial resources to cover the gap.

Quantifying the Resource Gap

In 2012, using the Integrated System for Medicine and Supply Management (Sistema Único de Gestión de Medicamentos e Insumos; SUGEMI) methodology, the National Medicines Management Team (Unidad Nacional de Gestión de Medicamentos), in coordination with the General Directorate for Control of Sexually Transmitted Infections and AIDS (Dirección General de Control de las Infecciones de Transmisión Sexual y SIDA), and the National Council on HIV and

AIDS (Consejo Nacional de VIH y el SIDA; CONAVIHSIDA) carried out the first national quantification and planning exercise for the 2013 purchase of adult antiretrovirals.

The total requirements for adult ARV medicines were estimated at a value of 7.8 million US dollars (USD). The Global Fund and CONAVIHSIDA would cover a total of USD 4 million equal to 51 percent of the total financial needs. The financial gap to cover the remaining 49 percent was USD 3.8 million.

Closing the Gap for Purchasing ARVs

On the basis of these estimates, in November 2012, a Global Fund mission authorized the DR as Principal Beneficiary to reallocate among spending categories to cover ARV purchases. At the same time, CONAVIHSIDA proposed using voluntary pooled procurement (VPP), the Global Fund's international purchase mechanism, with the goal of reducing procurement prices and delivery times.

In February 2012, the Unidad Nacional de Gestión de Medicamentos and CONAVIHSIDA technical teams revised the estimates, taking into account the cost savings achieved through the VPP. The total needed for adult ARV medicine purchases in 2013 was now calculated at USD 6.1 million, or a reduction of USD 1.7 million in relation to the original estimates of September 2012. Given the reductions in product prices, the Global Fund would now be able to finance 59 percent of the cost (USD 3.6 million), which would reduce the financing gap to be covered with national resources to USD 2.5 million.

For its part, CONAVIHSIDA project savings was estimated at USD 0.9 million from its purchase through a new provider (Partners

for Supply Chain Management; PSCM). In addition the gap will be reduced by another USD 500,000 because there are unused resources for ARV purchases on deposit at the Pan American Health Organization Strategic Fund. Between those two sources, the financing gap to be covered with national resources will be reduced to USD 1.1 million. Thus, the gap will be more than covered by the Ministry of Health's USD 1.9 million budgeted for the purchase of ARVs in 2013.

From Quantification to Action

The first step in bridging the resource gap was for all stakeholders to agree on the actual amount of money needed to purchase ARVs. SIAPS helped produce the relevant documentation for all significant parties involved and facilitated technical meetings to present and discuss the findings. Once the financial information was reviewed by the stakeholders, the next step was to come up with actions to close the gap. These interventions included changing to a new provider for purchasing ARVs; securing unused resources for purchases on deposit in the Pan American Health Organization account; and, for the first time, the DR's Ministry of Health budgeting for the purchase of ARVs. These strategies not only covered the USD 3.8 million gap, but generated a surplus for the procurement of diagnostic materials. Recent evidence has shown a significant increase in the availability of ARVs.

Closure of the Financing Gap for Adult ARV Purchases	USD	Gap Closed (USD)	Percentage
September 2012: Financing gap to be covered with national resources		3,809,865	100.0
February 2013: Financing gap to be covered with national resources		2,534,882	66.5
Savings from VPP/ PSCM purchases	910,637	1,624,244	42.6
Resources on deposit with PAHO Strategic Fund	500,000	1,124,244	29.5
Resources included in the MoH budget	1,900,000	(775,756)	

HIGHLIGHTED ACHIEVEMENTS

IR 5: PHARMACEUTICAL SERVICES IMPROVED TO ACHIEVE DESIRED HEALTH OUTCOMES



SIAPS APPROACH:
A holistic approach that strives to ensure patients receive medications optimized to their clinical needs, in doses that meet their individual requirements, for an adequate time, and at the lowest cost to them and their community.

To ensure product availability, SIAPS helps partners and national-level staff members build their capacity to conduct efficient quantification and supply planning. Because multiyear forecasts make it easier to advocate for resources to ensure commodity security, the program helps to set up coordination mechanisms for in-country stakeholders to estimate medium- to long-term needs. SIAPS also works 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 competition. The program helps countries develop and adopt procurement policies and procedures while also establishing appropriate organizational and institutional structures for supply chain management.

However, beyond the supply of pharmaceutical products, pharmaceutical services include educating and training staff, providing medicine information and counseling, monitoring medicine use to assure patient safety and achieve desired health outcomes, formulating policies and regulations to improve pharmaceutical care, and disseminating information and educational materials to promote public health.

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

To achieve these results, SIAPS uses a flexible approach to designing a tailored intervention, implementing and managing that intervention, monitoring performance, and measuring outcomes. We fully engage local partners to ensure that they are contributing to and building skills at each stage of the intervention and that the solutions are locally relevant. The key to many of our project achievements has been the broad-based support from all stakeholders, built through a participatory approach to project design and implementation.

SUPPLY PLANNING

Supply planning is a critical component of the supply chain management cycle that links facility-level information on services and commodities with national-level program policies and plans. Results are used to inform high-level decision making on commodity financing and procurement. It is a continuous process that requires regular monitoring and updates and relies on a well-functioning supply chain system. SIAPS helps partners and national-level staff members build their capacity to conduct efficient supply planning for their countries.

- » In **Swaziland**, SIAPS supported MoH in strengthening the quantification and procurement systems for medicines and laboratory commodities. SIAPS and MoH conducted quarterly supply planning for HIV, TB (first and second-line), and family planning commodities. In addition, SIAPS supported MoH in the first ever supply plan for laboratory commodities. As a result of SIAPS's regular and systematic supply planning support, the first quarter procurement budget for ART products and RH commodities was reduced by 6.4 percent and 69.2 percent, respectively.
- » In **Bangladesh**, SIAPS strengthened the capacity of the Ministry of Health and Family Welfare (MOHFW) to facilitate a large, interactive bidders' conference for 100 potential suppliers. SIAPS also assisted the Central Medical Stores Depot in the development of standard bidding documents and a service contract package, for which MOHFW had no prior experience.
- » Also in **Bangladesh**, SIAPS trained all 32 MOHFW line directors as well as Procurement and Logistics Management Cell staff in the use of the Supply Chain Management Portal (SCMP; an online procurement planning system), resulting in MOHFW developing 32 integrated procurement plans (one for each line director) with minimal SIAPS assistance.
- » SIAPS disseminated the malaria quantification manual (developed under SPS in English and French) to all SIAPS/PMI countries. This manual is designed to provide users with practical steps and guidance on how to carry out a national-level quantification of artemisinin-based combination therapies (ACTs) and rapid diagnostic tests (RDTs). The manual is intended for those

at the program level including malaria program managers, procurement officers, warehouse managers, implementing partners, and donor agencies. This manual differs from previously prepared quantification manuals in that it specifically targets quantification of ACTs and RDTs and provides guidance for the specific interaction between the two. SIAPS developed training materials based on the quantification manual, which were used for the first quantification training workshop in Bamako, Mali.

An effective supply chain management (SCM) system is an important component of a health care delivery system. The SIAPS field teams supported quantification, forecasting, and supply planning in the countries in the table below.

SIAPS Countries and Government Counterparts Supported for Quantification, Forecasting, and Supply Planning in Year 2

Bangladesh	DGHS and DGFP	5-year forecast and quantification of tracer drugs including MCNH products
Burundi	Malaria Control Program (PNILP)	First national quantification and forecasting for malaria commodities and quantification for ACTs and RDTs for 2014
Cameroon	AIDS Control Program (CNLS)	National forecasting for HIV and AIDS commodities for 2013–2017 in collaboration with the Clinton Health Access Initiative and UNICEF
Mali	PNILP	National quantification for malaria commodities and estimation and supply planning for contraceptive needs
South Sudan	NTP	Procurement of TB commodities through GDF
Swaziland	MoH	Annual forecasting for HIV, TB, Sexual RH Commodities, malaria, laboratory and essential medicines
Tajikistan	NTP and Principal Recipient of GFATM	Quantification of ethambutol for accelerated order through GDF

SUPPLY MANAGEMENT

A strong national-supply chain system makes logistics information readily available to facilitate evidence-based decision making, maximizes system efficiencies, helps integrate new medicine and diagnostic technologies, and increases health product availability. SIAPS works with countries to plan and organize strategies to ensure that pharmaceutical supplies are made available at the service delivery point at the right time, in the right quantity, and with the highest quality.

- » In **Swaziland**, SIAPS supported MoH in transitioning the TB medicines' and RH commodities' supply chains to the Central Medical Stores where MoH has assigned responsibility for these items to the lead pharmacists. This will ensure that gains from success of the HIV supply chain management can be replicated in the supply management of these priority products. SIAPS is also working to make sure that proper storage of pharmaceuticals is maintained to reduce wastage due to expiry and damage. One of the ways to address this issue is by reducing inventory holding. SIAPS facilitated the design of a TB max-min inventory control system to streamline with the existing central medicine store system and link to facilities and the National TB Control Program. This system allows facilities to utilize limited warehouse space efficiently and reduce the cost of inventory holding. The clinic laboratory

reporting and ordering system has also been revised to link with the ART laboratory monitoring sites.

- » In **South Africa**, SIAPS worked with the National Department of Health and other PEPFAR partners to create a Provincial Medicines Procurement Unit (PMPU) in Limpopo Province as a means of strengthening the pharmaceutical supply chain. As of the end of the program year, over 2,300 orders for 42 hospitals were processed by the PMPU. The medications (84 line items), mainly ARVs, are procured through a direct delivery voucher model managed by the PMPU. The NDoH has identified this model as a way of ensuring an uninterrupted supply of medicine and is expanding its use to Gauteng Province. With this new system in place, the medicine availability at Limpopo hospitals and clinics was 70 percent as of September 2013, up from 55 percent in May.
- » Upon WHO request, SIAPS rewrote the supply management section of the draft *WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for the Treatment and Prevention of HIV Infection*. Additionally, SIAPS was requested to work with JSI to review the supply chain management chapter of the WHO/UNICEF handbook for countries to introduce and scale up *Caring for Newborns and Children in the Community*.

PHARMACOVIGILANCE

Poor product quality, ADRs, and medication errors have a huge impact on a patients' health care. However, few countries have the structures, systems, or resources in place to develop a functional medicine safety system. Using a systems perspective, SIAPS supports programs to adopt both active and passive approaches to identify medicine-related problems including ADRs, product problems, and product use errors.

- » In **Namibia**, in FY12, SIAPS supported the Therapeutics Information and Pharmacovigilance Center (TIPC) in the initiation of active surveillance on the safety of patients on ART at two sentinel sites in Windhoek (Windhoek Central and Katutura State Hospitals) with a patient enrollment period of 6 months and patient follow-up of 12 months. In collaboration with the University of Washington (Seattle, WA, USA) and TIPC, SIAPS developed and deployed the data entry tool and is currently analyzing the cohort data of 470 patients enrolled in the active surveillance of safety of first-line ARVs at the two sentinel sites.
- » In the **DRC**, SIAPS assisted the National Pharmacovigilance Center to increase ADE reporting. The center has been receiving ADE notifications from four hospitals with Medicines and Therapeutics Committees in three USAID-supported provinces. For example, in Lodja Health District, Kasai Oriental, SIAPS supported the quarterly inventory of notifications made from Lodja's MTC, and transferred suspected quinine oral solution to the provincial health authority for quality control.
- » In **Swaziland**, MoH relies solely on spontaneous reporting of ADRs, which is heavily dependent on the willingness of the health workers to file the

reports. To strengthen and complement the spontaneous reporting, SIAPS, in collaboration with WHO/AFRO, developed a sustainable active surveillance system for the HIV/TB program. This system provides local data on medicine safety and generates safety signals for medicines used by HIV and TB patients. Currently, the system is being piloted in five hospitals: Good Shepard, Hlathikulu, Mbabane, MSF Matsapa, and Raleigh Fitkin with nearly 800 patients enrolled.

- » SIAPS completed and submitted country reports to the US FDA and USAID on the pharmacovigilance assessment findings for Bangladesh, Cambodia, Nepal, the Philippines, and Thailand. The assessment reports include key documentation and semi-structured interviews based on the indicator-based Pharmacovigilance Assessment Tool with key informants representing the ministries of health, national regulatory authorities, national public health programs, health facilities, industry, pharmacies, academia, professional associations, and clinical research organizations.

COMMUNITY CASE MANAGEMENT

CCM is a strategy to provide health interventions for common childhood illnesses beyond health facilities so that more children have access to lifesaving treatments. CCM involves CHWs trained to provide simple health care to sick children in their communities with limited access to health facilities.

- » In **Burundi**, SIAPS continued to support the malaria CCM pilot project (PECADOM). Evaluation findings demonstrated that 86 percent of children under five that presented with a fever were received by CHWs within 24 hours, 98 percent were tested with RDTs, and 97 percent of those that tested positive were treated with ACTs. (For detailed information on this achievement, see the success story, “Community Case Management of Malaria Increases Access, Diagnosis, and Treatment in Children Under Five” on the following pages.)

ANTIMICROBIAL RESISTANCE

Inappropriate antibiotic use, including overuse and misuse, is a serious global problem. Established and newly emerging infectious diseases are increasingly threatening the health of populations. Harmful consequences of irrational use include unnecessary adverse medicines events and rapidly increasing antimicrobial resistance (AMR) due to overuse of antibiotics. In 1993, the WHO Action Programme on Essential Drugs published the manual *How to Investigate Drug Use in Health Facilities*. This manual has been used to assess medicine use in hospitals, but does not address antimicrobials. The management and use of antimicrobials have clinical, economic, and environmental implications. In many countries, antimicrobials are the most frequently prescribed therapeutic agents, accounting for 30-50 percent of prescriptions. To address this gap, SIAPS developed the manual *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators*, which was published in English, French, and Spanish. This document helps DTCs, physicians, pharmacists, managers, and researchers monitor and assess antimicrobial use in their facilities. It defines 17 indicators (hospital, prescribing, patient care, and supplemental) to objectively measure

antimicrobial management and use. This practical manual also provides detailed step-by-step instructions to help design and carry out an assessment in hospitals. For each indicator, the manual gives the rationale, definition, data collection, calculation, instrument, and example.

- » In honor of World TB Day on March 24, a SIAPS staff member and XDR-TB survivor from the Philippines visited Washington, DC, and advocated for improved TB care and treatment at a variety of venues including the Senate and House of Representatives, the Women’s Health and Diplomacy Roundtable, and the USAID “Honoring Champions in the Global Fight Against Tuberculosis” event at the Newseum.
- » In Ethiopia, SIAPS provided technical and financial assistance to organize a training and orientation meeting with journalists on prevention and containment of AMR and RMU; 26 journalists working on the health programs of different federal and regional governmental and private radio programs, television programs, and print media participated. Almost all the journalists reported on RMU AMR after the training, including live interviews with end users.

Community Case Management of Malaria Saves Lives of Children Under Five in Burundi

The US Agency for International Development (USAID) has partnered with the African Leadership for Child Survival in a global initiative, “A Promise Renewed.” Led by the Governments of Ethiopia, India and the United States with UNICEF, “A Promise Renewed” seeks to reduce child mortality rates to 20 or fewer per 1,000 by 2035.

In Burundi, as well as in many other developing countries, malaria is the leading cause of death for children under five. One hundred percent of the population in Burundi is at risk of contracting malaria. Despite the efforts of Burundi’s Ministry of Health (MoH), timely access to health care is limited by financial constraints, geographic inaccessibility, and lack of awareness about malaria complications.

Community Case Management (CCM) of malaria for children under five is proving to be successful in reducing childhood mortality in many countries. Trained community health workers (CHWs) are equipped with malaria rapid diagnostic tests (RDTs) to test suspected cases of malaria in children under five and treat them with antimalarials in their homes, ideally within 24 hours of onset of fever.

The Intervention

In 2010, a CCM feasibility study in Cibitoke and Kayanza provinces showed that only 53 percent of families with children under five who were experiencing fever were seeking care within 24 hours of the onset of symptoms. To increase timely access to malaria treatment, the Burundi MoH, supported by the US Agency for International Development (USAID), piloted community case management of malaria (PECADOM) in three districts (Mabayi District of Cibitoke Province,

Malaria Indicators Study 2012

- 22 percent of children under five (n = 3,873) tested with an RDT were positive
- 17 percent of children under five (n = 3,783) tested with microscopy were positive
- The north region has the highest prevalence (31 percent RDT and 24 percent microscopy)
- 41 percent of sick children were not taken for care

Gahombo District of Kayanza Province, and Gashoho District of Muyinga Province). The provinces were selected based on the presence of USAID implementing partners while the districts were those that were the most affected by malaria.



Meeting of the health committee at Nyungu health center in Gashoho

In early 2012, a pilot CCM of malaria was introduced in Gahombo and Kayanza Districts through Pathfinder’s MCH project in collaboration with the USAID-funded Strengthening Pharmaceutical Systems (SPS) Program. SPS developed guidelines and job aids for the CHWs, an algorithm for CCM of malaria at the community level, patient

register/reporting forms (carbonless book), reference forms (carbonless book), CHWs' supervision checklist, CHWs' observation checklist, and health centers' supervision checklists. In October 2012, SIAPS took over the CCM pilot projects in the two districts.

Indicators for the CCM

- Percent of under-five children with fever received by CHWs within 24 hours
- Percent of under-five children with fever received by CHWs and correctly treated within 24 hours
- Percent of under-five children with fever referred to health facilities
- Percent of CHWs supervised

At the beginning of the pilot, USAID provided all commodities and supplies for the CHWs. Within six months, artemisinin-based combination therapy (ACT) and RDTs for CHWs were integrated into the normal supply chain of the districts with commodities coming from the stock at the national warehouse.

CHWs call the health center with the number of positive malaria cases to be included in the health centers' weekly report. In addition, the CHW provides a monthly report (a copy of the patient register) to the health center. SIAPS helped the national malaria control

program (PNILP) and districts to develop an integrated monthly report for health centers and a simplified database so the health centers' compiled reports can be used by districts.

CCM Results

In September 2013, SIAPS conducted an evaluation of the pilot project (covering October 2012–August 2013) with the following preliminary results:

- 36,200 children under five experiencing fever were able to access CHW services
- Of those children, 30,471 (84 percent) accessed services within 24 hours
- Of the 35,888 (99 percent) children tested for malaria, 24,667 (69 percent) were diagnosed positive using a RDT.
- 24,085 (98 percent) malaria cases were treated with ACTs.
- 20,957 (87 percent) of those cases were treated within 24 hours.

The data clearly shows an increase of families taking sick children to CHWs, to being tested and provided with treatment within 24 hours of the onset of fever. This rapid testing and treatment at the community level of care leads to a more rational medicine use, improves the health outcome, and reduces child mortality.



"The CCM of malaria strategy is very good. Since its implementation, the children are well cared for and we don't observe death of children at home because of malaria. When a child has a fever, even if at night, his mother takes him to CHW's home. The CHW wakes up and examines the child, gives him the test, and if the child has malaria he is directly treated. The strategy should be maintained and, if possible, expanded to other provinces."

- Amida Manariy, from Ngogomo Colline, one of the members of the health committee at Nyungu health center in Gashoho.



Systems for Improved Access to Pharmaceuticals and Services
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