Strengthening Pharmaceutical Services Program Six-Country Associate Awards: Final Report

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program built capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focused on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Abstract

This report summarizes the activities conducted under the SPS six-country Associate Award, which began on July 23, 2010 and ended on December 22, 2012. The countries included in the report are: Bangladesh, Brazil, Ethiopia, Namibia, The Philippines, and South Africa.

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TABLE OF CONTENTS

ACRONYMS

ACT	artemisinin-based combination therapy
ADR	adverse drug reaction
AMR	antimicrobial resistance
ART	antiretroviral therapy
ARV	antiretroviral
CRPHF	TB Reference Center Prof. Helio Fraga (Brazil)
DGFP	Directorate General of Family Planning (Bangladesh)
DoH	Department of Health (The Philippines)
DTC	Drug and Therapeutics Committee
EDT	Electronic Dispensing Tool
FDC	fixed-dose combination
FY	fiscal year
FMHACA	Food, Medicines and Health Care Administration Authority (Ethiopia)
FMoH	Federal Ministry of Health (Ethiopia)
GLC	Green Light Committee
MDR	multidrug resistant
MIS	management information system
MoH	ministry of health
MoHSS	Ministry of Health and Social Services (Namibia)
NTRL	National TB Reference Laboratory (Philippines)
NDoH	National Department of Health (South Africa)
NMRC	Namibia Medicine Regulatory Council
PEPFAR	US President's Emergency Plan for AIDS Relief
PFSA	Pharmaceutical Fund and Supply Agency (Ethiopia)
PBSP	Philippine Business for Social Progress
PMI	President's Malaria Initiative
PMIS	pharmaceutical management information system
PMTCT	prevention of mother-to-child transmission
RPM Plus	Rational Pharmaceutical Management Plus (Program)
SPS	Strengthening Pharmaceutical Systems (Program)
STGs	standard treatment guidelines
TB	tuberculosis
UNAM	University of Namibia
USAID	US Agency for International Development
WHO	World Health Organization
XDR	extremely drug resistant

INTRODUCTION

The US Agency for International Development (USAID) awarded Management Sciences for Health its five-year Strengthening Pharmaceutical Systems (SPS) Program in 2007 as a follow-on to its Rational Pharmaceutical Management Plus (RPM) Program. The mandate of the SPS Program was to build capacity within developing countries to effectively manage pharmaceutical systems, successfully implement USAID priority services, and ultimately save lives and protect the public's health by improving access to and use of medicines of assured quality.

Poverty, lack of economic productivity and opportunity, and social and political upheaval all contribute to inadequate access to life-saving medicines, and the burden falls mainly on susceptible members of society—the poor, women, and children. However, the international aid community has recognized and is addressing the need: new funding sources, such as the US President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and the Global Fund to Fight AIDS, Tuberculosis and Malaria, are making unprecedented sums of money available to procure medicines for deadly diseases.

The two greatest threats to successfully increasing access to medicines are inadequate pharmaceutical supply systems and the worsening human resource crisis. Infrastructure, management systems, information technology, and adequate experienced staffing are lacking in the health systems of many resource-limited countries. Regulatory authorities are stretched thin, with counterfeit and substandard products posing an increasing threat.

The SPS Program focused on achieving four key results—

Improving governance in the pharmaceutical sector. Good governance in public health implies the existence of up-to-date and well informed policies, laws, and regulations, and their appropriate enforcement. Governance improves by promoting accountability and transparency and involving civil society in the governance process.

Strengthening pharmaceutical and laboratory management systems to support public health services/interventions. Strengthening systems requires a long-term commitment and strategies that are flexible enough to adapt to changes, whether related to politics, finances, or personnel. For most countries, strengthening requires building a foundation for interventions that will yield sustainable improvements, such as curricula reform, while at the same time implementing activities that address more immediate problems, such as the need to train and retain existing staff.

Containing the emergence and spread of antimicrobial resistance. The emergence of extremely drug-resistant tuberculosis (TB) and resistance to new antimalarial medicines highlight the urgency of stepping up the rollout of critical interventions to address resistance—from the individual patient, community, and hospital levels to advocating for antimicrobial resistance (AMR) containment strategies at the national and international levels.

Expanding access to essential medicines. Expanding access to medicines requires that barriers to geographic accessibility, product availability, product affordability, cultural acceptability, and

appropriate use be addressed as part of an effective and efficient pharmaceutical management system.

The overall objective of the SPS Program was to improve access to and use of life-saving medicines and health commodities of assured quality to support priority health services in developing countries. To address the challenges under the six-country Associate Award, SPS used strategies and approaches similar to those it used for the Leader with Associate Award in the six Associate Award countries: **Bangladesh**, **Brazil**, **Ethiopia**, **Namibia**, the **Philippines**, and **South Africa**. This Associate Award began on July 23, 2012 and ended on December 22, 2012.

The SPS Program's approach to achieving the technical objectives of the Associate Award follows.

Improve supply chain management and commodity security. The SPS approach to supply chain management went beyond the traditional concepts of product availability by considering the four dimensions of access: availability, affordability, geographic accessibility, and acceptability, and by basing our interventions on the entire pharmaceutical management framework, which represents the coordination of activities to ensure the accessibility of appropriate, high-quality commodities. To increase supply chain efficiency, SPS assessed a country's or program's capacity to manage pharmaceuticals at all levels, from facility to national level. Then, using a stakeholder consensus approach, we identified areas for improvement and develop interventions to strengthen the system for the long term, such as building capacity among facility level staff to track medicine consumption or working with the central medical store to develop an efficient distribution plan. In Namibia, we provided technical assistance to the Namibia Medicines Regulatory Council to streamline the drug registration process. The result was a 30 percent increase in the number of registered antiretroviral (ARV) medicines and more than a 70 percent increase in the number of multisource generic ARVs.

Enhance the quality of pharmaceutical services. The SPS approach to establishing and improving pharmaceutical services encompassed pharmaceutical care, medication safety and pharmacovigilance, appropriate medicine use, and pharmaceutical sector governance. To ensure services that will result in optimal treatment outcomes, the SPS Program built systems to train health professionals and providers, provide medicine information and counseling, conduct drug utilization reviews, formulate policies and regulations for improved pharmaceutical care, and disseminate information and educational materials to promote public health.

SPS built the capacity of organizations and their staff members to better lead, manage, and provide appropriate oversight of different pharmaceutical management activities. With SPS's development of an infection control self-assessment tool combined with a continuous quality improvement methodology, several hospitals in South Africa and Swaziland experienced measurable improvements; for example, compliance with hand hygiene policies increased by 29 percentage points and observance of contaminated waste policies increased by 45 percentage points.

Build human resource capacity. Many countries face a dire shortage of skilled health care workers, including pharmacy personnel. SPS helped countries conduct comprehensive workforce planning to address their human resource challenges. This often involved a systematic approach to data collection and reporting that helped determine workforce needs, match workforce and educational outcomes, and built a compelling case for optimizing the number of funded posts in the public sector. The SPS Program used a capacity-building approach that involved pre-service and in-service activities and interventions that focused on both the people doing the jobs and the institutions responsible for training current and future health workers. We worked to address developing countries' limited expertise in pharmaceutical management and the dearth of people with the skills needed to provide technical assistance. For example, SPS supported the adoption of new guidelines for TB control and developed multidrug-resistant (MDR)-TB guidelines and training materials in Brazil. Our nationwide capacity-building programs focusing on case management, diagnostic capacity, and monitoring of MDR-TB cases contributed to a 12 percent increase in the DR-TB cure rate from 2004–2010.

Address information system challenges. Information for timely and informed decision making is critical for the successful management of pharmaceutical systems supporting national health programs. In addition to the timely and accurate collection and reporting of data, an important objective in a pharmaceutical management information system (PMIS) is to assure that staff at all levels of the health care system have the ability to analyze and use many of these data to make better decisions. SPS promoted a comprehensive pharmaceutical management approach to ensure that the PMIS captures information on both products and patient-focused parameters. We worked with partners to assess the existing PMIS, analyze gaps, and develop a system that meets stakeholder needs, including harmonizing and coordinating donor activities and reporting. SPS developed electronic and manual pharmaceutical management tools that can be adapted for different country contexts. We introduced the first patient medication records at Ethiopian dispensaries and provided automated record keeping and inventory control tools. As a result, over 100 public hospitals, 400 health centers, and 25 private facilities benefited from a common patient recording system that covers about 180,000 ART patients.

INDIVIDUAL PORTFOLIO SUMMARIES

Bangladesh Overview

Over the past few decades, USAID has supported strengthening the supply chain management system for reproductive health commodities in Bangladesh to ensure commodity security. While advances were made, problems still hindered the continuous availability of reproductive health commodities. Major stakeholders, including the Directorate General of Family Planning (DGFP) of the Ministry of Health and Family Welfare, the World Bank, the United Nations Population Fund, and USAID all agree that addressing procurement management in the DGFP was urgent.

Since the fall of 2009, the SPS Program provided technical assistance to the DGFP and other national stakeholders to improve procurement management systems for reproductive health commodities, build up existing distribution and management information systems (MIS), and increase local capacity to strengthen health systems. Initially, we conducted an options analysis of supply chain issues and developed culturally sensitive interventions to address identified gaps. SPS also conducted an in-depth review of the existing procurement management system and obtained agreement from the DGFP on detailed recommendations for improvement. In addition, SPS developed a training needs assessment, a capacity-building strategy, and a comprehensive procurement guidance manual to serve as the basis for procurement training. SPS conducted a review and options analysis of DGFP's warehousing and distribution infrastructure and also provided support to the Social Marketing Company, a nonprofit organization, to review and strengthen its procurement management systems.

SPS reviewed DGFP's web-based logistics management information system, upazila (subdistrict) inventory control system, and the warehouse inventory management system to determine their functionality and identify enhancements. SPS then designed a web-based procurement tracking system, which provides stakeholders easy access to procurement information. In addition, existing logistics reports were reformatted and new ones developed to ensure accurate, accessible, and timely data is available to support evidence-based decision making.

Objectives, Interventions, and Accomplishments

Objective 1. Improve the availability of commodities to support care and treatment of priority health conditions, including reproductive health, by strengthening commodity management systems

Improving reproductive and other health care services requires the availability of essential commodities. We supported reproductive health service delivery in Bangladesh by helping to develop systems for timely procurement and appropriate storage and distribution, thereby helping local counterparts avoid stock-outs. SPS helped DGFP build sustainable capacity in forecasting, supply planning, procurement, warehousing, and transportation and distribution management.

Interventions

- Provided technical assistance to DGFP management and staff to strengthen their skills and capacity in forecasting, quantification, and supply planning for reproductive health commodities
- Provided technical support to the DGFP to strengthen their procurement management systems and procedures
- Supported the DGFP in strengthening the systems and operations of a comprehensive supply chain management system for reproductive health commodities

Accomplishments

- Implemented a centrally coordinated mechanism (Logistics Coordination Forum) for routine national-level forecasting, (public and private sectors), quantification, and supply planning in collaboration with stakeholders
- Proposed a national-level body (DGFP Forecasting Working Group) with structure and terms of reference; initiated implementation of Pipeline software for supply planning.
- Conducted quarterly meetings of the Logistics Coordination Forum to review consumption trends, discuss pipeline status, and make procurement adjustments to ensure timely programming with suppliers
- Provided technical support to the DGFP to manage routine procurement processes under the Health Nutrition and Population Sector Program, including preparing tender documentation, developing technical specifications, verifying and authenticating documents, sourcing suppliers, and expediting orders
- Drafted comprehensive guidelines for DGFP to manage procurement based on existing policies, laws, regulations, and procedures
- Organized monthly update meetings with the DGFP Procurement Unit to review the progress of procurement packages and update the web-based procurement tracking system
- Worked with the DGFP Procurement Unit to update procurement status at the quarterly Logistics Coordination Forum meetings
- Produced monthly monitoring reports of reproductive health commodity supply to ensure continuous availability at service delivery points
- Carried out order processing, inventory management, warehouse management, shipment and route planning, and transport management
- Provided on-the-job training and tools to stores staff in upazilas to ensure accurate logistics data reporting through the upazila and warehouse inventory management systems

Objective 2. Strengthen commodity management information systems to support evidence-based decision-making

A comprehensive MIS is required to manage reproductive health commodities effectively in Bangladesh. This involved enhancing the functionality and content of existing DGFP tools, the upazila inventory management system, the warehouse inventory management system, and the web-based logistics MIS. SPS supported the electronic generation of routine programmatic, analytic, and strategic information reports to support forecasting, procurement planning,

monitoring and evaluation, and health system information systems reporting requirements in Bangladesh.

Interventions

- Strengthened the implementation and use of the DGFP MIS for reproductive health commodities
- Provided support to enhance MIS reports
- Provided support to enhance the functionality of MIS tools
- Developed and facilitated the use of a system and/or tools to track the progress of commodity packages through the procurement process

Accomplishments

- Continued to work with DGFP staff to conduct monitoring and supervisory visits to upazilas and warehouses to check data accuracy and validate data in the upazila inventory management system and warehouse inventory management system
- Rolled out the upazila system to new sites, conducted a training of trainers session, and helped DGFP train new users and provide refresher training to existing users
- Continued to contract with the local information technology firm to provide technical support and maintenance for the systems and to ensure continued functionality of the upazila and warehouse inventory management systems and the web-based logistics MIS
- Generated and disseminated routine logistics reports (e.g., monthly contraceptive commodity status report and DGFP contraceptive inventory tracking report) and other reports that the DGFP and other stakeholders need
- Reviewed the logistics data and information needs of various offices and departments within DGFP and modified the required reports to support decision making
- Implemented procedures to ensure timeliness of information and support evidence-based decision making, including defining specific roles and responsibilities for regular updates of dashboards and alerts that are readily available through the web-based logistics website
- Conducted a functionality analysis of existing tools and recommending enhancements, including an analysis of the pros and cons of emerging technology and tools
- Began preparations to implement an electronic upload procedure for paper-based logistics reports (Form 7b) and adopting available technology such as pen drives, CDs, GPRS/EDGE (general packet radio service/enhanced data rate for global evolution) or the Internet to reduce data transfer time and data entry errors
- Developed and implemented an online procurement tracking system that approved users use to monitor the status of all active procurements. The system is able to provide early warning alerts to enable timely actions to avoid procurement delays
- Trained 968 participants on upazila inventory management system software for 313 new sites. As a result of the training, all 486 Upazila officials have the knowledge and skill to run the software smoothly. Usage of the software system among the Upazilas was increased (can be monitored through the online portal) and staff are now able to auto-generate supply plans, issue vouchers, and monthly 7B reports

Objective 3. Promote commodity security by increasing the technical capacity of DGFP, national institutions, and networks in supply chain management through information sharing, replicating best practices, and collaboratively addressing relevant commodity management issues

Building local capacity to manage supply chain functions and strengthening the expertise of indigenous institutions is crucial to ensuring sustainable improvements under this objective. SPS developed a strategy to ensure reproductive health commodity security in the long term by strengthening the technical capacity of the DGFP and other local institutions to be providers of technical support and training in supply chain management. Our capacity-building initiatives went beyond traditional training by including procedures for mentoring, monitoring, supervision, review, and refining roles and responsibilities, job descriptions, secondments, etc.

Interventions

- Provided technical leadership and coordination in supply chain management of reproductive health commodities
- Advocated for commodity security of reproductive health commodities at all levels
- Provided technical assistance and support to build the capacity of indigenous institutions to provide supply chain management technical assistance and training

Accomplishments

- Served as secretariat of the DGFP Logistics Coordination Forum that oversees reproductive health supply chain management systems and facilitated quarterly meetings
- Coordinated stakeholder activities on supply chain management issues
- Worked closely with national organizations to identify opportunities for collaboration and capacity building in areas such as training, study tours, problem-solving workshops, and monitoring and supervision
- Supported SPS, DGFP, and partner staff participation in local and international conferences, workshops, and meetings to promote networking and sharing experiences in reproductive health commodity security
- Explored avenues to highlight the impact of US government investments by disseminating and sharing experiences and success stories resulting from reproductive health commodity security and supply chain management work in Bangladesh
- Conducted a needs assessment of DGFP and the Social Marketing Company as a basis for developing a capacity-building strategy through a consultative process; collaborated with the Central Procurement Technical Unit to conduct a training course for DGFP procurement staff
- Provided technical assistance and support to the Central Procurement Technical Unit to develop curricula and training programs for DGFP to build capacity in procurement and supply chain management

Brazil Overview

Brazil continues to be ranked as one of the 22 highest TB burden countries in the world. Although considerable progress has been achieved over the last several years and innovative

strategies have been introduced for better TB control, Brazil is still below United Nations Millennium Development Goal targets for TB control.

Since 2004, USAID/Brazil funded the RPM Plus and SPS Programs to strengthen pharmaceutical management in Brazil's TB program. Initial work entailed working with key TB partners, including the National Tuberculosis Program and Secretary of Health Surveillance, Oswaldo Cruz Foundation (Fiocruz/MoH), the TB Reference Center Prof. Helio Fraga (CRPHF/Fiocruz), the National Institute of Quality Control (INCQS/Fiocruz), Farmanguinhos/Fiocruz, and the Network of Public Pharmaceutical Manufacturers, the National Coordination of Laboratory Network, the Public Health Laboratory Network, and TB state and municipal groups.

Since 2007, SPS helped strengthen the nationwide diagnosis and treatment of MDR-TB patients, management of second-line medicines, and overall DR-TB surveillance; for example, the number of DR-TB treatment centers has expanded from 62 to 132, which has increased geographic accessibility. Also, we developed the web-based e-TB Manager© information management tool, which was implemented in all TB centers. SPS supported the adoption of new evidence-based guidelines for TB and DR-TB control and developed MDR-TB guidelines and training of trainers' materials. In addition, we conducted nationwide capacity building programs in all 132 reference centers focusing on case management, diagnostic capacity, monitoring of MDR-TB cases, and information sharing at all levels. These interventions contributed to a 12 percent increase in DR-TB cure rate between 2004 and 2010.

SPS strengthened DOTS and overall TB drug management by institutionalizing a permanent product quality assurance-testing program for first- and second-line drugs. As a result, Brazil was recognized by international organizations, including the Green Light Committee/Global Drug Facility at the World Health Organization (WHO), for promoting the use of quality assured medicines. SPS also supported the transition to fixed-dose combination (FDC) TB products by training providers in all 27 states in their rational use and by providing technical assistance to the public manufacturer of the new FDCs. In addition, SPS supported the national public health laboratory network to achieve international standards, implement quality systems according to ISO norms, and promote accreditation processes through innovative methodologies such as using LABMOST in five public health laboratories.

As a result of these achievements, SPS was recognized for its expertise among local TB partners and served on the MoH TB advisory committee to provide input into national TB policies.

Objectives, Interventions, and Accomplishments

Objective 1: Support the move to fixed dose combination regimens and the local production of new pharmaceutical forms for first-line TB treatment.

The successful uptake of the new TB treatment regimens based on FDCs required revising and strengthening pharmaceutical management procedures, including updating national treatment guidelines, protocols, and reporting and recording tools. SPS facilitated the use of FDC-based treatment regimens to improve treatment adherence and therefore increase the TB cure rate while

decreasing mortality rates. The government of Brazil strongly supports domestic manufacture of medicines, including anti-TB drugs. Brazil has been taking measures to bring domestic FDC production to international standards.

Interventions

- Provided technical assistance to key government agencies and partners to promote the appropriate use of TB medications in accordance with the new guidelines and to transition to FDC regimens nationwide
- Strengthened the TB supply chain management systems (including forecasting/ quantification, procurement, storage and distribution) to ensure an uninterrupted supply of quality-assured drugs
- Provided training to health professionals on pharmaceutical management for TB medicines

Accomplishments

- SPS was instrumental in supporting the national policy change for adoption of new regimens for first-line treatment (2RHZE/4RH) and introducing quality assured FDCs, which led to decreasing the TB pill burden from nine or six tablets to four or three tablets per day depending on the patient's weight. This switch helped strengthen patient adherence, thereby limiting the risk of monotherapy and reducing the emergence of drug resistance.
- SPS provided technical assistance in all steps of new FDC development (two in one and four in one FDCs) with the public manufacturer Farmanguinhos, the two in one forms having finished bio-equivalence studies. Four in one FDCs formulations are being evaluated, and a technology transfer agreement between a WHO-prequalified supplier and Farmanguinhos is being finalized to ensure a future autonomous supply of quality assured FDCs at national level.
- SPS strengthened DOTS and overall TB drug management by institutionalizing a permanent product quality assurance/quality testing program for first- and second-line drugs with government agencies. As a result, Brazil was recognized by international organizations, including the Green Light Committee/Global Drug Facility at WHO, or the TB Global Alliance, Bill and Melinda Gates Foundation, and the Clinton Foundation for promoting the use of quality-assured medicines and the implementation of adequate quality assurance policies. These leading organizations incorporated SPS Program results as key reference data in their most recent publications.
- This quality assurance program coordinated by SPS was instrumental in preventing the entry of substandard TB drugs procured by an international agency on behalf of the National TB Program/Ministry of Health (MoH). The event led to a new procurement process with a WHO prequalified supplier of quality-assured four in one FDCs.
- SPS created a task force with the National TB Program to develop interactive methodologies and conduct capacity building workshops to support the new regimen changes in all 27 Brazilian states (3069 health care workers directly trained and 8000+ health care workers trained through training of trainers program).

Objective 2. Strengthen NTP mechanisms to address anticipated challenges resulting from DR-TB and MDR/XDR-TB

Since 2004, SPS helped strengthen the nationwide diagnosis and treatment of MDR-TB patients, management of second-line medicines and overall DR-TB surveillance and expand access for DR-TB treatment and the implementation of the web-based e-TB Manager© information management tool. The tool is implemented in all DR-TB centers, and is now the MoH official tool for DR-TB management at country level. SPS also collaborated on the new edition of the TB guidelines and changes in TB policy as a permanent member of the MoH TB Steering committee.

Interventions

- Provided support to increase DR-TB detection rate
- Supported the development of training materials based on the new DR-TB guidelines and provided training to health care professionals
- Provided support to strengthen drug management for MDR/extremely drug resistant (XDR)-TB treatments
- Supported decentralization of the TB management information (surveillance) system to include patients who are on re-treatment under DOTS (not yet considered to be MDR-TB cases)

Accomplishments

- The detection rate of DR-TB patients countrywide has consistently been improving over the years with a significant increase of new cases notified in the system (20+ percent of cases notified comparing data from 2006 and 2009, and 30+percent comparing data from 2009 and 2010). An earlier notification process has led to an earlier start of treatment, offering a better prognosis
- The number of DR-TB treatment centers expanded from 62 to 154, increasing geographic coverage; 450 health professionals were capacitated in DR-TB management in all the 27 states of Brazil in 2010
- The DR-TB cure rate has consistently been increasing over the years, with a trend of decreasing mortality and treatment failure
- WHO and other international TB organizations fully acknowledged the innovative aspects and potential of the e-TB Manager for better recording and reporting, second line drugs management procedures, and overall DR-TB surveillance and are promoting the tool as a best practice for DR-TB control in international events.
- The e-TB Manager database has eight years of data available since inception in 2004, offering an exceptional potential source of knowledge for the DR-TB epidemic to analyze. As of 2010, Helio Fraga MDR-TB surveillance database had data from 4769 patient / case notification forms, 15,678 patient follow-up forms, and 2582 post-cure forms.
- e-TB Manager was awarded a special prize from Oswaldo Cruz Foundation / ENSP – 2010 – in the ‘’Innovation in Health Care’’ category
- SPS strengthened overall DOTS activities of Rio de Janeiro state by procuring logistical support for almost 2000 interventions (e.g., active case findings, bringing defaulters back to

health centers, sputum and results transport, food supplement distribution, capacity building of health care workers, and coordination meetings)

Objective 3. Strengthen the laboratory network to improve TB and DR-TB control

Introducing new treatment regimens based on the Brazilian list of approved TB drug products posed a major quality assurance challenge. We developed a tool (LABMOST) to strengthen laboratory management and technical services and help implement pharmaceutical quality assurance systems. Using LABMOST led to the successful accreditation of the National Institute of Quality Control as compliant with the ISO 17025 standard. Five state laboratories use LABMOST to help decentralize product quality testing. We helped expand the accreditation of drug quality control laboratories throughout the decentralized network. LABMOST is also being used to bring the CRPHF's quality assurance system up to international standards through the accreditation of the National Institute of Metrology. CRPHF needed additional technical assistance to become accredited.

Interventions

- Facilitated the coordination of stakeholders, partners, and working groups to ensure effective program implementation and sustainability
- Supported the expansion of the TB drug quality testing program
- Supported CRPHF by developing a quality system framework and related tools to build capacity at the state level (public health laboratories network)

Accomplishments

- SPS supported the national public health laboratory network to achieve international standards, implement quality systems according to ISO norms such as ISO/IEC 17015 (drugs and products quality testing laboratory network for sanitary surveillance) or ISO 15189 (TB public laboratory network for epidemiological surveillance). SPS also promoted laboratory accreditation processes through innovative methodologies such as LABMOST in partnership with the INCQS/Fiocruz in several public health laboratories or national reference laboratories (Amazonas, Bahia, Amapá, Federal District, Ceará, CRPHF/Fiocruz–RJ, IPEC/Fiocruz–RJ)
- SPS helped its main partner, CRPHF, to assume its national reference role within the national laboratory network, by implementing an external quality assurance program for smear microscopy at 27 lacens. Twelve out of the 27 public labs are also now supervised regularly for culture and drug susceptibility testing, in response to recommendations made during the previous WHO assessment
- As a result of these achievements, the CRPHF started the process to become accredited according to ISO norm 17025 with SPS support. CRPHF was also recognized as fully proficient by WHO South American Supranational Laboratory. The head of CRPHF lab was also recently invited to join the core experts group of Global Laboratory Initiative/WHO.
- SPS coordinated the establishment of complex private and public partnerships with several entities—international organizations or consortiums such as FIND, the Gates Foundation, the Union, the Brazilian TB–Network, MoH, CRPHF, and private companies such as Becton and

Dickinson and BioMérieux—to introduce new rapid TB tests using molecular biology (GeneXpert and HainlifeScience tests), which WHO has recommended). A final protocol was developed and agreements reached on the technical steps to introduce these new tools (validation, feasibility in operational/routine conditions, cost-effectiveness and impact studies). Once signed and implemented, this public-private partnership will produce a model for introducing these new tools in Brazil and set the stage for a policy transfer to other countries.

Ethiopia Overview

The SPS program in Ethiopia contributed to PEPFAR and PMI program targets by providing technical support to facilities that provide antiretroviral therapy (ART) and artemisinin-based combination therapy (ACT) services, including a pharmaceutical management information system. SPS played an important role in assuring the sustainability of interventions by introducing robust systems for patient-oriented pharmacy services in health facilities and strengthening human resource and organizational capacity. For example, SPS provided technical assistance and resources to key pharmacy stakeholders, such as the Food, Medicines and Health Care Administration Authority (FMHACA), the Pharmaceutical Fund and Supply Agency (PFSA), schools of pharmacy, the Ethiopian Pharmaceutical Association, Ethiopian Druggists Association and the regional health bureaus. SPS helped FMHACA strengthen governance in the pharmaceutical sector by improving policies, laws, and regulations; standardizing and streamlining work procedures, and also through developing standards and facilitating discussions with relevant stakeholders. With PFSA and the regional health bureaus, SPS engaged in improving the pharmaceutical services of health facilities by promoting rational drug use.

Ethiopia's Federal Ministry of Health (FMoH) has been leading a sector-wide reform effort aimed at significantly improving the quality and accessibility of services at all levels of the country's decentralized health system. As part of this reform, the ministry developed the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) in which SPS led the development of the pharmacy chapter and helped health facilities implement some aspects of the guidelines.

Under the Associate Award, SPS support was broadly focused on—

- Promoting rational medicine use and safety
- Strengthening the managerial, organizational and human resource capacity of prime partners to effectively manage pharmaceutical systems and services in Ethiopia,
- Strengthening the national capacity for the safe, accountable and timely disposal of pharmaceutical waste at the central and regional levels
- Improving the quality of services provided by rural drug vendors
- Strengthening the PMIS

This report summarizes the major activities accomplished by SPS–Ethiopia through the Associate Award in collaboration with government of Ethiopia stakeholders and other partners.

Objectives, Interventions, and Accomplishments

Objective 1. Promote partnership and collaboration among stakeholders to improve pharmaceutical services

Effective partnerships are essential to leverage resources, share experiences, avoid duplication, and ensure optimal service delivery. SPS collaborated with and strengthen the capacity of partners and stakeholders to improve pharmaceutical services.

Interventions

- In collaboration with other US government partners, provided technical support to strengthen the coordination function of the HIV/AIDS Prevention and Control Office, the National Malaria Control Program, and PFSA
- Promoted operational partnerships and collaboration among implementing agencies, partners, and stakeholders
- Advocated for harmonization of tools and approaches to support pharmaceutical management systems strengthening
- Collaborated with the Ethiopian Pharmacists Association and the Ethiopian Druggists Association in implementing improved pharmaceutical management practices

Accomplishments

- SPS helped the FMoH conduct a national malaria performance review—both desk review and field assessment—in collaboration with stakeholders. The review team compiled the report and presented it to stakeholders
- PFSA, SPS, and the World Health Organization (WHO) set up a collaborative agreement to conduct training on rational medicine use and drug and drug and therapeutics committees (DTCs) for health care providers. The training was completed for 181 health professionals representing 91 public health centers, 4 hospitals, 6 regional health bureaus, and 1 regional PFSA
- Similarly, a memorandum of understanding was signed with Johns Hopkins University-Technical Support for the Ethiopian HIV/AIDS Initiative to collaborate on providing training on adherence, drug information systems, and AMR in their catchment areas. This was an exemplary collaboration that created synergy between two PEPFAR implementing partners that were funded through the US Centers for Disease Control and Prevention and USAID

Objective 2. Provide assistance to strengthen institutional and human resource capacity for the delivery of quality pharmaceutical services to support expanded access to ACTs and ART services

Expanding quality pharmaceutical services in Ethiopia depends on adequate availability of a trained and experienced health workforce. The government is expanding pharmacy and other health professional training through public and private sector initiatives at all levels of the health system. SPS provided both pre-service and in-service training for health workers, mainly pharmacy professionals, as part of its capacity building efforts. SPS worked with schools of

pharmacy to carry out pre-service ART training for graduating pharmacy students. Likewise, SPS's in-service training program helped pharmacy personnel from public and private health institutions develop their skills.

Interventions

- Improved the organizational capacity of health facilities to support the provision of professional pharmaceutical care
- Supported the development and implementation of standard operating procedures for pharmaceutical management to strengthen institutional and human resource capacity
- Developed training materials based on the national treatment policies and guidelines and provide training in pharmaceutical management for ART and malaria
- Provided technical assistance to the schools of pharmacy to incorporate modern pharmaceutical management concepts in their curricula
- Supported the provision of in-service training and continuing professional development activities

Accomplishments

- Under the Associate Award, SPS's regional pharmaceutical associates organized a training of trainers' course on ART for pharmacists and university staff who constitute the trainers' pool for future ART trainings. As a result of the training, the pharmaceutical associates facilitated training requests from SPS collaborators and partners in the regions on their own.
- As part of its capacity building efforts, SPS collaborated with partners and provided trainings on DTCs and standard operating procedures for health professionals drawn from public and private health facilities. Under the Associate Award, 55 training events were organized for 1,540 professionals in collaboration with PFSA, WHO, regional health bureaus, the Clinton Foundation HIV/AIDS Initiative, the Ethiopian Catholic Church, HIV/AIDS Care and Support Program, and other US government partners. About 40 percent of trainees were druggists and pharmacy technicians, while 31 percent were pharmacists. SPS receives frequent requests from implementing partners to support trainings in their respective catchment areas for pharmacy and nursing personnel. SPS willingly participates in these trainings and its achievements in this particular activity have reached 192.5 percent.
- Pre-service ART training session was organized for Addis Ababa University Pharmacy graduating students in two parallel sessions: 61 pharmacy graduates successfully completed the course and were duly certified. This program was organized in collaboration with John Hopkins University/Technical Support for the Ethiopian HIV AIDS Initiative.
- SPS collaborated with PFSA to institutionalize DTCs in the health care system including building the staff capacity of PFSA, regional health bureaus, and zonal health offices to actively participate in DTC functions and provide support to nearby DTCs. PFSA and SPS organized an eight-day training of trainers' course on DTC for 29 health professionals drawn from PFSA, regional health bureaus, and zonal health offices.
- A total of 112 pharmacy and malaria personnel from Oromia region were trained at four antimalarial drug management training sessions on malaria disease and management of antimalarial drugs.

- In collaboration with the Ethiopian Pharmacists Association, SPS conducted two sessions of continuous education training on malaria and antimalarial drug management for 70 pharmacy professionals in the private retail outlets.
- SPS supported the Ethiopian Pharmacists Association to conduct two continuing pharmacy education sessions on "communication skills to enhance pharmaceutical care" and "professionalism and regulation in pharmacy practices: international perspective." The sessions were attended by 108 professionals (60 practitioners working in retail drug outlets attended the first session and 48 pharmacists working in different sectors attended the second one).

Objective 3. Promote rational medicines use and medicines safety

Improper medicines use and poor adherence to treatment potentially lead to AMR, adverse drug reactions, and poor response to treatment. To achieve optimal treatment outcomes, SPS worked with the government to put in place national systems to monitor adverse drug reactions and ensure patient safety. DTCs are a critical mechanism to improve drug use, make transparent and evidence-based medicine selection decisions, and involve all health care providers in patient care.

Ethiopia's FMoH has been leading a sector-wide reform aimed at improving the quality and accessibility of services at all levels of the country's decentralized health system. As part of this reform, the ministry developed the Ethiopian Hospital Reform Implementation Guidelines, which focus on hospital management functions including pharmacy services. SPS has provided technical support to 19 hospitals to implement the guidelines to identify medicine use problems, improve medicine use, and promote DTCs.

Rural drug shops are the lowest level drug retail outlets in Ethiopia, but they serve the majority of the Ethiopian population. These shops operate predominantly in rural settings and they dispense medicines according to a list approved by the FMHACA. Taking into consideration the scope of the services provided by rural drug vendors and the number of beneficiaries of their services, SPS in collaboration with FMHACA and Oromia Regional Health Bureau initiated a program to improve the quality of service and access to essential medicines provided to the rural population through trainings provided to rural drug vendors.

Interventions

- Supported the establishment and proper functioning of national, regional, zonal, and institutional DTCs to oversee the promotion and implementation of rational medicines use strategies and interventions
- Supported the development and implementation of appropriate strategies to contain AMR at all levels of the health care system
- Supported the establishment of drug information services to provide unbiased information on medicines to providers and patients
- Provided technical assistance to strengthen adverse drug reaction monitoring and pharmacovigilance systems
- Promoted the rational use of medicines in the private sector including to rural drug vendors

Accomplishments

Support Drug and Therapeutics Committees at Health Facilities

- SPS, in collaboration with Ethiopian government stakeholders gave health facilities technical support to conduct meetings on DTCs and sensitized facility staff members on the need for the committee and its benefits. SPS in collaboration with PFSA supported 174 health facilities to establish DTCs throughout the country (87 percent achievement of target).
- SPS helped DTCs develop facility-specific medicine lists. Under the Associate Award, medicine list development workshops were organized by 26 hospitals. These workshops were attended by health professionals, mainly DTC members, staff representing different hospital departments, and professionals from the regional health bureaus, zonal health offices, and PFSA. A total of 26 facility-specific medicine lists were printed and handed over to the respective health facilities.
- Nineteen drug information services were established in six regions of the country (95 percent of the target). Drug information pharmacists have been assigned and are answering drug-related queries in addition to providing educational information on drug use, interactions, and new or withdrawn drugs by e-mailing the information to the medical staff or by posting the information on a notice board. A standard operating procedure to govern the activities of drug information services was also provided by SPS.

Improve the Quality of Services Provided by Rural Drug Venders

- SPS supported the FMHACA in its work to develop the first rural drug vender formulary. The formulary was developed in a workshop with experts from the Faculty of Medicine and School of Pharmacy, Addis Ababa University, FMHACA, SPS, and professionals from selected hospitals. The formulary and medicines list were printed and distributed to rural drug vendors by SPS.
- Under the Associate Award, SPS provided trainings to 217 rural drug vendors drawn from Oromia Region in five training sessions. The main purpose of the training was to bring changes in the skills of rural drug vendors concerning drug supply management and rational medicines use in general, and to improve their drug handling, storage, and inventory management system. SPS developed a rural drug vendor training curriculum, training materials, and job aids for this purpose. In addition, 46 experts/officials from the regulatory office of the zonal health department and FMHACA attended the training.
- Regional FMHACA and SPS office staff members in collaboration with zonal health offices made joint supportive supervision visits to trained rural drug vendors to provide support on dispensing and counseling services, storage, and segregation of expired drugs. There are indications that rural drug vendors are improving as the visiting teams saw that dispensing and counseling at the rural shops have became more patient-centered.

Promoting Rational Medicines Use

- SPS worked with FMHACA to organize three training events on proper medicine use for 89 health care providers from private hospitals. The objective was to create awareness among

physicians, pharmacy professionals, health officers, and nurses working at private health facilities to enable them promote proper medicines use through rational prescribing and dispensing of medicines.

- An electronic copy of the standard prescription form was distributed to 200 model health facilities. A total of 185 facilities also received standard treatment guidelines. Medicines dispensing and counseling job aids that were distributed to the health facilities helped the health facilities to improve dispensing counseling. Reports from 105 facilities noted that labeling and dispensing counseling practices have improved in the health facilities thanks to this intervention.
- SPS supported 17 DTCs to conduct prescription audits. The audit results indicated areas that needed targeted interventions.
- SPS collaborated with FMHACA and the Ethiopian Television and Radio Agency to present a one-hour talk on rational medicines use, where SPS and FMHACA experts responded to questions from the program facilitator and from the general public. There had been a series of interventions using electronic and print media on different aspects of rational medicine use, self-medication, adherence to treatment, and AMR.
- SPS regional pharmaceutical associates visited 167 health facilities to help implement rational dispensing practices and patient counseling as well as strengthen DTCs. SPS helped ARV dispensing units of health facilities to update patient information sheets and upload patient data to the Electronic Dispensing Tool (EDT). Moreover, data have been collected from health facilities to assess prescribing patterns using prescribing indicators. Pharmacy professionals at the targeted facilities have been mentored to improve their dispensing and counseling skills.
- Information, education, and communications materials supporting AMR control were distributed to 48 health facilities to help improve the rational use of antibiotics. After receiving the materials, 29 health facilities initiated patient education sessions with the aim of promoting rational medicines use.

Promote Recognition and Prevention of Adverse Drug Reaction and Pharmacovigilance

- SPS, in collaboration with the FMHACA and regional health boards, helped 27 health facilities conduct face-to-face discussions with health professionals on adverse drug reactions (ADRs). Over 100 health professionals attended the sessions and discussed challenges and ways to enhance drug safety monitoring and reporting.
- SPS provided technical assistance to six major health facilities in ADR monitoring and reporting. Allergy cards were developed and distributed to 29 public and private facilities in Addis Ababa, together with a job-aid for health service providers for patient education on drug allergies to be used during the regular morning patient health education sessions and also to be posted in waiting rooms. A pharmacovigilance newsletter has been produced and distributed.
- Twenty-one facilities sent 70 ADR reports to the WHO Vigibase at *the* Uppsala Monitoring Centre.

Objective 4. Provide support to strengthen the managerial and organizational capacity of PFSA, FMHACA, and regional health bureaus to effectively manage pharmaceutical systems and services in Ethiopia

Following the conclusion of a business process re-engineering exercise, FMHACA and PFSA roles changed; FMHACA now develops and monitors standards, while PFSA's mandate has been expanded to include managing the FMoH's supply chain, ensuring appropriate pharmaceutical services, and promoting rational medicines use through capacity building. Regional health bureaus are also responsible for various aspects of pharmaceutical management. To adequately fulfill their new and expanded mandates, SPS provided technical assistance to these national institutions to help them provide the oversight required to ensure the sustainable provision of quality pharmaceutical services.

The auditable pharmacy transaction system allows pharmacy services and transactions to be tracked, so they can be measured against standard treatment guidelines and international WHO indicators to measure rational drug use and pharmaceutical services. The auditable pharmacy transaction system enables pharmacy and finance professionals in the hospital to track all medicine transactions in the pharmacy on daily basis, check for accuracy of drug prices and pharmaceutical service quality, and make the transaction transparent, accountable, and auditable. In addition to providing accurate information on hospital expenditure on medicines and other supplies, the system is proving to be an important tool to curb the leakage of medicines and supplies from hospitals. The system was created by SPS in collaboration with Debre Markos Hospital management, Amhara Regional Health Bureau, and Amhara Bureau of Finance and Economic Development, and is compatible with the Ethiopian Hospital Reform Implementation Guidelines.

Interventions

- In collaboration with other US government supply chain management partners, provided technical assistance to FMHACA, PFSA, and the regional health bureaus to develop appropriate management and organizational support systems for pharmaceutical services
- Provided technical assistance and support for the review, update, and implementation of policies, laws, and regulations governing the pharmaceutical sector
- Supported the development of national standards and guidelines to help ensure improved governance in the pharmaceutical sector

Accomplishments

- The auditable pharmacy transaction system was successfully implemented at Debre Markos referral hospital after approval by Amhara Regional Health Bureau and Bureau of Finance and Economic Development; a scale-up of the system to other facilities in the region and beyond is underway. Among the 12 standards in the Ethiopian Hospital Reform Implementation Guidelines, the auditable pharmacy transaction system covers seven pharmacy standards.
- Joint PFSA–SPS meetings were organized to assess the progress of plans between PFSA and SPS at regional level in the presence of the PFSA branch managers, forecasting and capacity

building officers, assistant hub managers, and SPS Regional Pharmaceutical Associates. Each planned activity and obstacles for its accomplishment were discussed.
- The senior SPS pharmacist seconded to FMHACA spearheaded the preparation of facility standards for health posts, health centers, primary hospitals, general hospitals, and comprehensive specialized hospitals.
- SPS conducted six rounds of regional consultative workshops on specialty centers and ambulatory health care standards. FMHACA acknowledged SPS and USAID-Ethiopia for their continued technical support in the development of various regulatory standards: 13 standards were developed (5 approved by FMoH executives and 8 are scheduled for approval).
- A lack of clear policy, regulations, and guidelines on pharmaceutical waste disposal prompted health facilities to accumulate and hold to these unusable commodities for an extended time. To tackle this problem, SPS helped FMHACA draft a national framework and disposal directive on pharmaceutical waste management. The documents were finalized after SPS and FMHACA solicited stakeholder feedback through a national workshop. The workshop's 36 participants were drawn from the Ministry of Health, the Environmental Protection Agency, regional health bureaus, FMHACA branches, private and public health facilities, private importers/wholesalers, pharmaceutical manufacturers, retail medicine outlets, and SPS. Once endorsed by the concerned regulatory bodies, these documents are expected to serve as standard guides for management of pharmaceutical waste for the country.

Objective 5. Strengthen PMIS to support evidence-based decision making

SPS supported the generation, collection, and management of patient medication records at pharmacy level since the start of ART program in Ethiopia. The patient medication record system enabled recording of information related to patient demographic characteristics, medicines dispensed, and rational medicines use. SPS developed and implemented different management information system tools, including the EDT.

Interventions

- In collaboration with other relevant US government partners and government counterparts, helped develop a comprehensive PMIS for the recording, reporting, analysis, and presentation of patient- and product-related data to support decision making
- Provided support for upgrading and rolling-out the EDT to relevant ART sites and to selected malaria sites and provide on-the-job training and mentoring to ensure rational dispensing
- Provided continued support to the paper-based PMIS systems in ART and malaria sites as required
- Ensured the collation of information related to medicine use outcomes (such as adherence indicators, adverse drug reactions.) for pharmaceutical policy and medicine selection decisions, including individualized treatment options

Accomplishments

- During the Associate Award period, SPS provided support to over 500 ART sites (400 sites using paper-based tools and 165 sites using electronic tools). The support includes provision of

different forms, computers, printers, backup drives, and RW-CDs. SPS also provided some sites that have a heavy patient load with both Internet and telephone connections. The sites with computers were trained and given software support to properly use the EDT.

- SPS distributed manual PMIS tools to 565 health facilities to maintain patient information. Six private hospitals that started pediatric ART service were supported by providing the necessary manual form of the EDT and given training.
- Collection and compilation of national and regional ART patient uptake, including cumulative regimen reports had continued. The information was collected from 565 ART sites, compiled and shared with SPS management, USAID, Supply Chain Management System project, Regional Logistic Associates, regional health bureaus, HIV & AIDS Care and Support, I-TECH Ethiopia, Clinton Health Access Initiative, regional HIV/AIDS Prevention and Control offices, and Johns Hopkins University-Ethiopia.
- SPS with PMI funding conducted 11 continuous results monitoring system exercises to track progress and performance on availability/stock status, expiry, staffing, training, ADRs, infrastructure, dispensing, testing and treatment indicators. The report is used as a source data for quarterly end-use-verification reporting to PMI.

Namibia Overview

Since 2007, the SPS Program helped strengthen the pharmaceutical management system of Namibia's Ministry of Health and Social Services (MoHSS) by building on the work started by its predecessor, RPM Plus. In Namibia, SPS contributed to five PEPFAR program areas: adult treatment, pediatric care and support, TB/HIV, strategic information, and health systems strengthening. An overview of the activities leading up to the Associate Award follows.

SPS provided technical assistance to the Namibia Medicines Regulatory Council (NMRC) to streamline the drug registration process. The result was a 30 percent increase in the number of registered ARVs and more than a 70 percent increase in the number of multisource generic ARVs, including FDCs and pediatric formulations. SPS also developed an electronic medicines registration database (PharmaDex), and a strategic framework and systems to sustain NMRC achievements, which led to over 1,500 product evaluations since 2005.

Other SPS/Namibia accomplishments included the development of a pharmacovigilance and medicines safety system implemented through the new Therapeutics Information and Pharmacovigilance Center. In addition, we helped follow-up on a suspected increase in zidovudine-associated anemia identified through spontaneous reporting. An evaluation used a novel method for linking electronic health records that contained clinical, laboratory, and pharmacy data, and preliminary findings were used to change adverse event prevention practices. SPS also helped MoHSS secure funding from the Global Fund to increase active surveillance of medicines, develop pharmacovigilance guidelines, improve medicines information services, and enhance vaccines safety monitoring.

Assessments of Namibia's health system highlighted the dire shortage of pharmacists and pharmacist's assistants in public health facilities. One problem is that Namibia did not have a school of pharmacy and trained few pharmacist's assistants at the National Health Training Center—until 2007, a maximum of eight students per year, which was insufficient to meet the

country's needs. With our support, the Training Center was able to increase their training capacity, increasing the national coverage from 3.5 to 5.5 per 100,000 population.

SPS also developed tools to improve the pharmaceutical management information system, such as the EDT, which was originally developed for the Namibian context. The tool has been used to track ART regimen-switching rates, monitor drug resistance, and support health system decision making. To improve product selection, SPS also revamped Namibia's essential medicines selection system, revised and published the essential medicines list, and developed comprehensive national standard treatment guidelines.

Objectives, Interventions, and Accomplishments

Objective 1. Strengthen medicines regulatory capacity

Strengthening the capacity of regulatory authorities in developing countries requires prioritizing activities to ensure safety, quality, and efficacy of essential medicines and other health products in the country. The SPS Program collaborated with NMRC to develop a five-year strategic plan and helped streamline the registration process as well as develop supportive systems and institutional capacity. SPS helped institutionalize systems that enable NMRC to rely on decisions by stringent regulatory authorities and concentrate its limited resources on in-country monitoring for quality, safety, and effectiveness of approved medicines.

Interventions

- Provided support for the implementation of strategies and best practices to improve both regulatory capacity and process
- Strengthened NMRC capacity for timely registration of second-line HIV/AIDS and TB medicines, vaccines, and diagnostic devices

Accomplishments

- Continued to provide technical assistance to Pharmaceutical Control and Inspection and the Quality Surveillance Laboratory in fiscal year (FY) 11. As a result of SPS support, 263 dossiers of applications for registration of medicines were evaluated and 246 were registered. Nineteen of these were ARVs, while one was an anti-TB product. The laboratory was able to test 11 percent more samples than in FY10, having tested 265 (76 percent) out of the 351 that were received during the reporting period as compared to 209 (65 percent) out of 324 received in the previous year. Pharmaceutical Control and Inspection completed 14 local inspections were completed.
- Supported the development of a protocol for quality surveillance and testing of TB medicines as well as provided support for tests on selected medicines by a WHO-accredited laboratory in South Africa. Out of a sample of 32 anti-TB medicines that were tested, 3 percent failed.
- Helped map regulatory processes (medicine registration, safety, quality testing, inspection, and licensing) and revise five guidelines on inspection and licensing of pharmaceutical importation, pharmacovigilance, and postmarketing surveillance activities; completed guidelines for the Quality Surveillance Laboratory's quality management system.

- Consolidated the draft of 50 regulatory standard operating procedures and submitted them for formal approval by MoHSS.
- Continued to advocate for the transformation of the NMRC into an administratively and financially independent entity following agreements with technical experts in MoHSS on the transformation process. This is critical for the effectiveness, efficiency, and sustainability of the pharmaceutical governance and regulation in the country.

Objective 2. Improve treatment outcomes through effective use of evidence generated from pharmacovigilance activities

Increasing access to new essential medicines demands robust postmarketing surveillance systems to ensure the safety and effectiveness of these medicines. Pharmacovigilance systems promote adverse event detection, evaluation, and mitigation, which lead to improved treatment outcomes. Pharmacovigilance data informs treatment guideline revisions, such as the recent decision related to stavudine. There was also a need to in better understand the postmarketing safety profile of ARVs in Namibia, including long-term toxicity and impact of moderate to severe adverse drug reactions on patient treatment adherence. The MoHSS, with our support, established the Therapeutics Information and Pharmacovigilance Center (TIPC) to address the full spectrum of medicine safety and effectiveness activities including ensuring medicine quality, monitoring adverse drug reactions and medication errors, providing medicine information, and conducting comparative effectiveness reviews to inform the medicines selection process. SPS provided additional technical support to develop capacity to meet this mandate.

Interventions

- Implemented risk management strategies to reduce moderate to severe adverse events that impact on patient adherence and treatment outcomes
- Provided technical support for the implementation of prospective active surveillance for monitoring the safety and effectiveness of ART medicines

Accomplishments

- Helped the TIPC introduced the adverse events reporting forms (safety yellow forms) to the admissions team at the Windhoek Central Hospital and Katutura Intermediate Hospital. The forms were included in the patient files to improve recording and reporting of adverse effects of medications among in-patients.
- Continued to help the MoHSS analyze medicine safety signals—
  - In FY11, 455 adverse drug events were reported, 31 percent higher than in FY10.
  - A total of 154 therapeutic queries were reported to the TIPC, 36 percent higher than the previous reporting period.
  - The analysis of adverse drug event reports showed that 84 percent of the reports were ARV- related, while 10 percent were anti-TB medicine related.
- Assisted the TIPC conduct digital video conferencing sessions and supported the MoHSS's Technical Advisory Committee to draft and disseminate guidance on managing nevirapine-associated rash; drafted protocols to investigate nevirapine rash; and evaluated tenofovir-

associated nephrotoxicity. The actions show how pharmacovigilance contributed to patient care and improved treatment outcomes.

- Provided technical assistance for the development of an ARV drug interaction chart as part of the TIPC adverse events risk management strategies. This tool provides easily accessible information on all clinically significant drug interactions to clinicians to ensure that adverse events are prevented and treatment outcomes optimized.
- Supported the design, printing, and dissemination of 2,500 copies of the TIPC publication, *Medicine Watch*, which provides health workers with updated information on medicine safety issues.
- With support from the University of Washington, developed a draft implementation plan for the establishment of the active surveillance system; submitted the plan to the MoHSS technical working group on pharmacovigilance, and subsequently submitted it to the Global Fund Program Management Unit for approval; supported the MoHSS to develop data collection form to be used in the active surveillance system.

Objective 3. Expand the pool of skilled human resources for more effective pharmaceutical services

Both short- and long-term interventions contributed to the SPS strategy to increase human resources to deliver pharmaceutical services. Short-term interventions included continued salary support for key MoHSS pharmaceutical staff positions, supportive supervision, in-service trainings and professional development activities, and task-shifting. SPS also supported long-term human resource sustainability by providing technical assistance to training institutions.

Interventions

- Strengthened institutions and curricula for developing human resource capacity for delivery of pharmaceutical services
- Developed and implemented strategies to capacitate health care workers for the provision of pharmaceutical services

Accomplishments

- Provided financial support for three tutors at the National Health Training Centre and gave technical assistance to enhance the training of pharmacist's assistants. Through this support, National Health Training Centre graduated 15 pharmacist's assistants, all of who were deployed to health facilities immediately upon graduation.
- Provided mini-lab equipment to the University of Namibia (UNAM) Department of Pharmacy for teaching basic thin-layer chromatographic techniques to pharmacy students, with emphasis on pharmaceutical quality control.
- Supported the UNAM Coordinator of the Pharmacy Course, to deliver a presentation at the Africa Regional Tuberculosis Pharmaceutical Management Conference in South Africa. His participation in the Conference strengthened the capacity of UNAM Department of Pharmacy to provide technical assistance on pharmaceutical management in various areas including implementation of continuing professional development and in-service training to

health workers in the country, focusing on HIV, TB and other priority public health conditions.

- Helped develop the curriculum (guides and teaching modules) for the Bachelor of Pharmacy course at UNAM and helped inaugurate the BPharm program. A total of 25 applicants were admitted into the pharmacy course and enrolled into the first year of the program. The Pharmacy Course Coordinator and the Pharmacotherapy Lecturer assumed duties in October 2010 with SPS support. Teaching timetables were developed and lecturers and other resources were assigned. SPS developed a list of appropriate reference books and equipment.
- Provided salary support was provided for seven MoHSS and two UNAM technical advisory positions.

A total of 486 health care workers were trained through SPS-supported in-service trainings

Training topics	Number of Health Workers Trained
Medicines safety	104
PMIS	47
Infection Control (training of trainers)	28
E-TB Manager tool	28
HIV drug resistance monitoring and ART data quality training	123
Standard treatment guidelines (training of trainers)	43
Regional standard treatment guidelines	111
Operational research	2
Total	**486**

Objective 4. Improve access to priority health interventions through coordination of programs, decentralization, and integration of pharmaceutical services delivery

The increasing number of patients receiving ART was overburdening district hospitals, which could have compromised quality of care. This situation was exacerbated by lack of coordination among different programs and the logistical challenges the patients have to overcome to access care across providers. For instance, patients who received prevention of mother-to-child transmission (PMTCT) medicines or opportunistic infection prophylaxis and who also received ARVs or other chronic disease medicines typically moved from one clinic to the other to receive their medicines. As part of MoHSS's efforts to decentralize ART services, SPS helped strengthen pharmaceutical management and dispensing at lower-level health facilities to support the scale-up of referral and outreach programs. If lower-level facilities could adequately increase their services, then patients could access medicines for PMTCT, ART, TB, and opportunistic infection medicines more conveniently.

Interventions

- Provided coordinated and integrated delivery of TB/HIV, PMTCT, and pediatric pharmaceutical services

- Implemented the use of the mobile version of the EDT to dispense medicines and track outcomes in hard-to-reach locations in Namibia

Accomplishments

- Provided technical assistance to the Pharmacist Coordinator at the Directorate of Special Programs of MoHSS to develop simple Excel-based datasheets to aggregate and report data on MDR- and XDR-TB stock and patient information. The data generated by datasheets was subsequently reported at two TB program review meetings, and the same data was used for quantification of second-line TB medicine needs.
- Helped MoHSS train 28 health workers in preparation for the piloting of the e-TB tool in three hospitals. SPS also provided technical assistance for a pharmaceutical management assessment of the TB program, and completed a draft report and submitted it to MoHSS for review.
- Helped analyze pediatric ART data from 2006 to 2010 to highlight treatment trends; shared the findings with MoHSS stakeholders and presented them to the MoHSS Technical Advisory Committee. The analysis followed a quarterly ART PMIS report highlighting declining coverage of pediatric patients. The committee formed a subcommittee to investigate pediatric issues further and formulate appropriate recommendations. SPS also provided assistance by reviewing PMTCT guidelines and the pediatric ART care booklet, which will enhance pediatric ART care and monitoring.
- Supported a decentralization survey; the report was compiled and submitted to the management of the Directorate of Special Programs and Pharmaceutical Services for review and approval. One facility was upgraded, enabling 122 patients to have improved access to full ART services. Nine facilities were upgraded following recommendations from similar surveys, bringing full services to 4,783 people in the previous three years.
- Deployed the EDT was deployed to Aranos Health Centre, while the EDT-mobile and the electronic training manuals were rolled out to five more sites. The total number of sites with EDT-mobile version is 42. The ART patient population in outreach sites comprises 14 percent of the total ART patient population. The EDT-mobile sets were also being used as additional ART dispensing points in two high-volume hospitals to decrease patient waiting time and improve efficiency. In addition, an electronic EDT manual was finalized and rolled out to all sites to ensure sustainable training and mentorship of EDT users.
- Provided three tablet-counting machines to three high-volume hospitals that do a lot of pre-packing of medicines. Prior to the handover of the machines, SPS helped the three facilities conduct baseline surveys on manual pre-packing. The machines reduced the work load and enabled the re-allocation of labor resources to other patient management functions.

Objective 5. Implement and sustain institutional interventions to contain the emergence and spread of antimicrobial resistance (AMR)

Inappropriate use of medicines wastes resources can cause adverse events and poor treatment outcomes and can contribute to AMR. The SPS/Namibia strategy for addressing inappropriate use of medicines began with strengthening the essential medicines selection system including treatment guidelines, building the capacity of DTCs, and designing and implementing interventions to improve treatment adherence and control the emergence of AMR. In addition,

SPS enhanced MoHSS's capacity to monitor HIV drug resistance early warning indicators using the EDT.

Interventions

- Scaled up cost-effective interventions in health facilities that improve adherence to ART
- Helped strengthen and sustain the essential medicines selection system
- Supported the implementation of standard treatment guidelines and the revision, update, and publication of a new edition of the Namibia essential medicines list

Accomplishments

- Supported the countrywide rollout of the MoHSS ARV treatment literacy approach. Through this support, materials were televised by the Namibia Broadcasting Corporation on World AIDS Day 2010. The literacy materials were incorporated into the MoHSS's medicines adherence counseling curriculum, and 48 health care workers from 8 district hospitals were trained.
- Collaborated with WHO and MoHSS to conduct an early warning indicator training workshop in April 2011. The workshop equipped health facilities to monitor early warning indicators as well as conduct regular data validation between EDT and ePMIS at the facility level to enhance data quality. The workshop was attended by medical officers from 35 hospitals and covered the significance of HIV drug resistance to ART sustainability and capacity-building for monitoring early warning indicators.
- Supported data collection for the adherence survey in 20 targeted health facilities. Survey Warehouse, a private research firm conducted the exercise. It was the first in a series of surveys that aimed to help formulate initiatives on ART adherence. In total, 36 health sites will implement adherence initiatives including applications of comprehensive approaches in promoting, measuring, and monitoring patient adherence to ART.
- Worked with the MoHSS's Quality Assurance Division to train 28 trainers in infection control. This was followed by supportive supervision visits conducted in seven pilot sites to determine progress in hand hygiene and medical waste management practices. In addition, infection control activities were scaled up in 29 health facilities.
- Provided technical support to the implementation of Namibia's standard treatment guidelines (STGs) and monitored their use. Namibia launched the first edition of the comprehensive STGs, which were developed with SPS technical and financial support. Prior to their launch, SPS helped conduct a one-day national health care workers training of trainers workshop for participants from all 13 regional health directorates and health training institutions. Copies of the STGs were made available countrywide in both electronic format and hard copies. The STGs were posted at www.nmrc.com.na. In addition, SPS developed a number of supporting job aids, such as posters and algorithms on selected priority disease conditions.
- Conducted a pre-assessment in selected health facility to collect information on key prescribing practices and to provide baseline data for evaluating the effectiveness of STG usage in the facilities. Preliminary findings of the analysis highlighted inadequate prescriber compliance to treatment guidelines on selected conditions. The findings will form the basis for subsequent review and revision of the treatment guidelines.

- Helped MoHSS revise, update, and publish the next edition of Namibia's essential medicines list (Nemlist). With support from SPS, 28 suggestions for inclusion into the Nemlist were approved by the Ministry's management committee during the reporting period.

Objective 6. Support operations research and monitoring and evaluation activities

Lack of appropriate documentation, evaluation, and operations research can result in an inability to learn from what interventions are successful and which can be replicated. Operations research can help determine the effectiveness of interventions and guide decisions on their wider use.

Intervention

- Implemented priority operations research related to pharmaceutical services, appropriate use of medicines, and treatment outcomes

Accomplishments

- Collaborated with MoHSS to identify priority topics for operations research and enabled findings from such research to inform policy decisions. We promoted research to advance and sustain best practices and successful pharmaceutical management interventions deployed during the program.
- Supported training for two MoHSS staff in operational research covering evidence-based policy making process, research methods, and evaluating research and policy implementation outcomes. The staff members were drawn from the HIV/AIDS Response Monitoring and Evaluation Division and the National Pharmaceutical Policy Coordination Unit.
- Supported the submission and presentation of the following 10 abstracts highlighting the work of SPS in Namibia at the ICIUM conference in 2011:
  - Tracking of inter-facility patient transfers and retention on antiretroviral treatment in Namibia
  - Using mobile technology to strengthen HIV/AIDS management in remote areas
  - The effectiveness of therapeutics committees in addressing key public health problems
  - Improving access to art services in Namibia through decentralization
  - Strengthening patient adherence monitoring through the EDT
  - Risk of anemia associated with zidovudine (AZT)-based HAART in Namibia
  - Use of an indicator-based system for assessing, monitoring, and improving pharmacy practice
  - The Namibia treatment literacy approach: empowering patients with knowledge on antiretroviral therapy through audiovisual materials
  - Cost of ARV medications in the Namibian private sector—a limitation to increased access
  - Reported renal adverse events in patients on HAART in Namibia: analysis of the national pharmacovigilance data base for presentation during an international workshop on HIV treatment, pathogenesis, and prevention research

The Philippines Overview

Since 2007, the SPS Program has worked with the Philippine Department of Health (DoH) and other regional- and country-level partners and stakeholders to promote pharmaceutical management best practices in TB and ensure improved access to quality health care and treatment.

SPS conducted an Asian-Pacific regional Pharmaceutical Management for TB and MDR-TB workshops in Manila that included a rapid assessment of pharmaceutical management practices for MDR-TB and the development of country-specific improvement plans. We also conducted a Pharmaceutical Management for TB and MDR-TB workshop in the Philippines as part of a five-country workshop series to review country-specific progress in achieving improvement plan objectives and develop a revised action plan. Since 2007, SPS has participated in both the Global Drug Facility and Green Light Committee (GLC) monitoring missions to the Philippines as well as the expedited GLC technical assessment of the MDR-TB treatment and management component of the Global Fund grant. GLC recommendations suggested that the National TB Reference Laboratory (NTRL) needed to increase its leadership and management and human resources capacities to effectively perform its role as manager of the laboratory network.

In 2008, SPS began developing a Philippine-specific version of MSH's e-TB Manager tool to manage drug-resistant TB. As part of the adaptation of e-TB Manager, SPS provided technical assistance to the Tropical Disease Foundation—the Global Fund Principal Recipient at the time—to strengthen pharmaceutical management practices and reporting for MDR-TB. Subsequently, the transfer of the Global Fund Principal Recipient to the Philippine Business for Social Progress (PBSP) resulted in the DoH taking over technical responsibility for the e-TB Manager. Despite the changes in responsibility, e-TB Manager implementation continues to move forward. MSH and DoH signed a memorandum of understanding relating to the technology transfer of the tool in time to pilot the Philippine version of the program by July. In 2011, DoH reviewed its information system architectural engineering and decided to create a unified system using a software platform other than JAVA, leaning on the experiences of the e-TB Manager implementation.

Objectives, Interventions, and Accomplishments

Objective 1. Support the establishment of a national information system for the programmatic management of drug resistant TB

The transfer of the MDR-TB program to the DoH included oversight of the electronic medical records system for MDR-TB patients. The Philippine DoH also currently supports an electronic MIS for drug-sensitive TB. The two primary objectives now are to house the MIS for TB and MDR-TB on a web-based platform and integrate the databases for TB and MDR-TB management into a single electronic MIS; e-TB Manager may become the platform for integrating the TB and MDR-TB MIS if its performance meets expectations during the pilot phase.

The process for integrating and scaling-up the TB MIS involved expanding the MIS to include categories of DOTS cases (i.e., pediatric, prison, TB/HIV co-infected) and integrating it with the e-TB Manager's platform for MDR-TB patients. Following the integration, SPS supported the development, testing, and implementation for the new system similarly to the process for implementing and rolling out of e-TB Manager for MDR-TB as described below.

Interventions

- Developed training materials and modules to be used during trainings of e-TB Manager users
- Reviewed and monitored progress of the e-TB Manager pilot project implementation
- Developed a monitoring and evaluation tool for TB treatment centers and the central and regional warehouses

Accomplishments

- Customized e-TB Manager for piloting and rollout in the Philippines. In conjunction with the pilot, we provided the DoH with a generic version of the materials to adapt and use during the training of trainers and user trainings.
- Completed adaptations and adjusting minor program errors to finalize and validate the pilot version of the e-TB Manager tool; enhanced several versions of the e-TB Manager to address DoH requests
- Conducted an e-TB Manager users training at several facilities and making required minor adjustments.
- Conducted a national level training-of-trainers session to support the implementation of e-TB Manager and provide associated training materials; conducted several trainings to increase DoH capacity to manage the system, including addressing users' challenges and maintaining and handling the server.
- Provided program and information technology support remotely to country counterparts to quickly address scale-up barriers; continued to monitor the case management and drug management modules to ensure operations were being conducted according to protocol and to effectively troubleshoot tool challenges
- Helped the DoH develop a monitoring and evaluation tool for TB treatment centers and central warehouses that use e-TB Manager, beginning with the pilot facilities.

Objective 2. Improve pharmaceutical/logistics management for TB-related medicines and products

In accordance with WHO recommendations, the National TB Program adopted standard treatment regimens to improve MDR-TB patient outcomes. This policy change substantially affected medicine availability, patient adherence, and provider prescribing practices, underscoring the need for policy guidelines and a facility-level operations manual. The National TB Program asked us to help develop a pharmaceutical management manual that addresses both first- and second-line medicines management. The manual will serve as a resource for training staff on appropriate practices.

Delays in the procurement process for second-line medicines, ineffective quantification, and a lack of expertise in quantification had wide-ranging effects. The central warehouse and treatment centers reported an excess supply of some medicines and a shortage of others. The DoH needed skills-building exercises using tested methodologies and tools to improve long-term forecasting, procurement, and logistics processes.

Under the Global Fund grant for MDR-TB, additional pharmacists were hired to support expanded treatment and detection coverage as well as increases in target enrollment, and the National TB program planned to open new treatment sites. Each site would then be responsible for opening satellites to increase access to TB services. At the request of the PBSP, the Lung Center of the Philippines, and the DoH, SPS conducted pharmaceutical management training with a focus on using accurate country data to support the quantification of second-line medicines for GLC procurement.

Additionally, PBSP developed a procurement and supply management plan for the Global Fund grant; however, Global Fund queries on the plan prompted a request for us to help address technical issues. We helped PBSP finalize the plan by the deadline.

Interventions

- Adapted pharmaceutical management training materials for the Philippines and provided training to pharmacists in the DoH, PBSP, Lung Center of the Philippines, and treatment centers in TB drug management focusing on programmatic management of drug-resistant TB
- Provided support to the Lung Center of the Philippines in the area of forecasting and quantification of TB medicines in support of procurement for MDR-TB medicines
- Developed a manual of procedures to standardize pharmaceutical/logistics management of TB medicines policies and improve practices

Accomplishments

- Trained 15 pharmacists and staff from the National TB Program, PBSP, Lung Center of the Philippines, select regional treatment centers, and central medical stores, on TB and MDR-TB pharmaceutical management. The training focused on forecasting and quantification of second-line medicines. This training was followed by an intensive training on pharmaceutical management, comprising a series of six sessions and on-the-job mentoring of the pharmacists from the Lung Center and PBSP.
- Helped the TB program collect accurate and timely forecasting assumptions for new and existing patient projections and integrate new standard treatment regimens
- Helped counterparts use tested tools and methodologies to quantify medicines based on assumptions and projections
- Provided technical assistance to the National TB Program, Lung Center of the Philippines, and central medical stores to validate assumptions and calculations in preparation for placing the GLC order
- Adjusted assumptions from the validation session as appropriate
- Provided support to the TB program to procure second-line medicines from the GLC in accordance with the order schedule

- Met monthly with drug managers to develop the forecast and discuss the country's pharmaceutical situation. Procurement forms for 2011 and 2012 were produced as a result of the quantification and discussions
- Worked with the DoH and partners to establish working groups to develop policies and address policy conflicts relative to pharmaceutical operations including selection, procurement, distribution, and rational use. This group meets every month to discuss the drug status
- Developed a draft framework for the pharmaceutical management manual to address current and projected issues
- Drafted the procurement and supply management procedure manual; however, the TB program asked SIAPS to develop a shorter and action-oriented document for rollout

Objective 3. Improve management of the National TB Program Laboratory Network

The National TB Reference Laboratory (NTRL) provides guidance and oversight to the laboratory network of TB microscopy and culture/drug sensitivity testing services. WHO/GLC assessments of national TB laboratory services in 2009 found several system weaknesses relating to service coverage, specimen referral, recording and reporting, supervision, quality assurance, infection control, implementation of new technologies, and the need to integrate with the private sector.

In 2010, SPS was asked to assess the organizational capacity of NTRL to carry out its mandate of policy development, research, service provision, quality assurance and monitoring, and training and capacity building. Through structured interviews, site visits to representative facilities at each level of the health system, and a three-day participatory leadership and management assessment workshop, SPS identified several areas for TB laboratory systems strengthening over the next three to five years. The main underlying reasons hindering NTRL were (1) insufficient human resource capacity, (2) a lack of TB laboratory operations costing information to guide planning and budgeting, and (3) insufficient organizational leadership and management skills capacity at the central and intermediate levels. To address these deficiencies, SPS focused its technical assistance on human resource development, financial management and budgeting, and strengthening management, leadership, and organizational capacity at central and intermediate levels.

Interventions

- Assessed NTRL's organizational capacity to carry out its mandate with a particular focus on management, strategy development, and leadership
- Assisted the DoH in the transfer of responsibility from the Tropical Disease Foundation lab to the NTRL

Accomplishments

- Conducted four leadership and management development workshops for managers and their teams from NTRL, Lung Center of the Philippines Laboratory, Quezon City Health

Department, and Manila Health Department. Teams were introduced to leading and managing practices that have been field-validated and developed action plans. In the period between each workshop, teams received mentoring toward apply new practices to carrying out their action plans
- Reviewed NTRL human resource needs to carry out its mandate for national TB laboratory services; determined the number of positions needed and their respective functions
- Using the findings of the review, helped the NTRL develop a human resource plan with a revised organizational chart that provides justification for new positions and associated budget

South Africa Overview

Since 2003, the RPM Plus Program and then the SPS Program provided technical assistance in pharmaceutical management to the Government of South Africa at the national, provincial, and local levels. The goal of this assistance was to strengthen the capacity of pharmaceutical services to improve access to and use of health commodities for the treatment and care of those affected by HIV/AIDS. Under PEPFAR, our activities included conducting a rapid assessment of PMTCT services to identify gaps and target interventions to improve the management of PMTCT medicines and promote the use of new PMTCT guidelines. SPS also developed quantification models for HIV/AIDS products and trained staff accordingly. These models were specifically tailored to the South African national standard treatment guidelines for HIV and AIDS, TB, PMTCT, and post-exposure prophylaxis.

In support of medicine safety, SPS developed and conducted pharmacovigilance training programs and provided technical assistance in pharmacovigilance implementation at national and provincial level, especially to the KwaZulu-Natal province. SPS developed a tool for monitoring patient adherence to ARVs that the National Department of Health (NDoH) has adopted for nationwide implementation and which was incorporated into the national standard treatment guidelines. We also supported rational medicine use through our assistance to DTCs at provincial and institutional levels. These committees now play a key role in promoting compliance with standard treatment guidelines, reviewing drug use practices and expenditures, developing provincial medicine formularies, and assigning prescriber levels. SPS also supports the update of standard treatment guidelines, development of formularies, and training of workers on rational use.

To address the critical issue of AMR, SPS has helped strengthen the infection control program within the NDoH's Quality Assurance Directorate and seconded a deputy director for infection control to this directorate. SPS has also developed and implemented an infection control assessment tool and capacity-building programs in nine provinces, initiating the national rollout of the infection control program. In response to HIV/TB, MDR-TB, and XDR-TB objectives, SPS provided assistance and training in TB drug supply management, monitoring adverse drug reactions for MDR-TB, and implementing infection control strategies to address TB drug resistance.

The SPS Program has also provided support to government organizations, such as the Medicines Control Council and Pricing Committee, and to statutory organizations, such as the South

African Pharmacy Council, to address a wide range of policy issues including development of staffing norms for pharmaceutical services, standards of pharmacy practice, regulations and norms for dispensing practices, and policies and legislation to reduce the price of medicine and to improve medicine availability to communities. In addition, we have helped develop and implement pharmaceutical management indicators in support to the provinces' mandate to improve quality of services to support the national quality improvement initiative.

Objectives, Interventions, and Accomplishments

Objective 1. To improve governance in the pharmaceutical sector through advocacy and development and implementation of appropriate systems

SPS's strategy in South Africa for improving governance in the pharmaceutical sector involved developing and implementing systems to ensure accountability, transparency, and maximum stakeholder participation. We continued to support key national pharmaceutical policy initiatives and helped set norms and standards designed to increase the quality of pharmaceutical services in the HIV/AIDS program, with a focus on preparing for the launch of the national health insurance program.

Interventions

- Supported measures to improve governance with regard to compliance with standards for pharmaceutical services
- Provided technical assistance at the national and provincial levels to develop staffing norms, pricing guidelines, standard operating procedures, and standards for pharmaceutical care
- Promoted the development of public-private partnerships and participation of civil society in the management of pharmaceutical services
- Provided support to strengthen the registration process for new ARV formulations, especially fixed-dose combinations

Accomplishments

- To receive Global Fund money, SPS helped the NDoH choose an accredited pharmaceutical distributor from the private sector to distribute ARVs; developed terms of reference and request for quotation documents; evaluated bids
- Continued to support KwaZulu-Natal's Centralized Chronic Medicine Dispensing Unit; expanded the project to include community centers and places of worship; held a workshop with community volunteers who provide assistance at these collection points
- Provided comprehensive assistance in analyzing the current pharmacy human resource situation in the country, trends over the last 10 years, and recommendations to address pharmacy human resource challenges in South Africa
- Provided assistance to the Medicines Control Council regarding the regulation of medicines and clinical trials; helped draft policy regarding package inserts a pre-industry process for regulatory stewardship, and the protocol for the HIV vaccine
- Worked with the Office of Standards Compliance on the National Core Standards for Health Establishments. These standards are aimed at setting the benchmark of quality of care against

which the delivery of services will be monitored; created an extended pharmacy audit and checklists for pharmaceutical services

Objective 2. To strengthen pharmaceutical management systems by developing solutions and sustainable capacity for the implementation of best practices in quantification, procurement, inventory control, distribution, and use of pharmaceuticals

The planned expansion of the national HIV/AIDS program targeting about 500,000 new patients per year required a stronger pharmaceutical management system to ensure the availability of health commodities, uninterrupted services, and optimal treatment outcomes. To assure sustainability of the advances under this objective, we built public sector capacity, rather than carrying out the tasks on behalf of local partners.

Interventions

- Updated quantification model, tools, and approaches for HIV/AIDS, sexually transmitted infections, TB, opportunistic infections, and postexposure prophylaxis in accordance with new guidelines and trained national and provincial pharmacy and procurement staff in routine quantification and supply planning
- Built capacity for appropriate ordering, receiving, storage, and inventory management of medicines at national, provincial, and site levels
- Provided technical assistance for the establishment of appropriate pharmaceutical systems to support specialized programs such as PMTCT and TB/HIV at the provincial and national levels
- Provided technical support to health personnel to manage expanding ART services at all levels

Accomplishments

- Continued to support the Pharmacy Quality Improvement Initiative, which focused on medicine availability, waiting times, and assessment of prescribing and dispensing practices. After assessments were conducted at facilities in the Northern Cape, North West, and Mpumalanga, medicine availability improved at these sites. These tools were subsequently incorporated into the National Core Standards tools.
- Provided support in monitoring and evaluation of pharmaceutical services in Eastern Cape and KwaZulu-Natal. In KwaZulu-Natal, indicators were finalized, and in the Eastern Cape, a project plan was developed and facility visits scheduled. In KwaZulu-Natal, the monitoring and evaluation system is still in place and managed by the province with no outside support.
- Installed Infomaker© reporting software at all provincial depots in Western Cape, KwaZulu-Natal, Gauteng, Eastern Cape, and Free State as part of the plan to support the implementation of a national data warehouse at the NDoH.

Objective 3. To promote appropriate use of medicines and patient safety and contain the emergence of antimicrobial resistance (AMR) by implementing

selected interventions and strengthening Pharmaceutical Therapeutics Committees and infection control programs

SPS has conducted interventions in many countries to ensure the continuing effectiveness of existing antimicrobials and avoid the need for new, more costly second-line medicines. Technical assistance in South Africa focuses on committees and programs such as strengthening pharmaceutical therapeutics committees and infection control programs. Robust pharmacovigilance and infection control measures also help ensure the safe and effective use of ARVs and other medicines.

Interventions

- Supported the development and implementation of interventions to promote appropriate medicine use at national, provincial, and institutional levels
- Strengthened the role of pharmaceutical and therapeutics committees and monitor their performance to ensure appropriate selection and use of medicines
- Supported the implementation of revised standard treatment guidelines
- Helped NDoH expand its infection control program with interventions at the national and provincial levels
- Rolled out adherence measurement tools nationwide to support patient adherence and containment of AMR
- Strengthened pharmacovigilance at the national and provincial levels

Accomplishments

- Continued to help strengthen provincial pharmacy and therapeutics committees; for example, SPS conducted ABC analyses on provincial medicine expenditure and pharmacoeconomics evaluations, supported pharmacy and therapeutics committee governance, evaluated submissions of unregistered medicines, developed therapeutic alternatives when medicines are not available, and reviewed formularies.
- Conducted a study on HIV-positive patient adherence to co-trimoxazole prophylaxis in collaboration with the NDoH.
- Provided assistance to the NDoH's Quality Assurance Directorate in the development of the national infection prevention and control plan and manual. Activities during this period included improving hand hygiene practices (11 public healthcare facilities are now registered as part of the WHO Patient Safety Initiative and National Hand Hygiene Campaign Phase 1), development of a core curriculum for infection control for inclusion into basic nurse training, and a national surveillance system for healthcare acquired infections and rational use of antimicrobials.
- Supported KwaZulu-Natal to implement surveillance activities at ART sites; assisted in the development of tools, including an electronic data management system and trained personnel at 21 sentinel surveillance sites; helped develop the antiretroviral cohort adverse drug event monitoring study at seven of the sites.
- Adapted the SPS indicator-based pharmacovigilance assessment tool for the pharmaceutical industry in South Africa; assessed 25 pharmaceutical companies and presented the findings and recommendations during a national workshop. The tool was also used to assess the level

of pharmacovigilance in the public sector in collaboration with the Nelson Mandela Metropolitan University.

Objective 4. To expand access to essential medicines through advocacy for policy changes, support for decentralization, and introduction and deployment of electronic tools to ensure availability of essential medicines

SPS South Africa's strategy to improve access to essential medicines and ARVs involved advocacy and support to system changes related to decentralization and introducing electronic tools to improve data collection and reporting. These activities helped assure the availability of essential medicines in the most remote facilities and the delivery of services at facilities more accessible to patients.

Interventions

- Implemented computerized systems for drug supply and patient management at facility level and strengthened capacity for the use of pharmaceutical information
- Supported the establishment of a national pharmaceutical management information system
- Provided support to national and provincial pharmacy staff on monitoring and evaluation of pharmaceutical services

Accomplishments

- Continued to work with the NDoH, Supply Chain Management System project, and Clinton Health Access Initiative in supporting the US government's ARV procurement, including auditing provincial depots and treatment facilities, convening quantification and information workshops with national and provincial counterparts, facilitating meetings with the Medicines Control Council and Pricing Committee to address regulatory issues, and providing input on the impact of the new HIV standard treatment guidelines.
- Appointed and deployed 10 pharmacists, designated as ARV monitors, to all the provincial pharmaceutical depots, together with an ARV Monitoring Officer at the NDoH. The monitors reported regularly on the status and consumption of ARVs and TB medicines in the facilities and provincial depots. Stock-outs of ARVs decreased from 12.0 percent countrywide when monitoring first started to 2.4 percent. Success with the monitoring of ARVs and TB medicines led to vaccines and tracer chronic medicines also being monitored on a bi-weekly basis. All 11 positions were taken over by the NDoH.
- Developed a new pharmaceutical leadership development program covering topics such as governance, legislation and ethics, finance, human resources, advanced medicine supply management, and monitoring and evaluation; made support visits to participants to ensure that they were on track with their projects. This program was so successful we are organizing its expansion to other provinces.
- Introduced a database of overstock situations at facilities in Gauteng province to facilitate exchange between facilities and reduce waste, which resulted in the redistribution of stock valued at rand (R) 884 586 and cancellation of back orders worth R284 997.
- Assisted NDoH with the quantification of ARVs for the 2010 tender. This process was complex due to the expansion program for HIV testing and treatment and the introduction of

revised treatment regimens; implemented international benchmarking in the ARV and TB medicines tenders, which led to a 53 percent saving in the ARV tender and a 36 percent saving in the TB medicines tender, compared to previous tenders.

- Helped NDoH improve Limpopo provincial depot practices, which had transitioned from private sector outsourcing to being managed by the province. Specific activities included evaluating stock usage and preparing weekly stock availability reports; stock availability improved from below 50 percent in April to approximately 65 percent by June 2012. We conducted an ABC analysis to determine depot stock levels, prepared an activity based budget using the cost per patient day equivalent and cost per headcount for hospitals and primary care facilities, respectively.