

Pharmaceutical Management Interventions that Improve Country Health Systems

The Strengthening Pharmaceutical Systems Program



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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses 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.

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INTRODUCTION

The U.S. Agency for International Development's (USAID) Office of HIV/AIDS held a meeting in January 2009 to solicit input from partners on developing a strategy and approach to strengthening health systems; this document responds to that request for information on SPS experiences. The activities that we describe below are interventions that Strengthening Pharmaceutical Systems (SPS) and its predecessor program, Rational Pharmaceutical Management (RPM) Plus implemented that were funded largely by the President's Emergency Plan for AIDS Relief (PEPFAR) (exceptions noted). These examples do not comprise the full range of SPS's HIV/AIDS-related interventions, but are selected activities that have been in place long enough to demonstrate success and that illustrate a connection to overall health systems strengthening.

The meeting was organized according to the six building blocks that the World Health Organization (WHO) describes in their Framework for Action, *Strengthening Health Systems to Improve Health Outcomes*. This document is also structured around those six health systems building blocks, which are—

- I. Service delivery
- II. Health workforce
- III. Information
- IV. Medical products, vaccines, and technologies
- V. Financing
- VI. Leadership and governance (stewardship)

Although the SPS Program carries out activities to strengthen supply chain management, we also address a wide range of pharmaceutical management issues that help improve overall health outcomes such as governance, pharmaceutical financing, standards for pharmaceutical services, pharmacovigilance, rational medicine use and antimicrobial resistance, integrating new health technologies, and the role of the private sector.

In our HIV/AIDS-related work, SPS designed interventions explicitly to help scale up antiretroviral therapy (ART) programs, but our underlying implementation strategy has been to strengthen the pharmaceutical management system for a wider range of medicines and supplies, not just those related to HIV/AIDS. In addition, SPS has taken the approaches and tools developed under PEPFAR and adapted them both for other health system issues and for other countries. Similar to the large role the country's HIV/AIDS services play, the pharmaceutical system is a large part of the overall health system; by strengthening individual components, the whole system benefits.

Following is a matrix that summarizes some of the problems, interventions, and results of selected activities with links to the corresponding areas of the text that provides further detail.

Even after the PEPFAR program has ended, it will have “brought up the system for all of our clients.” —Jane Masiga, Mission for Essential Drugs and Supplies, PEPFAR partner in Nairobi

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Table 1. Summary of the Strengthening Pharmaceutical Management Systems Program

Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
I. Service Delivery	I.a. Accredit pharmacy services	Low standard of pharmacy services	Accreditation improves service quality	South Africa (SA) Ethiopia (ET) Tanzania (TN)	SA—A national report on the status of accreditation showed considerable improvements ET—389 ART health facilities supported to meet minimum package for pharmacy services
	I.b. Facilitate decentralization and patient down-referral	Shortage of pharmacists	Decentralization reduces patient load, costs, and improves access	South Africa Kenya (KE) Rwanda	SA—Expanded beyond ART to include other chronic illnesses KE—100 ART satellite sites established; 90% reporting regularly
	I.c. Develop and implement procedures and tools for medication counseling and treatment adherence monitoring	Poor dispensing practices and patient adherence	Good adherence improves treatment outcomes and reduces drug resistance	Kenya Namibia (NA) South Africa Zambia (ZM)	KE—Policy adopted nationally for all ART sites SA—Adherence tool adopted for nationwide implementation ZM—Training materials adopted for nationally
	I.d. Establish pharmacovigilance systems and infection control programs	Shortage of expertise and weak system to implement medicine safety practices	Pharmacovigilance and infection control improve patient safety and treatment outcomes	Namibia South Africa Swaziland (SA) Guatemala	NA—Establishment of national center for all essential medicines SA, SZ—Infection control interventions show improvements from baseline measures
II. Health Workforce	II.a. Implement Monitoring-Training-Planning (MTP) Approach	Inadequate training and limited skill level of health workers	Innovative approach builds skills and provides local problem-solving ability	Kenya Tanzania Uganda Rwanda	Comparative study showed improvement over traditional training approach
	II.b. Help Ministry of Health (MoH) identify sources of pharmacy personnel in the short	Severe shortage of pharmaceutical personnel	—Personnel shortage limits delivery of health services in short	Namibia RTRC (Uganda, Tanzania, Kenya,	NA—Doubled the number of pharmacy staff; 64% absorbed by Ministry of Health and Social Services (MoHSS)

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Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
	term and establish the Regional Technical Resource Collaboration (RTRC) to build institutional training capacity for the long term		term —Institution strengthening improves training capacity of training/academic institutions for long term	Rwanda) Ethiopia Rwanda (RW)	NA—Improved training capacity by 300% (from 8 to 24 pharmacist assistant graduates; target of 50 graduates in 2010) RTRC—Regional training materials developed and ongoing training programs established ET—Supported four schools of pharmacy to conduct pre-service training to over 700 students; assigned over 600 final-year pharmacy students to ART facilities during summer vacations RW—Capacitated the National University of Rwanda to train 117 pharmacy students in pharmaceutical management
	II.c. Build private sector capacity to dispense HIV-related medicines	Private sector pharmacy providers uninvolved, and therefore, untrained in ART interventions	Private sector increases the pool of providers beyond the public sector; many seek care in the private sector	Ethiopia Kenya Rwanda	ET—Legislation changed to allow private sector pharmacies to provide ART services; over 800 providers trained in collaboration with the Ethiopian Pharmaceutical Association KE—Over 1,000 private providers trained in ART topics RW—Supported the National Association of Pharmacists by training 17 members to train private-sector pharmacists
III. Information	III.a. Establish systems to collect, report and use pharmaceutical data to support health system decision-making at all levels	Inefficient system to track medicine availability and use	Accurate data supports informed decision-making for treatment and ART scale-up	Kenya Namibia Ethiopia Rwanda	KE—Documented procurement cost savings; data from 291 sites reporting NA—Facilities in 11 of 13 regions reporting accurate data ET—More than 400 facilities reporting and over 130,000 patient medication record actively maintained at ART

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Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
					<p>pharmacies RW—Support to 189 ART sites resulted in 85% reporting monthly with 70% accuracy</p>
	<p>III.b. Develop and implement the ART Dispensing Tool</p>	<p>Lack of accurate pharmaceutical management data for decision making</p>	<p>Accurate data facilitates strategic planning for ART scale-up and reporting to central level and donors, and minimizes wastage, errors, and inefficiency</p>	<p>Côte d'Ivoire Ethiopia Kenya Namibia Rwanda Tanzania Vietnam Zambia</p>	<p>—Over 1,000 facilities using ART tool to collect, analyze, and report program data —Tool adapted for malaria —Used to track patient treatment adherence and defaulting —Used to quantify medicine needs —Time savings results in shorter patient wait times —Improved data accuracy ET—Monitored medicine formulation change and tracked treatment defaulters NA—Used to calculate ART regimen modifications and switching rates NA—Used in antiretroviral (ARV) resistance monitoring program</p>
<p>IV. Medical Products, Vaccines, and Technologies</p>	<p>IV.a. Monitor progress by developing and tracking PEPFAR pharmaceutical management indicators</p>	<p>Lack of evidence to evaluate interventions</p>	<p>Indicators allow for benchmarking and tracking performance</p>	<p>Ethiopia Kenya Namibia Rwanda</p>	<p>—Quantitative data available by quarter since 2005; improvements tracked over time —Used system-wide for pharmaceutical management monitoring</p>

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Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
	IV.b. Implement a decision-tracking tool, technical guidelines, and procedures to improve evidence-based product selection	Outdated standard treatment guidelines (STGs) and essential medicine lists (EMLs)	Updated EMLs and STGs improve treatment and reduce costs	Ethiopia Namibia South Africa Rwanda Zambia	ET—STGs printed and disseminated NA—National EML revised SA—National EML revised RW—STGs printed and disseminated; national EML revised (2005, 2008) ZM—National STGs, EML, and essential laboratory supply list revised
	IV.c. Improve medicine use by strengthening DTC capacity	Lack of government and institutional capacity to monitor medicine use	Medicine misuse reduces treatment effectiveness and increases costs and promotes development of antimicrobial resistance	Worldwide Namibia Kenya Ethiopia Rwanda	—Trained over 800 from 69 countries NA—Established national pharmaceutical management information system KE—Reduced top antimicrobial consumption by 62% ET—Established 80 operational DTCs and trained members RW—Trained 165 pharmacists, nurses, and hospital directors in DTCs
	IV.d. Develop and implement Quantimed, an electronic quantification tool	Inability to quantify ARVs accurately	Accurate quantification assures medicine availability and cost efficiency and facilitates ART scale up	Kenya Namibia Rwanda Zambia	—Used as the national quantification tool in four countries —Adopted by SCMS project for quantification
	IV.e. Renovate storage areas and pharmacy medication counseling areas	Stigma among patients and unsecure storage space for medicines; pilferage of ARVs	Confidentiality improves patient adherence and improved storage reduces losses	Ethiopia Kenya	ET—Confidential patient counseling now provided in 200 facilities and infrastructure, including storage capacity, upgraded in 350 facilities
	IV.f. Develop and implement	Lack of supply chain information	Patients need medicines	Lesotho South Africa	LE—31 people trained at 4 sites SA—200 people trained at 91 sites

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Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
	RxSolution to strengthen supply chain management	results in medicine stock-outs and losses	available at all times and better information management improves system performance	Swaziland	SA—Used to facilitate decentralization of ART services through prescription transfer SA—Used to monitor WHO’s early warning indicators for drug resistance SW—147 people trained at 13 sites; use of tool resulted in Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) release of ARV procurement funds
	IV.g. Build institutional capacity to quantify, procure, store and distribute pharmaceuticals to minimize wastage and shortages in government and private-sector supply chains	Inadequate pharmaceutical supply chain cannot handle increased volumes	Patients need an uninterrupted supply of medicines	Ethiopia Kenya (MEDS and KEMSA) Namibia Rwanda Uganda (UG)	ET—Since 2004, HIV/AIDS medicine supply to facilities has been uninterrupted with no expiries or losses MEDS—Number of HIV/AIDS patients served has increased from 2,400 to 125,000 patients, with USAID targets met or exceeded KEMSA—Assessment completed and recommendations officially accepted by MoH UG—Backlog of 3.8 million doses of antimalarial distributed in three weeks
	IV.h. Improve procurement efficiency by assisting regional bodies to establish multi-country initiatives	Inefficient procurement systems cause high medicine prices and inventory overages and shortages	High prices stretch resources and inefficient inventory management results in wastage and lack of availability	East Central and Southern Africa (ECSA) (14 countries) Ethiopia	ECSA—Created coordinated informed buying mechanism as a first step toward bulk procurement ET—Worked with suppliers to schedule staggered shipments, which reduced expiries and maximized insufficient storage space

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Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
V. Financing	V.a. Estimate central medical store (CMS) service costs	Higher ARV volumes without cost-recovery mechanism increases costs to CMS	CMS needs to sustain financial and operational viability	Lesotho	—Costing study completed and mark-up/handling fees established —Fees accepted by Global Fund for reimbursement to CMS
	V.b. Estimate cost implications of ART regimen changes using ART Dispensing Tool	Lack of information on switching regimens to second-line	Treatment switching rates provide a benchmark for case management quality and contribute to accurate resource allocation	Namibia	Data from tool provided information for tertiary ART site to calculate regimen switching rate of 3.7%, which provides basis for improvements to case management and resource allocation
	V.c. Publish and promote the <i>International Drug Price Indicator Guide</i> (not funded by PEPFAR)	Lack of price comparison data for international procurement	Informed procurement reduces costs	Worldwide	—Procurement officers regularly consult list procurement assessment/planning —30 worldwide sources contribute to price information
VI. Leadership and Governance	VI.a. Develop and implement coordinated donor procurement mechanism for ARVs	Lack of donor coordination, transparency, and efficiency	Poor donor resource utilization leads to system inefficiencies	Rwanda	—National and international stakeholders actively participate in the system —Parallel supply chains combined into one, which streamlines operations —Monitoring and reporting system consolidated; treatment costs drop 33%
	VI.b. Implement procedures to streamline national	Backlog of product registration applications	ARVs unavailable in the country, including generic	Namibia	—Fast-track registration process established for ARVs —Drug registration database

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Building Blocks	Intervention	Problem	Why Important?	Countries Where Implemented	Evidence of Success/Impact
	health product registration process		products, which keep prices high and availability low		(PharmaDex) created; over 1,400 products evaluated since 2005 —All ARVs in STGs are registered, including generic products
	VI.c. Introduce procurement standard operating procedures (SOPs), and monitoring systems for oversight to increase transparency of procurement and supply system	Weak public health procurement system	Improved accountability and transparency result in a more efficient system and better public trust	Kenya	—SPS assessment resulted in recommendations for improvements —MoH accepted recommendations and is putting into place new operational/management procedures
	VI. d. Work with regional bodies and countries to identify gaps, share best practices, develop and adapt generic models and draft pharmaceutical policies, legislation, and strategic plans	Lack of strategic planning and policies	Strategic plans and policies provide a framework for pharmaceutical sector strengthening at all levels of the health system	Democratic Republic of Congo (DRC) East Central and Southern Africa (ECSA) Kenya	ECSA—14-country advisory network established (Regional Pharmaceutical Forum) KE—National laboratory capacity improved through development of national policy guidelines, strategic plan, national standards, standard training curriculum, standard operating procedures (SOPs), and lab reporting tools, which were accepted for national rollout
	VI.e. Develop and implement SOPs for laboratory and pharmacy services	Lack of SOPs	SOPs promote efficiency, serve as a standard for monitoring quality of services, and provide a basis for training curricula	Kenya Ethiopia Namibia Zambia	SOPs institutionalized by government for all ART sites

I. SERVICE DELIVERY BUILDING BLOCK

I.a. Enhancing service quality by setting standards and establishing accreditation programs

PEPFAR has been instrumental in increasing the coverage for antiretroviral therapy (ART) services in developing countries. As programs continue to scale-up, assuring the quality of services becomes more challenging. One method to address the issue is to establish and monitor standards and an associated accreditation process for programs, processes, and even health care providers.

South Africa put in place new legislation requiring accreditation for health care facilities in 2005. To support the Department of Health, RPM Plus and SPS **assessed over 1,100 public pharmaceutical facilities in nine provinces** to define their strengths and weaknesses, and provide strategies to meet the new accreditation requirements related to pharmaceutical services. In addition, RPM Plus and SPS trained more than 300 facility staff members in how to use the accreditation audit data collection tools. As a result of the assessments, RPM Plus worked with provinces to improve infrastructure, human resources, systems, and processes needed to fill pharmaceutical gaps. In addition, a national forum was organized to evaluate progress made towards reaching compliance with the new legislation. After the interventions, a national report on the status of accreditation showed considerable improvements in pharmaceutical services following the audit. In **Ethiopia**, RPM Plus helped define the ART pharmacy minimum package of services as part of an accreditation process and supported **127 public and private hospitals and 262 health centers** with staffing, training, storage, and patient/inventory management tools to meet the minimum package needed for accreditation.

Without the support of the staff of RPM Plus and the dedication of the pharmacy staff involved, we would not have been able to make the improvements that have been made in pharmaceutical services throughout the province.

—Ms. Lullu Peteni, Director of Pharmaceutical Services in the Eastern Cape, South Africa

I.b. Decentralizing health care services, including antiretroviral therapy

A key objective to improving quality of and access to health system services is bringing those services closer to the community and the patient, which is at the heart of many countries' decentralization policies.

Because of a shortage of pharmacists, pharmacy assistants and nursing staff must fill the gap in lower-level clinics in **South Africa**. SPS is working with the government and stakeholders to down-refer patients who are stabilized on ART from hospitals to primary health-care clinics, while maintaining a centralized dispensing unit at the hospital. In addition to **reducing the patient load** for the hospital's pharmaceutical service, this strategy also **reduces transportation costs** for patients and brings services closer to home. Hospital pharmacy staff prepares

prescriptions which are delivered to a clinic closest to the patient. As part of its computerized tool, **RxSolution**, SPS developed a **down-referral module to facilitate the prescription transfer**. At the clinic, pharmacist's assistants or nurses dispense the antiretrovirals (ARVs) and review patients' treatment progress. The clinic returns progress reports and uncollected medication to the hospital. The system worked so well for ART patients in the first six months that it was **expanded to include over 1,000 patients needing long-term treatment for mental illnesses and other chronic diseases**.

Kenya also developed a decentralization model that uses the concept of a satellite ART site linked to a central ART site with the infrastructure and human resource capacity to provide mentoring. **SPS developed a "decentralization tool kit"** to help facilities take over new roles and responsibilities in pharmaceutical management. Rollout of the ART tool kit began in November 2007. As of January 2008, SPS had trained 60 staff members on the decentralization concept; logistics management tools and job aids had been disseminated nationally; 11 national standard operating procedures (SOPs) finalized; supportive supervision materials pre-tested in seven districts, and mentorship materials printed. Fifty central sites now support **over 150 satellite sites, while national reporting rates have improved to exceed 90%**.

RPM Plus also worked with the central medical stores in **Rwanda** (CAMERWA) to decentralize its ARV distribution program in response to a government decentralization policy. RPM Plus conducted a situational analysis and recommended options to help Rwanda shift to a pull distribution system, where facilities quantify needs and place their own orders rather than CAMERWA "pushing" prepacked kits. RPM Plus helped CAMERWA upgrade its warehouse infrastructure to accommodate the decentralized distribution. The recommendations and improvements **decreased CAMERWA's workload**, reduced the number of trips that ART sites have to make to pick up pharmaceuticals, and reduced the amount of stock immobilized in the distribution system.

I.c. Incorporating medication counseling and treatment adherence monitoring as part of pharmaceutical dispensing



Inappropriate dispensing or misuse, where a patient receives or takes the wrong medicine or dosage, reduces treatment effectiveness and can potentially cause antimicrobial resistance, which may lead to the need for second-line treatments that are often more expensive and cause more adverse reactions. When facilities implement interventions to improve ART counseling and treatment adherence, all patients at the facility end up benefiting, regardless of the reason they are there. The communication skills learned for ART transfer to any medicine dispensing experience.

In **Kenya**, SPS developed a medication use counseling checklist for ART which serves as a job aid for dispensers to use when counseling their patients. The checklist helps

the dispenser ensure that the patient and his or her representative adequately understand the proper use of the medicine, its storage, and the possible side effects.

The **national ART program has now adopted the checklist and has rolled it out to all ART sites**. SPS is now introducing a similar tool to address Uganda's need to promote the rational use of artemisinin-based combination therapy and other antimalarials.

In 2004, an RPM Plus assessment in **Namibia** identified inadequate medication counseling as a challenge confronting the scale-up of the national ART program. Namibia never had SOPs for dispensing or monitoring of use of pharmaceuticals. The RPM Plus Program helped develop national SOPs for dispensing ART and trained all dispensers and other pharmaceutical officers on how to use them. The SOPs were reviewed and **adopted by the MoHSS for nationwide use**. Most importantly, anecdotal reports from patients indicate that they are satisfied with the quality of counseling provided during dispensing.

In 2007, the RPM Plus Program developed and validated a multi-method adherence assessment tool for use in **South Africa** ART facilities. To assess the tool's feasibility, SPS tested it with all clients presenting for routine follow-up ART care over two months at two South African health care institutions. The pilot showed that the tool was simple and practical enough to use in routine ART adherence assessment and improvement programs, and as a result, the Department of Health **adopted the tool for nationwide implementation and included it in the new ART standard treatment guidelines**.

In **Zambia**, RPM Plus helped develop ART pharmacy SOPs on patient medication counseling. The procedures include special attention to patients who may have adherence problems. In addition, **101 MoH and Churches Health Association of Zambia** health facilities use the ART Dispensing Tool (ADT) to monitor treatment and track down possible treatment defaulters.

I.d. Promoting patient safety through pharmacovigilance and infection control

Medicine information and pharmacovigilance are critical because they give health care providers and patients unbiased information on safety and effectiveness of medicines to improve treatment outcomes. Pharmacovigilance is particularly important when countries approve and use new medicines, such as ARVs, with limited experience. However, developing countries are hampered by a shortage of both expertise and the capacity needed to build a medicines information and safety system from the ground up. In collaboration with **Namibia's** MoHSS, RPM Plus developed a model for Namibia that integrated medicines information and pharmacovigilance activities into one unit to capitalize on the potential synergy between the two areas and to leverage scarce resources. The launch of the Therapeutics Information and Pharmacovigilance Centre (TIPC) in 2008 **introduced broad-based medicines safety services to health care providers and the public**. Although the initial purpose of the TIPC was to support HIV/AIDS services, its **mandate now includes all essential medicines**. As of December 2008, the center had received and processed 59 adverse drug reaction reports (86% of which were related to ARVs), handled 107 therapeutics inquiries, and trained about 150 health care workers on medicine safety.

An example of how the TIPC contributes to patient treatment and safety is through its spontaneous reporting system on adverse drug reactions. In 2007, Namibia changed the backbone of its recommended first-line ART from stavudine to zidovudine because of concerns about peripheral neuropathy, lacking any local safety data to support the decision. However, in 2008, TIPC surveillance indicated that zidovudine-associated anemia was the most frequent ARV adverse effect (64%). The HIV/AIDS treatment committee can now rely on this and other adverse drug reaction data generated by the center to inform subsequent guideline revisions. Creating systems and linkages that facilitate the use of pharmacovigilance information to improve medicine safety is imperative, and to benefit the local population, this information needs to be used to develop and review treatment guidelines.

Nosocomial infections are a major threat to patient safety worldwide, and hospital-acquired infections often require second- and third-line treatments that come with serious adverse effects. Although numerous guidelines exist, changing the culture to promote infection control remains a challenge in hospitals. RPM Plus and Harvard University developed a self-assessment and rapid quality improvement approach to improve hospital infection control practices in resource-constrained settings. Field-tested in the Philippines and Uganda, SPS introduced the tool and approach to hospitals in **South Africa** and **Swaziland** in 2007. Hospital teams conducted baseline assessments and used the results to develop and implement workplans. National partners and SPS staff supported the teams' workplan implementation through workshops, site visits, telephone calls, and e-mails. After eight months, in-country partners reported that the teams took ownership of the process and **promoted an infection-control culture** within hospitals.

Measurable results came from the teams' workplan interventions: in one hospital, the proportion of staff following hand hygiene policies increased by 29 percentage points from the baseline (57% vs. 86%); another hospital increased its compliance with contaminated waste policies by 45 percentage points (38% vs. 73%); a third doubled its assessment score for hand hygiene (33% vs. 66%); and a fourth hospital's assessment score for waste management increased almost seven-fold (12% vs. 83%). Self-assessment and rapid quality improvement comprise a simple and sustainable approach that builds teamwork and networking and yields quantifiable results. Based on these successes, SPS also rolled the approach out in **Guatemala** in 2008.



II. HEALTH WORKFORCE BUILDING BLOCK

II.a. Giving local staff members the tools to strengthen the health care system from the inside out: the Monitoring-Training-Planning approach

RPM Plus developed MTP as an innovative approach to skills building and problem-solving that places training tools and responsibility in the hands of local staff. MTP participants learn how to mobilize their own resources, carry out the MTP program through collaboration with colleagues, and improve pharmaceutical management in their health facilities. MTP is unique in that it empowers users to take immediate action in response to a particular problem, while building the required skills and structures that improve long-term efficiency and quality. The Regional Technical Resource Collaboration incorporates MTP into its HIV/AIDS pharmaceutical management training in facilities and **around 200 people in Kenya, Malawi, Rwanda, South Africa, Tanzania, and Uganda have learned and adopted the MTP process.** After incorporating MTP in Uganda, 12 facilities reduced ARV stock-outs by 15%, reduced medicine expiries by 27%, increased the stock counts that matched physical counts by 80%, increased the number of up-to-date stock cards by 60%, and increased the number of facilities using SOPs by 50%. In Rwanda, seven district pharmacies that implemented MTP increased stock counts matching physical counts by 20%. Other countries had similar results. From their experience, MTP appears to be a **cost-effective and sustainable intervention** to build local human resource capacity. In addition, the MTP approach provided public facility staff the technique and motivation to prioritize problems and improve their health commodity management practices.

II.b. Addressing human resource shortages in the pharmaceutical sector for the short- and long-term

In **Namibia**, a lack of public-sector pharmaceutical staff is particularly acute; about 80% of pharmacists work in the lucrative private sector. In addition, Namibia has no professional pharmacy training institution available; pharmacists are trained abroad or come from other countries to fill positions. SPS has worked with the MoHSS to address shortages in both the short- and long-term.



For a more immediate solution, RPM Plus and the MoHSS increased the number of qualified pharmaceutical staff in public service by identifying priority vacant positions and delineating needed roles and responsibilities—ranging from national pharmaceutical quantification and logistic specialists to regional and hospital pharmacists. To expedite recruitment, RPM Plus worked with a local Namibian human resource firm to **recruit and hire new staff to fill government vacancies**, while the USAID provided financial support for the

positions. RPM Plus collaborated on developing the job descriptions with the MoHSS, and the new staff, although not government employees, work within the government structure and under

the supervision of the MoHSS. In two years, **28 new recruits doubled the number of government pharmaceutical staff, and none left for the private sector**. To assure sustainability, the MoHSS agreed to eventually absorb the positions into the government system—**64% of the new staff has already been added to public service**. This collaboration created a new mechanism to help the government quickly fill urgent personnel needs in the public pharmaceutical sector, while allowing it to gradually absorb the positions into its existing structure.

To address the long-term issues related to the lack of institutions available to train pharmaceutical staff, SPS has helped Namibia **expand the institutional capacity of the National Health Training Centre**. SPS provided technical and financial support to the center to renovate classrooms and offices and provide tutors and consultants. Activities include revising the pharmacists' assistant training curriculum and developing standards and qualifications for the pharmacists' assistant course, paving the way for national accreditation. Through these efforts, the National Health Training Centre **increased its capacity for training pharmacists' assistants by 300%** from the previous 8 per year to the current 24 per year. Phase 2 of this project will double the capacity to 50 pharmacists' assistants per year by 2010. The graduating pharmacists' assistants have quickly engaged in government efforts to decentralize ART services to remote parts of Namibia. Severe shortages of critical health care personnel, including pharmaceutical staff, call for a systematic approach to establish and strengthen the capacity of local training institutions to produce competent health care personnel in response to national needs.

The National Health Training Center has indeed become a cornerstone institution to train health care providers throughout Namibia. It plays a vital role, particularly in the battle against HIV/AIDS and Tuberculosis. I am pleased that the United States Government has been able to support this Center and continue to contribute to its development.

—U.S. Ambassador to Namibia Dennise Mathieu

In addition to addressing public institutions to help build pharmaceutical sector human resources, we have found that providing technical assistance to academic institutions in resource-limited countries and fostering regional collaboration is an efficient way to build institutional capacity. The SPS Program has provided technical assistance to Makerere University in **Uganda to develop and coordinate a regional network of institutions to build capacity in pharmaceutical management**. The Regional Technical Resource Collaboration for Pharmaceutical Management comprises groups from Makerere University, Muhimbili College of Health Sciences in **Tanzania**, University of Nairobi in **Kenya**, and The National University of **Rwanda**. These institutions are leading in-country initiatives to build the capacity of health care workers to manage medicines by developing and adapting training materials, training health care workers, and developing effective approaches for skills building in low-resource settings. SPS has provided technical assistance to Makerere University and Muhimbili University to establish ongoing HIV/AIDS pharmaceutical management training programs; over 100 health care workers managing HIV/AIDS and other health care commodities have been trained in Uganda, while over 40 have been trained in Tanzania. In addition, the collaboration has **helped set up a**

pharmacovigilance system for Uganda’s malaria control program, which broadens its initial HIV/AIDS-centered mandate. To address weak human resource capacity in the pharmaceutical sector in **Ethiopia**, RPM Plus supported national partners, such as the schools of pharmacy and the pharmaceutical association with pre-service and in-service training programs in pharmaceutical management; for example, **over 600 final-year pharmacy students spent their three-month summer vacations working in rural ART facilities** to give staff an extra hand and to give students on-the-job training.

II.c. Including the private sector in human resource capacity building

SPS also recognizes the need to include the private sector in strategic planning for a country’s health system. Oftentimes, interventions focus strictly on the public sector, which ignores a substantial proportion of health care providers and clients who seek care from the private sector. In **Ethiopia**, SPS advocated for a legislative change to allow the private sector to provide ART services. SPS then helped build capacity in the private sector to deliver ART, including training 25 private hospital pharmacists in ART and ARV management; providing over 40 private hospital and community pharmacies with standard operating procedures for ARVs management; training 20 private pharmacy professionals to manage three fixed-dose combination drugs; and collaborating with the Ethiopian Pharmaceutical Association to **train more than 800 private sector pharmacists in ART and ARV management, good community pharmacy practice, and pharmacy ethics**. Activities have now expanded to include malaria treatment. SPS has done similar work in **Kenya** by collaborating with the Pharmaceutical Society of Kenya to reach out to private sector ART providers. To date, SPS has conducted **eight seminars on ART topics that reached 1,058 private practitioners countrywide**. Collaboration with the Pharmaceutical Society and other professional organizations improved linkages and participant turn-out from the private sector and provided practitioners an opportunity to share experiences from different settings and inform their strategies for improving the use of ARVs and other medicines.

III. INFORMATION BUILDING BLOCK

III.a. Creating a pharmaceutical information system that supports health system planning and decision making

At the onset of the PEPFAR program in 2004 in **Kenya**, assessments revealed commodity management challenges that constrained initial scale-up, including inefficient systems to accurately track commodity usage and a lack of data needed to support commodity management decisions, such as pharmaceutical order quantities. RPM Plus worked collaboratively with the National AIDS and Sexually Transmitted Infection Control Programme (NASCO) and other partners to track HIV/AIDS commodity usage at ART sites. The intervention entailed developing a centralized consumption database and implementing reporting tools on ARV drug usage. These data are aggregated to track patient load and ARV consumption, and facility staff members receive feedback to improve on data quality. Resulting data contribute to calculating patient scale-up trends and regimen proportions, therapeutic value analysis, and ABC analysis, which is a way to rank the value of medicines by consumption. The **commodity tracking data inform program decisions**; for example, the ABC value analysis using consumption data showed that after substituting generics of nevirapine, its **value shifted significantly from 40% of the ARV budget in 2005 to about 9% in 2007**. ARVs that comprise bigger proportions of the budget, and that support the bulk of the patients have been closely monitored to assure they are available at all times. To significantly improve HIV/AIDS program performance and planning, resources should be focused on strengthening pharmaceutical management information systems that produce key data for program planners.

The rapid expansion of ART services in **Namibia**—from 800 ART patients in 2004 to 42,000 in 2007—created enormous needs for reliable data on ARV prescription and use for monitoring and evaluation, strategic planning, and decision making at all levels. In partnership with a team from the MoHSS, SPS **developed and implemented a facility-based pharmaceutical management information system to support ART services**. The intervention included (1) mapping data requirements, including those related to pharmaceutical availability and inventory management, rational medicines use and pharmaceutical care, human resource/workload, and medicine financing; (2) developing 22 indicators to monitor and evaluate ART pharmaceutical services; (3) developing SOPs and tools for data collection; (4) involving facilities' therapeutics committees as stakeholders in developing the information system; and (5) developing a reporting system for upward data collection from facility to central level with a downward feedback loop. **ART facilities in 11 of 13 regions are now producing timely reports on ART management**, including monthly ARV consumption and stock availability reports. Facilities use the data to identify weaknesses in service delivery, such as imminent stock-outs, and central-level planners use data to quantify and procure needed medicines and monitor scale-up. A key achievement of this intervention was empowering facility staff to



generate and analyze data, and then use their own data to identify program weaknesses and take action to address shortcomings—not just report the data upward.

In **Ethiopia**, SPS helped create reliable pharmaceutical information systems by developing SOPs and data management forms. **Over 400 hospitals and health centers now use standard forms** for patient registration, tracking, and inventory control, and over 140 hospitals use SPS's electronic ADT to keep pharmacy dispensing and inventory records. This is the first time that pharmacies have ever maintained medication records—over 130,000 patients on ART and medicines for opportunistic infections have medication records. In **Rwanda**, RPM Plus helped the Pharmacy Task Force, the AIDS Treatment and Research Center, and the National Integrated Program to Fight Malaria to develop reporting tools for use at facility and district levels to ensure adequate pharmaceutical management of ARVs, opportunistic infection medicines, antimalarials, and other essential medicines. RPM Plus helped the **Rwanda** MoH to develop and train staff on how to use several pharmaceutical management reporting tools. By September 2008, **all health facilities and district pharmacies were able to report to the central level** on the consumption of ARVs and opportunistic infection medicines, antimalarials, and essential medicines.

III.b. Designing user-friendly tools that provide pharmacy-based health system data

A challenge of sites that deliver ART has been collecting timely and accurate health data for strategic planning using a paper-based health records system. To address the problem, RPM Plus developed the ADT in 2005 to maintain the patient profile, history of medicines dispensed, and other patient information, such as appointments. The tool also maintains medicine consumption and stock status information in real time that is used to quantify the medicines needed and inform other program management decisions. Users of the tool can also easily generate reports to meet multiple reporting requirements. As part of an evaluation of the tool, ART sites in **Kenya** reported the ADT's greatest benefit as **time saved in preparing reports and estimating reorder quantities** and in **improving accuracy**. As a result, stock-outs in PEPFAR-supported ART facilities are negligible. Pharmacy staff found that the time the tool saves by printing medicine labels and electronically updating patient records has **reduced patient waiting time**. In addition, staff can now track patient appointments, which gives them a mechanism to **follow-up with treatment defaulters**.

In **Namibia**, where nearly 100% of ART facilities use the ADT, the MoHSS has developed plans to use the tool to collect data for the World Health Organization's (WHO) HIV drug resistance early warning indicators to monitor and prevent resistance to ARVs. The 16 indicators include: ARV prescribing practices, on-time ART drug pick-up, clinic appointment-keeping, percentages of patients lost to follow-up, patients still on first-line ART at 12 months, and ARV stock-outs and shortages. In its current version, the **ADT collects data to measure 11 of 16 early warning indicators**, compared with sites that were able to monitor two to six indicators based on paper records, which is time consuming and subject to error. Adapting the tool to include missing indicator information is being considered. This would make it a comprehensive,

one-stop tool to measure the full set of early warning indicators, thus allowing both facility and program managers to make early corrective decisions related to ARV adherence and resistance.

In **Ethiopia**, 109 sites use the ART dispensing tool to make program decisions and provide better patient follow-up; for example, data from the tool **identified early side effects associated with stavudine 40 mg**, which resulted in replacement with the 30 mg formulation. In addition, program **managers use the tool to identify patients who interrupt medication**, so they can initiate counseling services at the facility level.

Currently, **nearly 1,000 dispensers have been trained in how to use the ADT**, and the tool is **used by over 400 facilities in at least nine countries** including Côte d'Ivoire, Ethiopia, Kenya, Namibia, Rwanda, Tanzania, Vietnam, and Zambia. SPS has also adapted the tool for use in other public health programs, such as malaria.

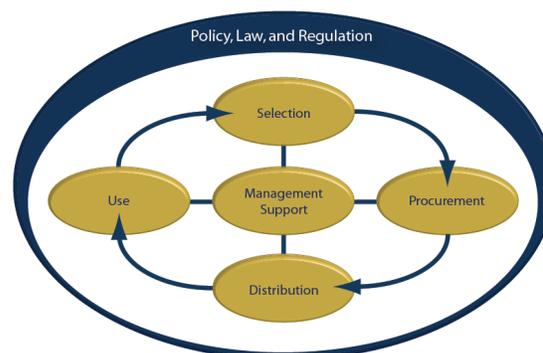
The ART Dispensing Tool is very useful, and so far, the only source of our data.

—Ndapewa Hamunime, HIV/AIDS Program Manager, MoHSS, Namibia

IV. MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES BUILDING BLOCK

The SPS approach is to not view pharmaceuticals as merely the beginning of a supply chain; instead, we base our interventions on the pharmaceutical management framework, which represents the flow of activities that must be coordinated to ensure that appropriate, high-quality medicines are available when patients need them. The framework emphasizes the cyclic relationships between selection, procurement, distribution, and use activities, all of which are enabled by a strong management support system.

Each component of the framework depends on the success of the previous component and contributes to the viability of the next. The entire framework relies on policies, laws, and regulations, which when supported by good governance, sustain the commitment to strengthen pharmaceutical supply systems.



Pharmaceutical Management Framework

IV.a. Developing indicators to benchmark and track pharmaceutical management performance

Key performance indicators are critical to the evaluation of any health system and its sub-components. With PEPFAR funding, RPM Plus and SPS worked closely with many countries to support the establishment and implementation of a core set of key pharmaceutical management indicators that the health care workers routinely collect and use to monitor and evaluate the extent to which pharmaceutical management strengthening takes place. Indicators measure components such as the adequacy of pharmaceutical reporting as well as the effectiveness of the pharmaceutical system in terms of ARV stock-outs. As an example, indicator data show that to-date, RPM Plus and SPS help 912 ART sites that support 447,542 patients in **Ethiopia, Kenya, Namibia, and Rwanda**—a 424% increase in sites and a 1,289% increase in patients since July 2005 (figure 1). By the end of 2008, **83% of monitored ART sites were producing accurate monthly stock reports**. Experience with these indicators has also helped SPS expand pharmaceutical management indicators to other health sectors, such as indicators for the President’s Malaria Initiative. Ultimately, these indicators could be consolidated into one set to measure the overall performance of a country’s pharmaceutical system and **could also be integrated into a fully functioning national health information system**.

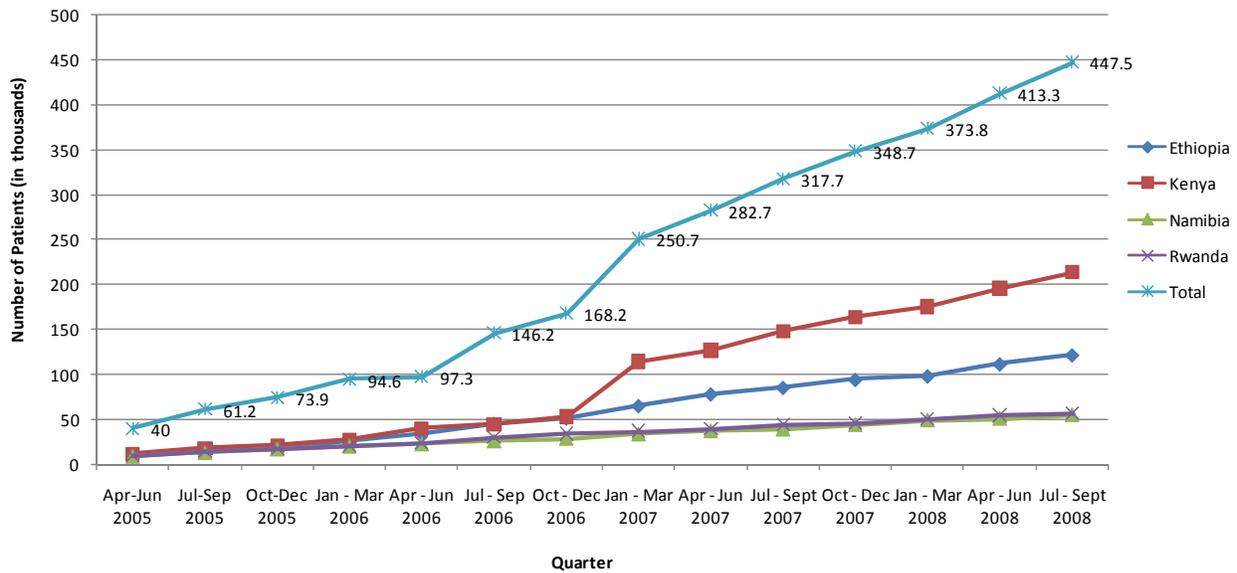
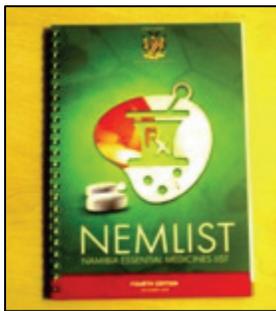


Figure 1. Number of ART patients enrolled at treatment sites receiving assistance from SPS

IV.b. Strengthening country systems to incorporate evidence-based medicine selection

A country's list of essential medicines should satisfy the priority health care needs of the population. In **Namibia**, the essential medicines list (EML) had not been updated since 2003, which meant that it did not include important medicines related to ART and opportunistic infections. SPS worked with the MoHSS to **revise the EML and improve the selection process**. Activities included developing technical guidelines for evaluating new medicines as well as SOPs to guide the activities of the committee, modeling the EML on standard treatment guidelines, and **adopting an RPM Plus/SPS formulary development tool from South Africa** to help track EML decisions. As a result, Namibia's EML, the NEMLIST, was updated in 2008 to reflect current treatment for priority conditions using the most cost-effective agents. In addition, palliative care medicines and other medicines to manage HIV/AIDS were added and scheduled **allowing nurse practitioners to prescribe, which improved treatment access**. The SOPs and technical guidelines for evaluating new medicines have made the EML selection process transparent and increased confidence in the system by health care workers. In the last quarter, the EML committee met four times and their deliberations were widely circulated for public input.



IV.c. Improving medicine use by strengthening therapeutics committees

Drug and Therapeutics Committees (DTC) are considered a key intervention in WHO's Global Strategy for Containment of Antimicrobial Resistance. By strengthening DTCs, both facilities and ministries of health create a reliable way to identify and address medicine use issues across all public health programs. DTCs have often focused on use of antibiotics, but as ARV use transitions to long-term, chronic treatment, drug resistance takes on greater significance and DTCs will have the tools to address usage issues.

The **Namibia** MoHSS requires that regions and their districts have functional therapeutics committees; however, many either lack committees at all or have committees that do not function well. Consequently, RPM Plus developed a strategy to strengthen five regional therapeutics committees to serve as models for other regions in the country. As a result, the five DTCs are now meeting regularly as stipulated in MoHSS terms of reference. In addition, the DTCs have identified problems and implemented solutions; for example, one DTC helped implement activities to improve inventory management, which **resulted in a reduction in stock-outs of essential medicines and wastage due to overstocking** because of better inventory management and record keeping. The five DTCs have also helped introduce a regional pharmacy management information system. Information from the new system has already pinpointed areas requiring attention, **such as over-use of antibiotics**, and is being used to design appropriate interventions to address problems.

Our therapeutics committees are now very active and this has helped the districts identify and timely address medicine use and related problems at the facilities.

—Chief Medical Officer, Erongo region, Namibia



In 21 DTC courses, RPM Plus/SPS and partners have trained 824 participants from 69 countries, who established or restructured over 85 DTCs and implemented hundreds of DTC-related interventions in resource-constrained settings. As an example of how a hospital DTC can have an impact, in **Kenya**, the DTC at Aga Khan University Hospital established a multidisciplinary antimicrobial subcommittee in 2006 to focus on interventions to contain antimicrobial resistance (AMR). The DTC did an ABC analysis (value of annual consumption in the hospital) on 793 pharmaceuticals for 2005 and found

that the top four products were antimicrobials, accounting for almost 10% of the medicines budget. The DTC endorsed the subcommittee's recommendations to restrict the use of certain products and to include a microbiologist in intensive care, where AMR threat is high. As a result, a 2006 analysis showed a **62% decrease in the top antimicrobial product consumption** compared with 2005. In 2007, the hospital collaborated with private providers, who refer many patients, to revise the hospital's antibiotic guidelines as a way to raise awareness and gain the

support of private-sector providers. In addition, in the public sector, SPS helped institutionalize a DTC at the national teaching and referral hospital, Kenyatta National Hospital. This committee has been able to **reduce the number of medicines by 48% from 980 to 550 items**.

The MoH in **Ethiopia** requires hospitals to have DTCs as part of their management structure; however, DTCs that had been established had fallen inactive. RPM Plus/SPS conducted several sensitization and training seminars for pharmacists, specialists, and medical directors about how DTCs can contribute to hospital operations, resulting in 80 newly functioning DTCs. SPS gives the hospitals ongoing support to the institutionalization of the committees. Similarly, **Rwanda** has trained 165 health professionals in how to establish and operate DTCs.

IV.d. Improving the procurement system by building capacity in the quantification of pharmaceuticals and commodities

Accurately quantifying needed ARVs is a major factor to successfully scaling up ART. Previous quantification methods were not effective in the context of unprecedented scale-up. RPM Plus has worked with sub-Saharan countries to develop effective methods to quantify ARVs for scaling-up ART, which also apply to all other pharmaceuticals and commodities. Examples include helping Kenya, Namibia, and Rwanda establish national committees to track and coordinate ARV quantification and procurement activities and develop consensus on assumptions and **building capacity of health system personnel to perform quantification for scaling-up**. RPM Plus/SPS has trained over 100 people how to use Quantimed, our quantification software. Kenya, Namibia, Zambia, and Rwanda use Quantimed for national ARV quantifications; in addition, Quantimed is now also used at the facility and national levels to quantify other medicines, such as antimalarials.

In **Rwanda**, RPM Plus helped the government establish a formal reporting and monitoring system for medicine consumption in 2005. The AIDS Treatment and Research Center and RPM Plus ensure that pharmacy staff at ART sites are trained to use the reporting tools. Multidisciplinary district teams have now integrated a step for data validation into quarterly pharmaceutical management supervisory visits. After three years, 85% of ART sites provide timely reports, and the resulting data has been used to conduct **six successful national ARV forecasts** and procurements using Quantimed. The quantification committee reported that for the December 2007 quantification, **data from 90% of the ART sites was available** for the forecasting exercise, and only 17 out of 169 sites required a field visit to collect data.

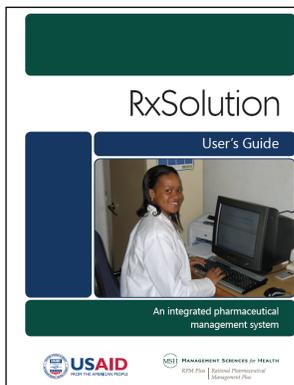
IV.e. Providing adequate infrastructure to assure patient privacy and safe medicine storage

Social stigma is a major deterrent to people seeking ART and treatment for other conditions, such as sexually transmitted infections and tuberculosis, so facilities need to assure confidentiality for patients and their records. Additionally, pharmacy infrastructure must offer secure storage for valuable ARVs. In **Ethiopia**, SPS assessed 35 hospitals designated as initial ART sites. None of the facilities had adequate secure storage space for ARVs or other medicines.



Although 33% of the facilities realized they were losing pharmaceuticals to damage, expiry, and theft, only one facility had a system of recording such losses. At the pharmacy, large groups of people crowded around a window to get their prescriptions; however, the noise and confusion made it impossible for pharmacists to give proper treatment instructions and made it likely that people could leave the pharmacy without understanding how to use their medications. As a result, SPS improved infrastructure in health facilities by renovating over 350 dispensing and storage structures, **building 200 confidential dispensing booths** and over 300 shelving units, and providing more than 100 computers and printers. Although SPS made these improvements initially with ART patients in mind, all patients benefit from the interventions. SPS made similar improvements in Kenya, where a wide variety of patients, not just those on ART, benefit from new space for private medication counseling.

IV.f. Developing easy-to-use tools that improve supply chain information systems



The SPS Program's **integrated computerized pharmaceutical supply management tool called RxSolution** manages orders, receipts, issues stocks, and dispensing at hospital and district levels: as of 2008, it was used at 91 sites in **South Africa** with 200 people trained, 13 sites in **Swaziland** with 147 people trained, and four sites in **Lesotho** with 31 people trained. In addition, SPS helped Swaziland's Ministry of Health and Social Welfare to implement RxSolution in its health system as a way to strengthen its pharmaceutical information and supply management system. As a result, the **Global Fund released funds to procure ARVs** and other medicines that it had withheld, pending such strengthening efforts. Public and private facilities in Swaziland now generate reports to monitor patient management, stock levels, and consumption trends and none have reported stock-outs. Swaziland also uses RxSolution as part of its execution of WHO's strategy to **monitor early warning indicators** of drug resistance.

IV.g. Getting medicines to patients efficiently by strengthening the supply chain

In the initial days of the PEPFAR program, RPM Plus conducted a number of assessments in target countries to determine their capacity to manage ART-related pharmaceuticals and supplies, which threatened to overwhelm health systems by sometimes doubling the volume of pharmaceuticals that systems had typically handled. The pressure to quickly incorporate these products and distribute them efficiently to assure that patients had access to treatment was enormous. Using assessment results, RPM Plus worked closely with public and private distributors to quickly address system problems that could restrain ART scale-up. For example, RPM Plus and SPS has had a long-term partnership with the Mission for Essential Drugs and Supplies



(MEDS), which is responsible for procuring and distributing PEPFAR products in **Kenya**. RPM Plus helped MEDS build capacity in how to accurately quantify ARVs and commodities and helped MEDS streamline its order processing and monitoring and evaluation systems. **MEDS now stocks over 800 products, including 31 ARVs, and is able to turn orders around in seven days.** Thanks to **more robust warehouse systems, its expiration rate for ARVs is 0.0008%.** Starting in November 2004 with the first order of ARVs covering 2,400 patients, with the support of RPM Plus, MEDS has scaled up its nationwide **services to over 1,500 facilities for essential medicines and commodities and 384 sites for ARVs covering over 125,000 ARVs patients** (figure 2)—meeting and exceeding all USAID targets.

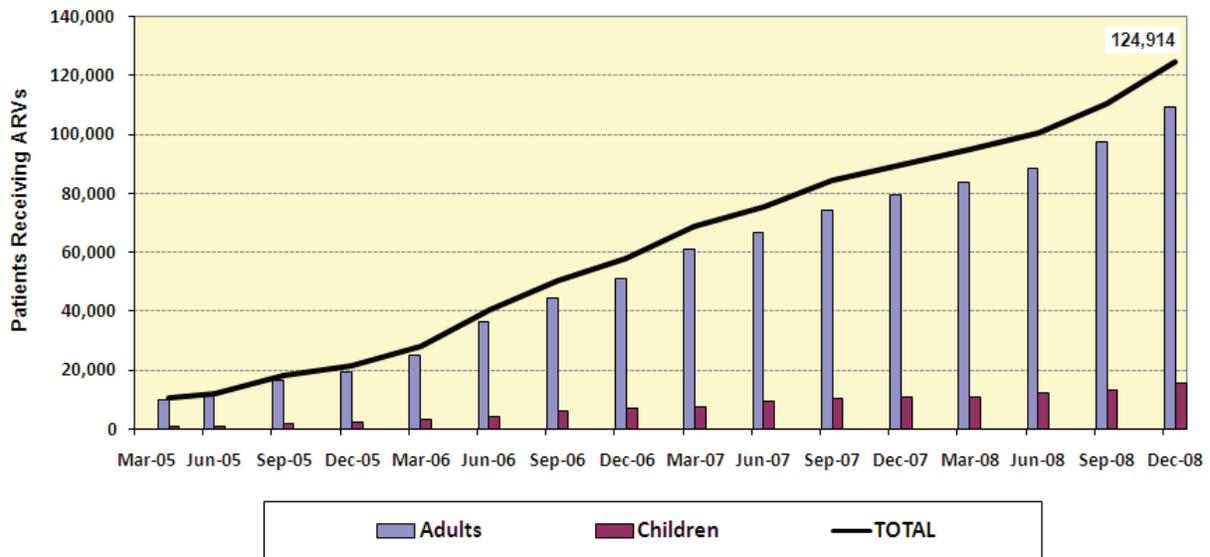


Figure 2. Patients served by the PEPFAR program through MEDS, April 2005–Dec 2008

Although MEDS is responsible for distributing HIV/AIDS products procured by PEPFAR in **Kenya**, KEMSA handles distribution of products not funded by PEPFAR. However, as KEMSA itself noted in a recent report, “The Agency continues to be overwhelmed with the day to day challenges of meeting basic mission requirements (procurement, receiving, storage, and logistics/distribution) because of effects of failed corrective actions and persistent inadequate funding.” Therefore, SPS is now working with KEMSA to strengthen not only its managerial capacity, but also to **institute operational changes to improve warehouse and distribution inefficiencies**. In a 2008 assessment, SPS recommended, among other things, that KEMSA develop strategic plans, policies, and SOPs for operations and functions, and indicators to monitor service quality. **The MoH has officially accepted the SPS assessment recommendations**, and SPS and KEMSA are moving forward to implement them.

When RPM Plus assessed **Ethiopia’s** distribution system to support the introduction of prevention of mother-to-child transmission (PMTCT) services, recommendations included targeting the Pharmaceutical & Medical Supplies Import & Wholesale Share Company (PHARMID) as the supplier and then strengthening PHARMID’s district-level distribution points, so facilities could collect supplies more efficiently. RPM Plus drafted commodity and information flow plans for the new products. Since these initial activities, HIV/AIDS services in Ethiopia have expanded dramatically, and SPS has continued to support the distribution scale-up. To address bottlenecks, SPS worked with PHARMID to shorten the supply chain by **scheduling quarterly product deliveries** directly from the main warehouse to the health facilities, thereby minimizing inefficient, unscheduled deliveries. In addition, improved storage practices coupled with more efficient inventory control and tracking have resulted in an **uninterrupted medicine supply to the facilities with no expiries and no losses since 2004, when RPM Plus started its support**.

Many of the practices RPM Plus carried out in countries to scale up HIV/AIDS services have been used by SPS to roll out artemisinin-based combination therapy for malaria under the President’s Malaria Initiative. For example, in 2006, **Uganda** had a backlog of 3.8 million doses of Coartem[®] due to shortages in labor and transportation resources at the national medical stores (NMS). SPS developed and implemented a plan to help the NMS process, package, and distribute emergency supplies by contracting with the private sector, and within three weeks, **the 3.8 million doses had been delivered—below budget**. To avoid future emergency situations, SPS worked with the NMS to develop a long-term distribution strategy that will strengthen the overall system, including **establishing a public-private partnership to relieve pressure on scarce NMS resources**.

IV.h. Increasing the efficiency of pharmaceutical procurement systems

The East, Central and Southern Africa Health Community (ECSA HC) promotes collaboration on health issues among its 14 member countries. ECSA countries are adapting their strategies to manage their health care systems in the context of expanding HIV/AIDS treatment programs and the need to scale-up best practices in health care. With support from USAID’s Regional Economic Development Services Offices, an RPM Plus assessment in eight ECSA countries in 2004 showed that most countries did not have a multiyear procurement plan and lacked systems

to monitor the procurement and supply system. To address procurement inefficiencies and cost, RPM Plus looked at the feasibility of ECSA countries entering into a pooled procurement arrangement. Based on an analysis of member countries' legal and policy issues, HIV/AIDS treatment policies, and logistics mechanisms, RPM Plus recommended that ECSA HC develop a strategy to pool procurement of HIV/AIDS-related medicines and supplies as a strategy to obtain competitive pricing. With assistance from RPM Plus, ECSA HC created a **business plan** and a **website** (www.ecsamedicines.com) to support **coordinated informed buying**, which is the first step toward pooling procurement. The website provides a database for members to monitor prices and share procurement information. Although the strategy initially focused on HIV/AIDS products, **countries now share information on all essential medicines.**

In **Ethiopia**, SPS has worked with PHARMID to facilitate the procurement of both PEPFAR- and Axios-funded PMTCT products. In addition to providing technical assistance in getting products into the country without delay by facilitating port clearance and communicating with suppliers about scheduling, RPM Plus/SPS created a **procurement tracking chart** to ensure that suppliers stagger their shipments, which has **prevented premature expiry due to overstocking** and has **overcome the problem of insufficient storage space.**

V. FINANCING BUILDING BLOCK

V.a. Determining appropriate handling fees to be charged by central medical stores

The expansion of HIV/AIDS programs in many resource-limited countries made it difficult for local supply chain systems to deal with the influx of the volume of donated drugs and commodities. One challenge includes the ability of the central medical stores to absorb increasing costs related to greater volume of procurement, storage, and distribution. In addition, local systems do not have the means to quantify these costs for reimbursement by the government or the respective donor.

In 2008, SPS developed a **cost allocation methodology** that is applicable to the operations of the National Drug Service Organization (NDSO), the central medical stores of **Lesotho**. Working closely with NDSO staff, SPS staff collected and analyzed financial data using the cost allocation methodology to derive the cost of handling donated products, mostly financed by the Global Fund. The results of the costing study, along with future volume projections, formed the basis of recommendations to determine the marginal mark-up (or handling fee) that the NDSO should receive from the MoH or a donor to maintain its financial viability. The **NDSO Board has approved the recommendations**, and as a result, the **Global Fund will now provide a reimbursement budget to NDSO** to compensate for handling the donated HIV/AIDS products. The NDSO will also use the results of the cost allocation study to establish its new mark-up rates for other donors and other non-HIV/AIDS products.

V.b. Addressing the cost implications of ART changes to second-line medicines

Lower antiretroviral prices, influenced by the introduction of generic products, have contributed much to the ability to scale-up HIV/AIDS programs. However, because second-line treatments are mostly innovator products, they are at least seven times more expensive than first-line regimens; this puts them in competition for resources with other health program priorities. Monitoring switches in ART regimens is necessary not only to assure that cases are being managed appropriately at the facility, but also to plan and allocate resources for second-line treatment at facility and national level. Such evidence-based monitoring requires robust information both on patient regimens and the cost implications of switching medicines.

SPS developed two tools, the ADT and RxSolution, to support data collection for ART programs. Both tools capture the information needed to track the number of patients who switch to second-line regimens and provide the related costs at any level of the health system—facility, regional, or national. ART programs and ultimately other priority health programs can use data from the tools to identify trends in treatment switching, evaluate the clinical appropriateness of the practice, and take corrective actions as needed. At the national level, these trends contribute to the review of national standard treatment guidelines. In addition, programs can use the information to budget for second-line medicines. For example, a tertiary ART site in Namibia used data from the ADT to determine that their one-year switching rate in 2008 was 3.7%. They

now have a benchmark for future comparison and also the data needed to estimate the allocation for second-line medicines.

V.c. Strengthening informed procurement with the *International Drug Price Indicator Guide*

Ready access to comparative price information for pharmaceuticals is essential to ensure procurement of medicines of assured quality for the lowest price. This is particularly important for new, expensive agents that are used in the prevention and treatment of HIV/AIDS. Every year, Management Sciences for Health publishes the *International Drug Price Indicator Guide*, which provides generic drug prices on the international market. The *Guide*, which is freely available online, helps users determine the probable cost of pharmaceutical products, including products for new HIV/AIDS programs, such as prevention of mother-to-child transmission. Users can **compare current prices paid with prices available on the international market and assess the financial impact of changes** to medicines lists. The database contains pricing from 30 worldwide sources for more than 1,100 pharmaceuticals, contraceptives, and vaccines, including antiretrovirals and drugs used to treat HIV/AIDS-related opportunistic infections, such as tuberculosis.

In **Nicaragua**, MSH's RPM Plus Program used the *Guide* to analyze the efficiency of the Ministry of Health procurement system in a 2002 study. As a result, the Ministry now regularly uses the *Guide* to compare local pharmaceutical prices with international averages, which improves their negotiating position with suppliers. In addition, the Ministry's Procurement Department has been providing MSH with pricing information for use in the *Guide* since the 2004 edition. The USAID Mission in Nicaragua has encouraged this collaboration, not only because it promotes efficient procurement, but because the publication of the Ministry of Health pricing information in the *Guide* indicates greater government transparency and accountability, which is a main objective in USAID's Nicaragua country plan.

VI. LEADERSHIP AND GOVERNANCE BUILDING BLOCK

VI.a. Managing donor pharmaceutical activities in Rwanda through the Coordinated Procurement and Distribution System

The Government of Rwanda (GOR) wanted to create a system to optimize donor resources, simplify pharmaceutical management, and standardize ART medicines and commodities, independent from programs supporting each ART site. As RPM Plus worked with the (GOR) and USAID to assemble the Coordinated Procurement and Distribution System (CPDS), the need to define a solid governance system to ensure transparency, good management, and efficient decision-making was obvious. RPM Plus **helped design and implement the CPDS by developing organizational governance documents and mechanisms for surveillance** and providing ongoing support in quantification, procurement, and distribution of pharmaceuticals. The effectiveness and the transparency of the system required not only that national and international stakeholders agree on roles and responsibilities, but also that they define procurement and distribution procedures and implement a monitoring and reporting system to ensure system integrity. Coordination provided by the new program in its first year or so **simplified ART pharmaceutical management and lowered costs**. For example—

- Average treatment costs decreased due to expanded use of fixed-dose combinations. In 90% of the most common regimens, **the cost per patient/month dropped from 30 U.S. dollars (USD) to USD 20**.
- No drugs procured through the CPDS were expired or were at risk of expiry, while in 2005, expired drugs valued at USD 70,000 had been procured before the CPDS.
- The quantification methodology provided precise data for national estimates— achieving **98% accuracy on patient numbers** for December 2005, based on March 2005 data.
- The inventory control was simplified since there is no need to maintain independent stock for each program. Since the establishment of the CPDS in 2005, multiple supply chains have been consolidated into one, which, combined with the standardization of products, has greatly simplified the management of ARVs for CAMERWA.

After one year, **the government officially adopted the CPDS for ARVs, with roll-out to other commodities**, including HIV test kits and medicines to treat opportunistic infections. The CPDS is proving that despite the urgency and the difficulties of managing ARVs in low-income countries, in-country coordination initiatives can empower local systems and institutions without compromising the efficiency of the national supply chain.

VI.b. Strengthening Namibia's capacity to quickly register pharmaceuticals and get them on the market

Namibia's pharmaceutical registration process was stymied by a growing demand for ARVs, resulting in a huge number of registration applications for medicines awaiting marketing approval that were backlogged because of inefficient procedures and lack of skilled staff. In September 2004, about a thousand applications were outstanding. At that time, 49 ARVs were on the market, but the backlog prevented access to valuable fixed-dose combinations and pediatric products. **RPM Plus worked with the government on interventions to streamline the registration process** and strengthen the infrastructure. Key was a policy change allowing priority to ARVs for registration and to create a proxy evaluation process to quickly accept products already registered in International Conference on Harmonization countries and other stringent regulatory authorities, including South Africa. Other interventions included training nonprofessional staff to receive and enter applications into a database. **The drug registration database, PharmaDex which was created by RPM Plus, manages the dossier review process** and facilitates data analysis. Since RPM Plus's intervention began in April 2005, **1,392 applications for new medicines were evaluated in the first year**. Of those, 14 ARVs were reviewed and approved. The 14 approvals included much-needed pediatric dosage forms and fixed-dose combinations that may help increase adherence; the addition of generic products helped decrease prices. All ARVs currently recommended for use in Namibia's ART guidelines comprise both registered generic and innovator products.

VI.c. Helping Kenya increase the transparency of its pharmaceutical procurement and supply system

Recognizing weaknesses in Kenya's public health procurement system, USAID asked SPS to provide technical assistance to the Ministry of Health to strengthen the existing system using Millennium Challenge Account threshold funding. SPS's work in this area has four components: (1) to strengthen the KEMSA's procurement capacity and accountability to apply the public procurement legislation that was updated in 2005; (2) to improve the supply chain management for essential medicines; (3) to establish capacity within the Ministry of Health to monitor the improvements made to the procurement system and supply chain and assess compliance to performance targets; and (4) to strengthen the supervision of medical supplies delivered to health facilities. Governance elements exist in all four components of this work, including—

- Reviewing KEMSA's governance structure, operations, and performance. SPS made eight major recommendations, of which five were adopted in a subsequent Ministerial Task Force Report. (Component 1)
- Helping KEMSA's Board of Directors and managerial staff improve their knowledge and practices in how to provide organizational oversight. (Component 1)

- Building capacity within KEMSA’s procurement procedures to improve transparency and accountability by alerting staff to updated public legislation, training them on technical evaluation, and helping develop SOPs for procurement. (Component 1)
- Collaborating with the Ministry of Health to conduct a survey to determine the extent of wastage and leakage in the pharmaceutical supply chain and make appropriate recommendations. (Component 2)
- Providing ongoing technical assistance to strengthen the Ministry of Health’s capacity to oversee KEMSA’s procurement and distribution performance. (Component 3)
- Working with management committees at the health facility level to improve their ability to supervise the preparation/placement/tracking of orders, record keeping, and storage practices. (Component 4)

As a result of SPS’s assessment, the MoH accepted SPS’s recommendations and are implementing suggested new procedures to increase transparency and accountability in Kenya’s pharmaceutical supply operations.

VI.d. Promoting good governance by strengthening the national pharmaceutical policies, legislation, and strategic plans

One of the reasons that so much emphasis has been placed on systems to ensure accountability related to ARVs is because of their high value and importance to countries’ health care systems. However, the efforts to improve transparency and governance related to ARVs are not in a silo and those efforts improve the system quality for all health programs.

In 2002, the **Democratic Republic of Congo**’s Ministry of Public Health established the national essential medicines program (PNAM) to implement the procurement strategies of the national pharmaceutical policy; however, since its inception, the PNAM has never developed a multiyear strategic plan that systematically addressed the system’s existing capacities and resources or the challenges to achieving its mandate. With five months of technical and financial support from the SPS Program, the PNAM **developed its first strategic plan** that constitutes a vision for strengthening the national pharmaceutical management system over the next five years. The Minister of Public Health officially presented the national pharmaceutical policy and the PNAM’s strategic plan at a December 27, 2008, ceremony.

ECSA countries are adapting their strategies to manage their health care systems in the context of expanding HIV/AIDS treatment programs and the need to scale-up best practices in health care. However, the RPM Plus Program conducted pharmaceutical management assessments in the region that revealed policy, systems, financial, and information and human resource constraints. To address these constraints and to encourage regional collaboration on pharmaceutical management issues, the ECSA Health Community and **RPM Plus launched a 14-country advisory network known as the Regional Pharmaceutical Forum** in 2003. The RPF provides technical leadership and helps ECSA member countries enable their policy

environments and incorporate the best practices needed to maximize access to medicines and commodities. Key accomplishments to improve policies and governance have included—

- Developing a performance assessment tool to periodically evaluate improvement in pharmaceutical management systems, applying the tool in eight countries, using the results to prioritize Regional Pharmaceutical Forum interventions.
- Developing a ***Generic Medicines Policy for ECSA Countries and Generic Medicines Policy Implementation Plan for ECSA Countries*** as models to guide ministries of health and other partners on how to develop or review their national medicines policies; Kenya and Swaziland have used the generic models as a resource to review or implement their country policies.
- Drafting a **Regional Pharmaceutical Strategy** for 2004–2007, now revised for 2008–2012, to support new interventions based on performance assessments carried out in select member countries.
- **Receiving recognition from the ECSA Regional Health Ministers Conference**, resulting in the establishment of a pharmaceutical program at the ECSA Health Community Secretariat. This will ensure timely implementation and sustainability of Regional Pharmaceutical Forum initiatives.

In **Kenya**, SPS has been an integral partner in **building the country’s national-level laboratory capacity** by serving as a member of Kenya’s newly established Laboratory Interagency Coordinating Committee, which advises the government on laboratory services improvement. SPS has also served as Secretariat and participated on several of the Committee’s subcommittees. In collaboration with Committee partners, SPS supported the development, launch, and dissemination of the following components of the national laboratory program: national laboratory policy guidelines; a national strategic laboratory plan for 2005–2010; various national standards, including those for blood transfusion; a training manual for laboratory diagnostics for malaria; ART standard operating procedures, and refresher curricula for laboratory and clinical staff. In addition, with the National Public Health Laboratory Service, SPS developed national laboratory reporting tools, including laboratory investigation report forms for 11 tests and for commodity management, **field-tested the tools in 40 facilities, and revised them for national rollout**. Over 2007–2008, SPS **trained almost 300 laboratory staff members** in various areas (figure 3), including SOPs and commodity management.

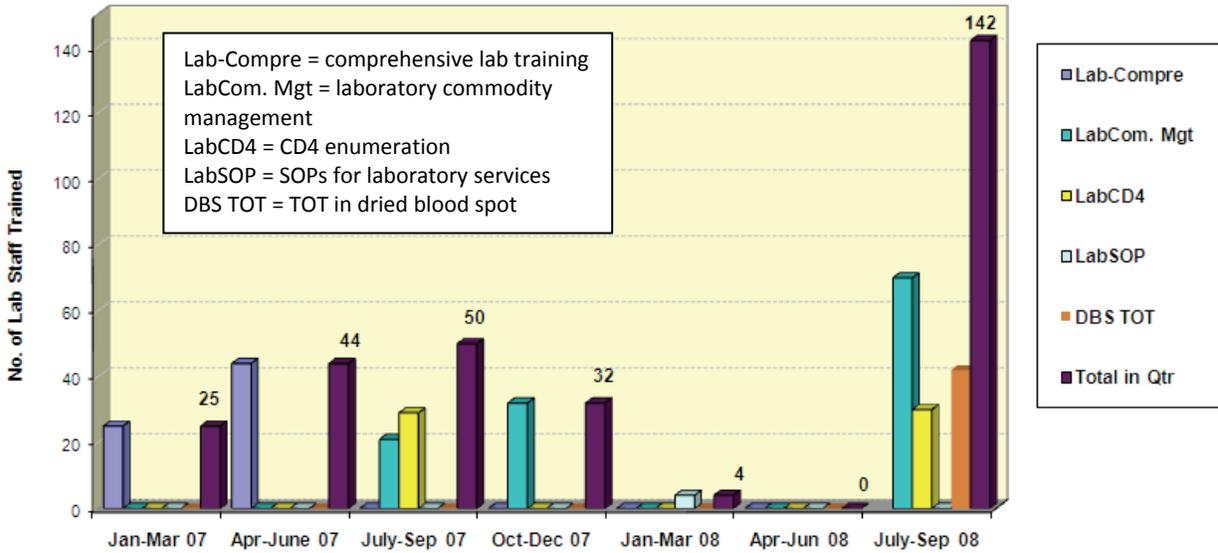


Figure 3. Laboratory staff members trained by SPS in Kenya: 2007–2008

VI.e. Developing and establishing standard operating procedures in laboratories and pharmacies



An essential component of starting and scaling up an ART program at the facility level is establishing SOPs for all departments that contribute to ART care, including the pharmacy and the laboratory. SOPs act as a standard for defining and monitoring the quality of service delivery and facilitating training efforts; they are critical to the successful rapid scale-up of safe and effective ART. However, few public institutions in developing countries have pharmacy and laboratory SOPs for existing services—so there is a lack of examples for ART program implementers to draw upon. In 2003, RPM Plus was working with the Government of Kenya and partners to implement an initiative for incorporating ARVs into the existing health care system in Mombasa. The program began ART delivery

at the first of four sites, Coast Provincial General Hospital. A key element of this initiative was the collaborative and inclusive approach to building local ownership and capacity for introducing and then scaling up access to ART, including the development of SOPs for the pharmacy and laboratory to support ART services. The resulting products were **institutionalized by the Government of Kenya for all ART facilities** and were widely distributed and **adapted by other nascent ART programs in Namibia, Ethiopia, and Zambia**. Once facilities embrace the use of SOPs for ART, it is easy to adapt and enhance them to cover other health care programs, and indeed, many SOPs developed for ARTs describe general procedures.