Strengthening Pharmaceutical Systems Activity and Product Status Report

Project Year 1, September–December 2007

Management Sciences for Health
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This report was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement Number GHN-A-00-07-00002-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

A report on quarterly progress achieved towards activities, products, and results

March 2008

Strengthening Pharmaceutical Systems Program
Activity and Product Status Report

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Strengthening Pharmaceutical Systems Program
Center for Pharmaceutical Management
Management Sciences for Health

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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.

Recommended Citation

Strengthening Pharmaceutical Systems Program. 2008. *Strengthening Pharmaceutical Systems Program: Activity and Product Status Report, September–December 2007.* Published for the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health.

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADDO	Accredited Dispensing Drug Outlets
AIDS	acquired immunodeficiency syndrome
AMR	antimicrobial resistance
ART	antiretroviral therapy
AQ	Amodiaquine
ARV	antiretroviral
AS	Artesunate
CESAG	Centre Africain d'Etudes Superieures en Gestion
COP	country operational program
CPDS	Coordinated Procurement and Distribution System [Rwanda]
DACA	Drug Administration and Control Authority [Ethiopia]
DOTS	internationally recommended strategy for tuberculosis control [WHO definition]
DTC	Drug and Therapeutics Committee
ECSA	East, Central, and Southern Africa
FTC	fixed-dose combination
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GDF	Global Drug Facility [Stop TB/WHO]
GLC	Green Light Committee
HIV	human immunodeficiency virus
IC	infection control
IMCI	Integrated Management of Childhood Illness
IR	intermediate result [USAID]
MCC	medicines control council [Namibia]
MDR	multidrug-resistant
MoH	Ministry of Health
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
NASCOP	National AIDS and STD Control Programme [Kenya]
NCAIDS	National Center for AIDS [China]
NCTB	National Center for Tuberculosis Control and Prevention [China]
NDOH	National Department of Health
NGOs	nongovernmental organizations
NHTC	National Health Training Centre [Namibia]
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMI	U.S. President's Malaria Initiative
PMTCT	prevention of mother-to-child transmission
PNA	Pharmacie Nationale d'Approvisionnement [Senegal]
PNLP	Programme National de Lutte contre le Paludisme [National Malaria Control Program]

PNLT	Programme National de Lutte contre la tuberculose [National Tuberculosis Control Program]
QA	quality assurance
RBM	Roll Back Malaria
REDSO	Regional Economic Development Services Office [USAID]
RMU	rational medicines use
RPF	Regional Pharmaceutical Forum
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems
STG	standard treatment guidelines
TA	technical assistance
TB	Tuberculosis
TFDA	Tanzania Food and Drug Authority
TIPC	Therapeutics Information and Pharmacoviligance Center [Namibia]
TOT	Training of Trainers
TWG	technical working group
UNION	International Union Against Tuberculosis and Lung Disease
URC	University Research Corporation
USAID	U.S. Agency for International Development
USD	U.S. dollar
USG	U.S. Government
USPDQI	U.S. Pharmacopeia Drug Quality and Information [Program]

NARRATIVES—GLOBAL PROGRAMS

ANTIMICROBIAL RESISTANCE

Overview

The rapidly growing problem of antimicrobial resistance (AMR) is rendering many first-line treatments useless, seriously impacting the treatment of malaria, tuberculosis (TB), HIV/AIDS as well as all other infectious diseases of major public health significance. Unless urgent, adequate, concerted, and sustained containment efforts are made, AMR will soon reverse all the gains achieved so far in treating infectious diseases and throw us back into a pre-antibiotic era. The AMR portfolio of Management Sciences for Health (MSH)/Strengthening Pharmaceutical Systems (SPS) will direct work to support the key activity areas identified in the U.S. Agency for International Development (USAID) intermediate results (IR) for SPS and AMR pathway. The activity areas are—

- Scaling up proven institutional interventions to minimize the spread of AMR
- Designing and implementing AMR interventions to improve medicines use behavior at the community level
- Implementing innovative AMR containment strategies and approaches at the global and country levels

Major Activities this Quarter

During its first quarter of implementation, the SPS AMR Portfolio continued to build on infection control (IC) achievements and experiences gained under its predecessor program, Rational Pharmaceutical Management (RPM) Plus. SPS provided technical assistance to in-country partners in Guatemala to conduct a four-day IC implementation workshop in November 2007, using the RPM Plus IC self-assessment materials recently translated into Spanish. The workshop was attended by 20 participants, including 11 representatives from 3 district hospitals and 1 departmental hospital, Ministry of Health (MoH) officials, and a University Research Co. (URC) representative. At this workshop, participants shared IC experiences and problems and drafted quality improvement work plans.

Field-testing of the hand hygiene poster initiated in South Africa during the last quarter progressed further with 39 additional questionnaires being completed by hospital doctors, nurses, pharmacists, microbiologists, and key MoH officials. SPS and Rustenburg Provincial Hospital staff presented the IC self-assessment tool and its implementation to representatives of the National Department of Health (NDOH) and other in-country organizations at the USAID Strategic Meeting in Durban on December 3.

During this quarter, SPS AMR Portfolio collaborated with the RPM Plus Armenia Country Program to further advance rational medicines use (RMU) trainings in Armenia. The first training course was provided in Yerevan over a five-day period, July 16–20, 2007. That training

was given with materials adapted for the Armenia context and translated into Armenian. Using graduates of the Training of Trainers (TOT) course in July, two additional locally led rational medicine use (RMU) training courses were conducted in Yerevan during this quarter. Prior to these courses, the RPM Plus/SPS team held a two-day refresher training for the eight identified trainers from the Yerevan State Medical University, National Institute of Health, and American University of Armenia to enhance their preparedness for facilitation at the trainings. Participants of these trainings—held on December 5–8 and December 11–14, 2007—included managerial staff of Yerevan and marzes polyclinics that oversee the use of medicines.

SPS pharmacovigilance work started from this quarter. In an effort to build on RPM Plus field experiences, information was solicited from the field offices on a potential SPS role in pharmacovigilance. A survey was conducted and 14 responses were received from different countries where MSH/RPM Plus/SPS has field staff. Data from the survey were analyzed and a report was produced summarizing feedback on core pharmacovigilance areas that were perceived by the responding MSH field staff as priorities from a field perspective. Also during the quarter a scope of work was drafted for the University of Washington to take a lead role in developing a detailed SPS pharmacovigilance framework document. SPS also did a preliminary literature search and desk review to help develop a pharmacovigilance assessment tool and indicators suitable for resource-constrained settings. The next steps for SPS are to draft the pharmacovigilance assessment tool and indicators and to engage the University of Washington for the framework development.

Drawing from country-level AMR activity experiences in Zambia and Ethiopia, SPS drafted a concept paper that proposes to collaborate with USAID/Regional Economic Development Services Office (REDSO) [USAID] to jumpstart a regional level AMR advocacy and containment initiative through the Regional Pharmaceutical Forum (RPF).

Regarding the country-level AMR activities in Zambia, SPS staff provided technical assistance by attending a multidrug-resistant tuberculosis (MDR TB) task force meeting held November 26–30, 2007, in Lusaka to develop national guidelines for managing the MDR TB program.

With regard to a new activity designed under the AMR Portfolio on improving community use of antimicrobials through the private Accredited Dispensing Drug Outlets (ADDO) in Tanzania, initial desktop research consisting of a literature review was completed including review of existing reports and surveys on the ADDO program and medicine use in the community in particular. Drafts of the activity concept, framework, and operational plan were created as well.

TUBERCULOSIS

Overview

The Stop TB Partnership members have been busy promoting DOTS and DOTS Plus activities in developing countries. Even with greater support than previous years from partners and donors alike including the Global Fund to Fight Aids, Tuberculosis and Malaria (GFATM), the Global Drug Facility (GDF), and the Green Light Committee (GLC), the millennium development TB goals for increased case detection and reduced prevalence by 2015 are not likely to be met by the majority of countries. Support by Ministries of Health only covers part of the TB populations in many countries. For partners and country TB programs alike, how to maintain this support plus expand to reach the rest of the TB population (private sector, rural residents, prisoners, HIV patients, and drug-resistant patients) remains a formidable task. In the area of TB drug resistance control alone (multidrug and extensively drug resistance [XDR]), the DOTS Plus Working Group at the World Health Organization (WHO) estimates that the number of treatable patients will reach 50,000 cases in 2007 and 800,000 in 2015.

With medicines and commodities being an integral part of TB control whether for first-line or drug-resistant disease, attention must continue to be focused on TB pharmaceutical management components to assure medicines being available when patients need them and their rational use. This can only be done by strengthening both human resources and pharmaceutical supply and monitoring systems, and improving pharmaceutical governance in developing countries.

Through the RPM Plus program, the MSH TB team has developed TB pharmaceutical management tools, facilitated national, regional and country workshops on TB pharmaceutical management, provided technical assistance to international and local partners ,and become a dependable source of expertise in the area of TB pharmaceutical management. The following workplan describes some of the accomplishments in more detail and outlines how the SPS program will continue to build on these activities to strengthen TB pharmaceutical systems.

SPS technical objectives have been formulated to address the pharmaceutical management component of USAID TB program results pathway and the Global Plan to Stop TB 2006–2015.

These technical objectives will also contribute to the SPS result areas—

- Expand access to essential medicines
- Strengthen pharmaceutical management systems to support priority public health services and interventions
- Improved governance in the pharmaceutical sector
- Contain the emergence and spread of antimicrobial resistance (AMR)

The SPS TB team has identified three technical objectives which are key to meeting the challenge of strengthening local TB drug management capacity—

1. Strengthen capacity of TB global initiatives and Stop TB partners in managing pharmaceutical commodities to address the goals of the Global Plan to Stop TB for DOTS expansion and strengthening
2. Increase the capacity of national health programs to design, apply, and monitor appropriate interventions to ensure uninterrupted supply of quality commodities for TB/HIV co-infection
3. Provide technical leadership in pharmaceutical management to Stop TB partners engaged in the development of new tools for tuberculosis

Major Activities this Quarter

Provide Technical Assistance to GDF

- Regular support to GDF was provided by SPS Senior Program Associate, permanently based in Geneva, especially on procurement and management issues.

- Program Manager for TB and Principal Program Associate attended the 17th GDF technical review committee in November 2007.

Provide Technical Assistance to GLC

SPS staff worked on GLC consultant checklist for conducting medicine management monitoring missions in GLC countries. The course for the field-testing the checklist has been scheduled while the checklist has been finalized.

Respond to MDR/XDR TB Threat

In conjunction with the GDF/GLC, SPS conducted an annual one-day workshop at the UNION World Health Conference on Lung Health "Confronting the challenges of HIV and MDR in TB prevention and care." Over 67 participants from national tuberculosis programs, essential medicines officials, nongovernmental organization (NGOs) consultants, and TB donors attended the workshop, many of whom represented the African nations.

Strengthen Laboratory Systems Management

SPS staff attended the Stop TB Partnership's DEWG Subgroup on Laboratory Capacity Strengthening Meeting in Cape Town, South Africa, November 7–8, 2007. The focus of this meeting was on (1) the recently updated WHO global policies for improving TB diagnosis approved by STAG in June 2007, and key issues relating to their implementation, and (2) the launch of the Global Laboratory Initiative in April 2008 at the global stake holders/funders meeting.

SPS TB laboratory staff attended at the 38th UNION World Conference on Lung Health, Cape Town, South Africa, November 9–12, 2007, including the attendance at the New TB Diagnostics Working Group Meeting, meeting with the UNION president, and meetings with WHO, Stop-TB, FIND diagnostics, and several stakeholders and project partners. In addition, in the capacity

as Secretary of the Bacteriology and Immunology Scientific Section of the UNION, SPS staff participated in several administrative and planning meetings—the Coordinating Committee Meeting of Scientific Activities, UNION Scientific Section Meetings, a meeting on scientific section restructuring and the meeting of the Scientific Programme Committee to agree on the program for the 2008 conference.

In December 2007, SPS was requested by the USAID-TB team to represent USAID interests in selected meetings and activities, sharing information on USAID activities on laboratory strengthening and informing/advising USAID of any programmatic areas where strategic investments are need to complement other activities/funding.

Disseminate Pharmaceutical Management for TB Tools and Materials

The French translation of *Managing TB Pharmaceuticals at the Primary Level* has begun.

NARRATIVES—REGIONAL PROGRAMS

ASIA AND THE NEAR EAST—REGIONAL DEVELOPMENT MISSION–ASIA

Overview

SPS, while building on the work of RPM Plus in the Asian region, will strengthen the ability of regional policy makers, health care providers, and institutions to improve pharmaceutical management, with an added emphasis on governance, financing of pharmaceuticals and pharmaceutical services, institutional capacity building, pharmacovigilance, and other system strengthening initiatives.

In 2007, the Regional Development Mission-Asia (RDMA) supported the establishment of a collaborative forum of U.S. Government (USG) partners addressing malaria control in the Greater Mekong Sub-region. SPS will work with the Mekong forum and build upon existing collaborative partnerships with regional and country institutions to ensure complementary expertise under a framework of common objectives. As a partner, SPS will provide technical assistance and training to build capacity in pharmaceutical management and strengthen pharmaceutical systems.

The RPM Plus program has been providing technical assistance in China since late 2004. After conducting an assessment of TB pharmaceutical management practices in two Chinese provinces, RPM Plus has worked closely with WHO, the National Center for Tuberculosis Control and Prevention (NCTB), and provincial counterparts to develop TB pharmaceutical management and implement standard operating procedures (SOPs) for provincial, prefecture, and district levels in Henan Province. Work in support of TB programs also includes the development of pharmaceutical management indicators and SOP training materials for introduction in an additional six provinces, and TA in monitoring SOP implementation.

During a visit to China in early 2007, RPM Plus provided a briefing to WHO and the National Center for AIDS (NCAIDS) on the SOPs implemented for TB pharmaceutical management in Henan Province. Given the recent approval of funding for Round 6 of the GFATM proposal for China, USAID suggested that RPM Plus conduct an exploratory visit to Yunnan province to survey the pharmaceutical management system supporting the ART program. USG support in Yunnan and Guangxi provinces has facilitated the implementation of anti-retroviral therapy and access to treatment for opportunistic infections. . SPS will build on existing TB pharmaceutical management work and ARV management in other countries to strengthen local capacity to manage ARVs and other commodities in China. SPS will further promote the introduction of pharmaceutical management best practices and innovative approaches to build requisite competencies to ensure improved access to quality care, support, and treatment.

Objective 1: Improve governance in the pharmaceutical sector in the RDMA region, particularly in the areas of medicines policies, regulation, quality assurance, procurement practices, and pharmacovigilance

Objective 2: Improve the care and treatment of priority health conditions, including HIV and AIDS, TB, malaria, other childhood illnesses, and contain AMR by strengthening pharmaceutical management systems

Objective 3: Strengthen regional and country-specific pharmaceutical management information systems to improve evidence-based decision making

Objective 4: Increase the technical capacity of country and regional institutions and networks in pharmaceutical management through sharing information, replicating best practices, and collaboratively addressing pharmaceutical management issues of local and regional importance

Major Activities this Quarter

SPS participated in the USAID Mekong Malaria Partners Meeting in Bangkok in October 2007. Current and new partners discussed past and planned activities to allow coordination of work plans, facilitate collaboration at country level, and contribute to improved malaria control in the region. SPS agreed to provide technical assistance to two Mekong countries as a follow up to the RPM Plus course on Pharmaceutical Management and Quantification for Malaria in November 2007, and to continue discussion with the Reproductive Health and Child Health Alliance and URC on pharmaceutical management of antimalarials in Cambodia.

Constraints to Progress

During the FY08, RPM Plus activities will be coming to a conclusion as the SPS program is initiated. It will be necessary to coordinate all activities, so that SPS activities build on those undertaken under RPM Plus, and to minimize any partner confusion about planned activities.Cambodia, Thailand, and Laos have been proposed for SPS technical assistance in pharmaceutical management for malaria. Although Cambodia is a priority, due to the pattern of development of drug resistance, it will be necessary to coordinate potential technical assistance needs with the current Mission strategy and existing programs. Agreement among the Cambodia Mission, the RDMA, the National Malaria Center, and others on specific roles is necessary prior to initiation of additional strengthening activities.

Next Steps

- SPS will conduct a visit to Guangxi province in China to learn about pharmaceutical management practices for HIV/AIDS. It is anticipated that SPS will collaborate with counterparts to adapt RPM Plus tools appropriate for assessing site readiness,

strengthening standard operating procedures, or monitoring availability and use of ARVs and other medicines.

- SPS and RDMA will finalize the selection of countries for follow-up technical assistance in pharmaceutical management and quantification for malaria.

EAST AFRICA REGION

Overview

USAID/REDSO (now USAID/East Africa) and the Bureau for Africa, Office of Sustainable Development (AFR/SD/HRD) has requested that with FY07 funds, SPS follow-on the work initiated under the RPM Plus program to enhance regional capacities in health systems and particularly, HIV/AIDS programs. Technical assistance (TA) has been provided to strengthen pharmaceutical management systems to assist increasing access to quality pharmaceuticals and health commodities. Specifically, interventions included pharmaceutical policy development, institutional and human capacity building, and direct technical assistance in selection, quantification, and procurement of public health supplies.

In fiscal year (FY) 2007, the focus will engaging various stakeholders including MoHs Divisions of Pharmacy and USAID Country Missions. Other existing vehicles for improving and accelerating appropriate medicine use in a sustainable manner, e.g., national pharmacy and therapeutics committees were targeted. The selected activities were implemented in synergy with other RPM Plus regional activities conceptualized under different Strategic Objectives, e.g., SO5 AMR/ID.

Technical Objectives

- To develop and advocate for implementation of enabling pharmaceutical policies for efficient commodity management systems to increase access to public health commodities in ECSA Region
- To increase the capacity for providing effective drug management within health delivery institutions and systems in the ECSA Region.

Major Activities this Quarter

- Negotiated the FY 2007 workplan with USAID/EA and obtained approval.
- Held the Fourth Regional Pharmaceutical Forum Meeting and revised and updated the "Regional Pharmaceutical Strategy for East, Central and Southern Africa, 2008–2012." Also, the regional forum was restructured and lead to a merger of the HIV/AIDS TWG with the Procurement TWG. Subsequently, a TWG on Medicines Regulations and Quality Assurance was created.

- Completed the draft “Medicines Policy Implementation Plan” and circulated it to members of the Policy, Legal Framework, and Management Support TWG for further input and consensus.
- Initiated discussions with the Washington-based AMR/SPS program with the aim of enhancing the AMR agenda in the region through collaboration with the Promoting Rational Medicine Use TWG.

WEST AFRICA REGIONAL PROGRAM (WARP)

Overview

The West Africa (WA) portfolio of SPS program received $500,000 in FY 2007 funding under the HIV/AIDS/CSH and FP/RH elements. SPS will support USAID/West Africa's strategy for the region to increase the adoption of effective policies and approaches to reproductive health, child survival, and HIV/AIDS in the region.

The overall strategy agreed upon with USAID/WA includes capacitating regional organizations and training institutions such as West Africa Health Organization , Association des Centrales d'Achats Africaines de Médicaments Essentiels, Centre Africain d'Etudes Superieures en Gestion (CESAG)/Senegal, Institut régional de Santé publique (IRSP)/Benin, Kwame Nkrumah University of Science and Technology (KNUST)/Ghana and University of Jos/Nigeria, and Ghana Institute of Management and Public Administration (GIMPA)/Ghana. The goal is to increase capacity of these and build networks to provide pharmaceutical management technical assistance in the subregion.

Major Activities this Quarter

After discussions with USAID/WA about strategies to be adopted under SPS, specific activities were identified and a draft work plan has been submitted to USAID/WA for approval.

SPSs started discussions and planning of two training activities, TOT in pharmaceutical management for academic staff, and a procurement and supply management training for mid-level pharmaceutical personnel in select Francophone countries, that shall be organized by CESAG and IRSP respectively (with support from SPS). The TOT is to take place March 24–29, 2008, in Accra, Ghana. Three institutions have confirmed their TOT participation—KNUST, GIMPA, and University of Jos.

CESAG and IRSP have both confirmed their commitment to organize the training of mid-level pharmaceutical personnel from select francophone West Africa countries. Discussions are ongoing to finalize arrangements for this capacity building activity.

NARRATIVES—COUNTRY PROGRAMS

DEMOCRATIC REPUBLIC OF THE CONGO

Overview

Every year, malaria causes 300 to 500 million cases of acute illness resulting in more than a million deaths worldwide of which 80 percent at least, occur in sub-Saharan Africa. The Democratic Republic of Congo (DRC) MoH places malaria among the country's leading endemic diseases, and the primary cause of morbidity in children under five years of age. In 2003, the national health information system reported 4.387 million cases of malaria resulting in 16,498 notified malaria deaths. The MoH estimates that annually each Congolese child suffers four malaria episodes and 59 percent of all outpatient consultations are for children under the age of five with fever/malaria (NMCP 2001). According to the United Nations Children's Fund MICS 2001 survey, during the 15 days prior to the survey the prevalence of fever, presumed as malaria, was 41 percent in children under age five. About half of these children were treated with common antimalarials.[1]

Under this workplan, SPS activities will build on the experience and achievements of its predecessor program, RPM Plus, and focus on providing support to the DRC MoH specifically on issues related to partner coordination, quantification, storage, and distribution. SPS will continue to provide technical support to DRC in the implementation of the new antimalarial treatment policy through the comprehensive approach proposed in the implementation guide "*Changing Malaria Treatment Policy to Artemisinin-Based Combinations*" prepared by RPM Plus in collaboration with the RBM partnership and the GFATM.

Much work remains to be done to support the implementation of effective malaria programs. As the DRC MoH works to rebuild and rehabilitate the health system and transition from multiple parallel systems (implemented through various international NGOs, to a centralized pharmaceutical management system, there is an opportunity to harmonize tools and practices related to pharmaceutical management with other technical areas. RPM Plus was instrumental in facilitating the harmonization of pharmaceutical management tools for malaria in DRC and assisting partners to coordinate their work of fighting malaria. However, this coordination needs to be consolidated to ensure appropriate collaboration and effective scale up of ACT distribution.

RPM Plus also provided support to the Direction for Pharmacy, Medicines, and Therapeutic Plants (DPM), the National Essential Medicines Procurement Program (PNAM) and the National Federation of Central Procurement Agencies to strengthen national and provincial level pharmaceutical management capacity in general. Continued support will be needed to further enable these agencies and divisions to assume more responsibility for managing the

[1] UNICEF. 2002. Enquête Nationale sur la situation des Enfants et des Femmes, MICS2/2001. Kinshasa, DRC

pharmaceutical supply system which is responsible for ensuring the appropriate management of antimalarials.

Major Activities this Quarter

- SPS held technical meetings with the NMCP to revise and finalize the malaria task force terms of reference to include malaria medicines and commodities procurement and distribution working group.
- Together with the DPM (MoH agencies, University of Kinshasa, DRC Pharmacy council, WHO), SPS is working to revise and update the DRC pharmaceutical legislation. Working groups have drafted various sections of the document.
- Participated in technical meetings with NMCP, Direction of pharmacies and medicines, the essential medicines procurement program and partners (WHO, UNICEF, Population Services International, United Nations Development Program/GFATM) to develop the procurement and supply management portions of the DRC malaria business plan for nationwide scale up of ACT.
- Participated in a workshop to identify indicators for the tracer lists that will be used for the new pharmaceutical management information system (SNIS-MED).

Major Constraints to Progress

- A major constraint to progress on technical activities during this quarter was the time needed to to recruit the planned technical consultant to assist in providing planned technical assistance and support to activities.

Next Steps

- Submit the revised malaria task force terms of reference, including the malaria medicines and commodities procurement and distribution working group, to the Minister of Health for signature.
- Hold a validation workshop with the direction of pharmacies and medicines and partners (MoH agencies, University of Kinshasa, DRC Pharmacy council, WHO) to pull together the final draft revised pharmaceutical legislation, engage a legal consultant to review and adjust the legal document as needed, and submit to the Government of the DRC for adoption.
- Finalize the DRC malaria business plan, particularly the procurement and supply management portions, along with NMCP and their partners.
- Continue to support the SNIS-MED development and implementation process in the initial provinces.

ETHIOPIA

Overview

USAID/Ethiopia has solicited support from SPS for the provision of technical assistance in medicine and related products' rational use and management for ART and PMTCT programs in Ethiopia. SPS will assist in national, regional, district, and health facility-level capacity development for delivery of ART and related services by ensuring access to and rational use of basic ART products through various interventions.

Although SPS is a follow-on to RPM Plus, and SPS will continue to work in all the RPM Plus technical areas, the new program incorporates additional technical components on governance in the pharmaceutical sector and drug financing that are of particular relevance to the Ethiopia country program, in addition to more systematic efforts to contain the emergence of resistance and improve medicines use. SPS will strive to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems.

Major Accomplishments this Quarter

- Library package of current pharmaceutical reference books for DTCs/Drug Information Centers and Schools of Pharmacy

  Basic technical reference books have been selected in collaboration with DACA to be used by Drug Information Centers to be established in hospitals that have DTCs. In addition, four pharmacy schools located in four regions will benefit from the up-to-date reference materials.

- AMR containment
  - AMR National Advisory Committee established

    SPS supported the formation of a national AMR committee that is vested with advisory and advocacy role. Several meetings were held under the chairmanship of DACA. SPS has an AMR point person who serves as a secretary to the committee. The initial activity of the national committee was to finalize its terms of reference and plan the undertaking of a national AMR situation analysis. Terms of reference for such an exercise is drafted and the study will be conducted soon.

- ARV treatment adherence
  - Adherence study in selected ART hospitals

    In collaboration with DACA and the International Network for Rational Use of Drugs (INRUD), SPS participated in a study to determine the level of adherence and quality of counseling in six hospitals representing three major regions. The study had components of determinants identification, selection, and validation of indicators. The study was conducted with the participation of DACA, RHBs, and hospital personnel

with support from SPS. This approach is an innovative approach to transfer skills, institutionalize practices, and ensure future follow up and implementation of recommended interventions in promoting adherence.

- Adherence workshop in Arusha

  Five East African countries involved in adherence indicator development and study participated in a five-day workshop in Arusha, Tanzania. The participating Ethiopian team included persons from DACA, HAPCO, SPS, USAID, and CDC. The workshop was organized by INRUD/MSH and the Swedish International Development Cooperation Agency. The meeting recommendation was for each country to continue the study by following up and promoting key interventions in using selected key indicators. The Ethiopia team also decided to hold a study report dissemination workshop for key stakeholders from all over the country.

Major Constraints

Although trainings have been conducted for establishing DTCs and some DTCs have been established, most are weak or non-functional. The main reason for this is the high turnover of trained staff. The DTCs were not institutionalized and lacked resources also.

Although personnel from DACA, RHBs and RPM Plus were trained to provide mentorship and follow up, this has not happened due to the delayed establishment or non-functionality of the DTCs.

KENYA—KEMSA

Overview

The Kenya Medical Supplies Agency (KEMSA) is a state corporation that was established and mandated by legal notice to operate a commercial service for procurement and sale of medicines and other medical supplies to secure health commodities for the public health institutions. Additionally, KEMSA advises the Health Management Boards and the general public on matters relating to the procurement, cost effectiveness, and rational use of medicines and medical supplies.
To date KEMSA has not fully realized its mandate owing to a myriad of constraints such as lack of adequate financial resources to capitalize its operations, procure enough medicines, and develop requisite systems; inadequate facilities; lack of a procurement plan; and skill-limited human resources, etc.To its credit, KEMSA has been able to successfully undertake several reform initiatives including appointment of an independent board, development of a business plan, and recruitment of professional staff. These modest gains made by KEMSA provide fertile grounds for further improvements such as those envisaged under the Millennium Challenge Account-Threshold Program (MCA-TP) Component Two (Improvement of Health Care Commodity Procurement and Delivery).

Under MCA-TP Component Two, the Government of Kenya has identified the MoH and its medical supplies procurement and delivery body, KEMSA, as being particularly susceptible to waste, fraud, and abuse throughout the procurement and delivery process. MCA-TP activities under this component will focus on improving KEMSA procurement capacity to make it transparent and accountable, and to strengthen the supply chain. SPS has been solicited by USAID/Kenya to provide support to KEMSA to reach the goals set for Component Two, specifically,

Objective 1: To strengthen KEMSA's procurement capacity and accountability systems

Objective 2: To improve supply chain management for health sector commodities

Objective 3: To establish institutional and human resources capacity to enable the MoH to monitor KEMSA procurement performance and compliance with good procurement practices

Objective 4: To strengthen support supervision mechanisms for improving timely access to drugs and medical supplies by rural health facilities

Major Activities this Quarter

- Presented, negotiated, and agreed upon FY 2007–2008 Work Plan Component Two MCA-TP-Kenya with Component Two implementing partners—USAID/OPH Kenya,

KEMSA and MoH's Department of Pharmacy, Division of Planning, Pharmacy and Poisons Board, and National Quality Control Laboratory (NQCL).

- Established the Technical Working Team and modalities for implementing the workplan involving all the parties concerned. These include partners and other funding agents currently supporting KEMSA (USAID/OPH, KEMA, MoH, Danish Agency for Development Assistance, GDC, World Bank and MSH/SPS). The working team held four planning meetings during this quarter.
- Conducted a rapid assessment for training needs for KEMSA directors and managers to establish KEMSA-specific requirements in corporate governance and procurement accountability.

KENYA—PEPFAR

Overview

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) emphasizes prevention of HIV infection, care and treatment of HIV-infected individuals and orphans through provision of antiretroviral drugs on a large scale in afflicted countries. Kenya is one of the 14 priority countries to receive this aid. SPS is among the partners assigned the task of implementing the plan.

Under Country OP 2007, MSH/SPS will continue work initiated under RPM Plus. SPS will work with USG PEPFAR Team, MoH departments (National AIDS and STD Control Programme [NASCOP], NPHLS, National Leprosy and Tuberculosis Programme [NLTP], Pharmaceutical Services) NGOs, private sector, and other ART implementation partners to strengthen the pharmaceutical management system to improve access and use of health commodities for the treatment and care of those affected by HIV/AIDS. Also, MSH/SPS will partner with Ecumenical Pharmaceutical Network (EPN) and other SPS associates to undertake activities in the health sector under the following technical objectives—

Objective 1: To expand access to ARVs and other essential medicines by providing TA in pharmaceutical management to the PEPFAR Interagency Team, Mission for Essential Drugs and Supplies, KEMSA and other supply chain organizations.

Objective 2: To increase the capacity of MoH/NASCOP to address pharmaceutical management issues in use of quality commodities for HIV/AIDS programs.

Objective 3: To increase the capacity of MoH/NPHLS, NASCOP to address issues to improve access to quality laboratory services for HIV/AIDS programs

Objective 4: To strengthen the pharmaceutical and logistic information management systems in support of MoH priority programs and KEMSA (P/LMIS)

Objective 5: To provide administrative and TA to MoH/NTLP to improve access to pharmaceutical services at site level in support of TB case detection, DOTS expansion, and TB/HIV collaboration and services

Major Activities this Quarter

Support to PEPFAR Supply Chain Management

- SPS worked collaboratively with the Mission for Essential Drugs and Supplies, NASCOP, and the USG Interagency team to ensure that the antiretroviral (ARV) medicines were distributed to 291 ART sites (of which about 72 percent are public sector). By end of December 2007, approximately 90,000 ART patients were receiving

ARVs. Also, a total of 301 prevention of mother-to-child transmission (PMTCT) sites (of which 79 percent are public sector sites) were receiving PMTCT ARV medicines. All sites received co-trimoxazole also.

- SPS also conducted training for 13 supply chain staff, including use of Quantimed (quantification software). Using Quantimed, MSH/SPS, in collaboration with MoH/NASCOP and its stakeholders, supported the quantification of pediatric ARV needs.

Support to NASCOP and the National ART Program centrally

SPS activities focused on developing tools and systems in support of decentralizing the ART pharmacovigilance framework. These activities have targeted improving governance and access to antiretroviral therapy. More specifically, the following was achieved—

- Developed training materials and tools for ART commodity mentorship
- Developed 11 national SOPs using those at Coast provincial hospital (IR1)
- Trained 61 health care workers from 21 ART sites on ART commodity management and 8 staff from 4 sites on ART dispensing tool respectively (IR4)
- Supported development of SOPs implementation plans for 8 ART sites of Church of God Relief institute
- Disseminated six key ART commodity management job aids to 393 ART sites nationally

Support to MoH/Department of Pharmacy

- SPS developed training materials for selected areas of pharmaceutical care for practitioners in private/community based settings, rational use of medicines, adherence and medication use counseling, and pharmacotherapy of HIV-related infections.
- SPS also conducted one-day training on adherence and medication use counseling for practitioners in private/community based settings for 50 health care workers.

Strengthening Laboratory Systems at National and Site Levels

SPS provided TA to NPHLS/MoH as follows—

- Supported the laboratory interagency committee to officially launch the national laboratory policy, the national strategic plan, SOPs in support of ART, and other standard support documents
- Finalized field testing of the generic laboratory commodity management curriculum based on the monitoring, training, planning approach in six pilot ART sites
- Field-tested laboratory data capture and transactional manual tools for both tests and commodities
- Finalized a curriculum on use of SOPs

KENYA—PUBLIC SECTOR PHARMACEUTICAL SYSTEMS

Overview

The USAID/Kenya Mission is committed to supporting the MoH's efforts to reverse the declining trends in health status of the Kenyan population as articulated in the National Health Sector Strategic Plan 2005-2010 (NHSSP II). The NHSSP II has enumerated key goals including ensuring the security of pharmaceutical products at all levels of health care. Under country operational plan (COP) 2007, SPS will provide technical and tactical assistance to strengthen the pharmaceutical systems for tuberculosis and reproductive health commodities. This support will include strengthening human and institutional resource capacity with the aim of improving commodity security at all levels of health care and is a continuation of support provided by RPM Plus previously.

SPS will work with MoH divisions (Department of Reproductive Health [DRH], NLTP) and KEMSA and its partners to provide support and technical assistance in strengthening systems that contribute to quality laboratory services.

Under the COP 2007, SPS formulated a package of focused interventions in support of selected priority divisions of MoH, KEMSA, USAID/Kenya mission, under following technical objectives—

> *Objective 1:* To provide technical, administrative, and operational support for TB activities undertaken by the NLTP to strengthen national efforts to ensure provision of pharmaceutical services at site level for TB case detection, DOTS expansion, and TB/HIV services.
>
> *Objective 2:* To increase the capacity of DRH to identify, prioritize, and address pharmaceutical management issues to improve access to, and use of, quality pharmaceutical products for RH programs.

Major Activities this Quarter

Provide Technical and Operational support to MoH/National Leprosy and TB Program Activities to Improve Case Detection, DOTS Expansion, and TB/HIV Activities

SPS worked collaboratively with the NLTP as follows—

- Supported the sensitization of 30 health workers on MDR TB awareness with a focus on detection, isolation, and treatment of infectious TB patients; currently, the estimated number of MDR TB patients is 250.
- Upgraded the central unit communications system from LAN to wireless systems

- Provided the central reference laboratory with lab reagents to meet impending shortages

Provided TA to Build the Capacity of DRH to Improve Access to Pharmaceuticals Supporting National Reproductive Health Services

SPS worked collaboratively with DRH in the following activities—

- Reviewed the reproductive health (RH) commodity management curriculum and training materials to incorporate stakeholder comments on the training materials
- Disseminated SOPs and orientated 100 RH field officers in three regional workshops on RH commodity management information data collection tools with the aim of ensuring access and documentation of commodity use
- Developed and completed various RH reports to support monitoring of the commodity security—
    - RH commodity issues tool)
    - Commodity usage (using commodity workbook)

These reports assisted in identifying a gap in the combined oral contraceptives stocks nationally. In turn, DRH used this information to advocate for supplementary resources from donors and stakeholders.

- Participation in the quarterly Family Planning (FP) Technical Working Group and FP/RH/HIV services integration stakeholder meeting. The latter meeting was held to develop policies and guidelines on implementation of service integration at all levels of the health care system.

NAMIBIA

Overview

The SPS/Namibia project activities are carried out in four broad objectives—

Objective 1: Strengthen relevant policies, legal framework and national management systems that support the implementation of the National Medicine Policy. In project year (PY) 01 the SPS project, under objective 1, will address the broader issues related to medicines regulation. This objective aims at providing support to build capacity in the medicines control council (MCC), enabling MCC to achieve and sustain a strengthened regulatory system that assures quality, safety, and effectiveness of medicines used in Namibia. SPS will achieve this by applying an integrated approach to medicines regulation with focus on ARVs. The goal is tol improve local capacity and lead to sustained awareness, improved stewardship in safeguarding public health, , and guarantee public trust in the safety of program medicines.

SPS will also continue throughout COP 2007 to support the implementation of the pharmacy management information system (PMIS). The PMIS which was developed and launch with support from the RPM Plus project is aimed at providing nationwide information on medicines use and will potentially become a powerful management information tool to guide policy decisions.

Objective 2: Strengthen human resources capacity through institutional capacity building, human resources development and improving systems capacity for the management of pharmaceuticals.Building on the RPM Plus experience, SPS Namibia adopted an approach to go beyond mere provision of pharmacy staffs to MoHSS and develop and implement strategies that will strengthen national human resources capacity for the management of pharmaceuticals and related health commodities. SPS is therefore working with the National Health Training Centre (NHTC) to strengthen the institution's pharmacists' assistants training program, support the programs curricular review, and provide equipment and other infrastructure that will improve the capacity of the institution to enroll and train more middle-level pharmacy staffs. SPS will continue to support salaries for seconded pharmacy staff members and provide training for health professionals. SPS is also working with partners like the Interim Health Professions Council and Pharmaceutical Society of Namibia to implement continuing professional development programs.

Objective 3: Strengthen health commodity management in treatment facilities through the development and implementation of relevant manual and electronic tools and improving inventory management. The third objective is aimed at improving systems for the quantification and ordering, storage and inventory management, and tracking and reporting on medicines consumption in the treatment facilities. Under COP 2007, SPS will continue to support further rollout of the ADT to provide technical assistance for training treatment facilities staff in pharmaceutical management, implementation of the SOPs, and provision of infrastructures to ensure adequate storage, inventory control and good dispensing practices.

Objective 4: Strengthen the selection, monitor effectiveness and improve rational medicines use through the implementation of proven strategies to promote rational use of medicines. The MoHSS pocket manual for health workers and the Namibia Essential Medicines List are now outdated. Under COP 07 SPS will provide support for their review and update. SPS will employ proven and evidence-based strategies in efforts to improve rational medicines use in Namibia. Under COP 2007, SPS will expand the support to the therapeutics committees to cover areas of containment of antimicrobial resistance, drug utilization reviews, compliance with clinical practice guidelines and infection control. SPS works closely with the therapeutics committees and provides TA and support for developing locally relevant projects and in implementing them to improve medicines use in the treatment facilities.

Major Activities this Quarter

At the request of the Namibia registrar of medicines, SPS developed a document titled "*Rosiglitazone in Namibia medicines register: evidence for regulatory decision*" to inform decisions on the status of the medicines in the Namibia medicines register. This document has the potential to serve as a case study and example for use in the training of medicines information staff, medicines control council (MCC) members, and other relevant MoHSS committees in the conduct of comparative effectiveness reviews. /

SPS has continued efforts to strengthen all aspects of medicines regulation in Namibia with continued support to the subdivision Pharmaceutical Control and Inspection which is the secretariat of the MCC. During the period under review, SPS met with the subdivision and reviewed plans for an integrated approach to medicines regulation. SPS supported the subdivision's request for an additional staff in their medicines registration unit, the move to a new office space with commitment to provide shelving to assist the cataloguing of dossiers in the new office, and the provision of other critically needed infrastructure. The subdivision was also supported to conduct a dossier review retreat. At this retreat, 80 dossiers were evaluated, and 9 were recommended for registration. A total of 37 medicines were registered in the period October to December 2007.

Plans to provide internet services and website for the MCC/TIPC was also initiated and finalized. The TIPC office set up is almost complete. The remaining electronic databases, journals and reference texts, quarterly updates of Micromedex, and the Cochrane library were received and installed. The TIPC national training was conducted November 26–29, 2007, with 25 participants in attendance. This training was follow-on to the TOT which was held earlier, July 11–12, 2007. Most of the July TOT participants were trainers for the November 2007 training. The MSH/SPS program provided support to the NHTC pharmacists' assistants training program by strengthening their institutional capacity towards increased production of mid-level pharmaceutical officers. MSH met with the institution to finalize plans towards that support.

A key achievement during the quarter was the approval of the NHTC request for support of classroom renovation and laboratory equipment procurement. This support spurred NHTC to increase enrollment and initiate the process towards revising their curriculum to ensure that there

is an increased production of adequately trained, mid-level pharmacists' assistants for Namibia public health system.

SPS is collaborating closely with the Directorate of Special Programs (DSP) in an assessment to identify outreach clinics to serve as service centers towards the decentralization of ART services. A rapid needs assessment conducted and a list of items needed to improve pharmaceutical care and other services at these sites was compiled. Medicine envelopes were purchased and dispatched while all the other items have been ordered. Strengthening systems at these facilities will improve the quality of service delivery, enhance adherence, and ensure that health workers are motivated. The outreach sites do not produce monthly reports—their patient numbers are included in the main hospital that conducts the outreach. SPS will continue to work with DSP to ensure that the distribution of medicines and the documentation and routine reporting on medicines used during these outreach are improved.

MSH/SPS has continued to provide support to treatment facilities that are using the ART dispensing tool. Through routine communication with those facilities, MSH is able to understand users' demands and requests for tool revisions and upgrades. During the period under review, the second version of the tool was completed. This October 2007 version has additional functionalities and benefits that reflect user needs. Currently, 28 facilities out of 35 providing ART in Namibia are using the dispensing tool. In collaboration with MoHSS, /SPS developed an implementation plan to update of the Namibia essential medicines list (NEM list), last revised in 2003. MSH/SPS is also providing support to strengthen the NEM list Committee and the committee's secretariat at the subdivision of National Medicines Policy Coordination. Support was provided for the review of submissions and adjudicating on applications for addition/deletions from the NEM list.

SPS continued efforts at strengthening selected therapeutics committees (TC) in Namibia. Between July and December, 2007, support was provided to six regions in implementing TC activities in their respective regions. These activities include improving inventory management and joint formulary/treatment guidelines development project. A training curriculum to be used in training potential members in regions that have yet to constitute or do not have functioning TCs was developed during this quarter. This curriculum was successfully applied during a one-day training for the Hardap regional TC in November 2007.

Next Steps

- Launch the TIPC scheduled for the last week of April 2008
- Draft SOPs for registration and inspection activities
- Renovate and install lab equipment at NHTC
- Finalize needs assessment tool for use in subsequent newly designated outreach centers
- Recruit information technology support staff for the pharmaceutical services division to manage the dispensing tool, Pharmadex, ART national consumption database, PMIS database, and the medicines formulary tool
- Conduct EML workshop to assist in developing systems and structures to support the committee activities
- Develop final drafts of the pocket manual and EML

RWANDA—PEPFAR

Overview

In June 2006, the follow-on project to RPM Plus was announced. As of Q1 of COP 2007 (FY 2008), SPS is the mechanism through which MSH will continue its work in Rwanda. During the COP 2004 and 2005, RPM Plus assisted the Ministry of Health with interventions to strengthen the pharmaceutical system at both national and peripheral levels. At national level, RPM Plus provided technical assistance to the Direction of Pharmacy, to the Central Medical Stores (CAMERWA), and to the Training and Research AIDS Center (TRAC) to integrate the components of pharmaceutical management into national strategies for improving access to ART, especially those related to quantification, procurement, distribution, and management information systems. At the peripheral level, RPM Plus led the development of curricula and training in pharmaceutical management to pharmacy staff from all ART delivery sites. RPM plus also collaborated with the National Reference Laboratory to develop the National Laboratory Policy and standard operating procedures of the laboratory tests required to monitor patients under ART.

In addition to these activities, RPM Plus was the lead agency for putting in place the Coordinated Procurement and Distribution System (CPDS) for ARVs. The CPDS emerged at the beginning of 2005 as a Government of Rwanda initiative aimed at maximizing the donor funds' purchasing power and ensuring quality products through a centralized supply for ARVs. During COP 2006, the MoH structure has been radically modified according to the approved decentralization policy. Under this policy, the roles and responsibilities of some MoH institutions such as TRAC have been redefined, and certain MoH Directions such as the Direction of Pharmacy have evolved into technical agencies called the Task Forces with more restricted functions (Pharmacy Task Force). SPS activities focus on three main technical objectives—

1. Provide technical support to the USG and Government of Rwanda partners in the institutional building and maintenance of the Coordinated Procurement and Distribution System (CPDS) of ARVs and other HIV/AIDS commodities

2. Provide technical support to the MoH and to CAMERWA to improve equitable accessibility of pharmaceuticals at the district level, and the quality of the pharmaceuticals available in the public sector.

3. Build the districts' capacity for assuming increasing responsibilities in pharmaceutical management, under the new policy of health care decentralization.

Major Activities this Quarter

As the process for finalization of the work plan for COP 2007 progressed, SPS continued TA and support to the CPDS resulted in the hiring and seconding of the CPDS coordinator who assumed

her position on October 1, 2007, SPS fully furnished and equipped the office space for the coordinator. In technical support of the coordinator, RPM Plus/SPS sponsored the coordinator's participation in a training on pharmaceutical management in Cape Town, South Africa, in November 2007.

During this reporting period, SPS, TRAC, the Supply Chain Management System (SCMS), and the CPDS Coordinator met and developed a plan of action for the transfer of activities and functions related to quantification from SPS to SCMS. In preparation of the CPDS sixth quantification of ARVs, the above organization organized and executed a data validation exercise at selected ART sites. SPS will participate in the finalization of the quantification process for the CPDS. In addition, in support of the MoH, SPS organized, sponsored, and facilitated the implementation of comprehensive quantification training for all pharmaceutical products. A total of 30 staff members from several programs were trained.

SPS facilitated the development of opportunistic infections reporting tools/instructions to be utilized at the health facility level. The tool was reproduced and full implementation is expected during the second quarter. In addition, SPS helped develop a reporting system to allow for effective communication between the central, district, and health facility levels in support of the planned implementation of the active distribution. Tools for the reporting system were printed and implementation is expected during the second quarter in collaboration with Pharmacy Task Force.

Regarding implementation of decentralization policy, SPS has already engaged in the required contractual and tendering processes necessary to begin rehabilitating 10 additional district pharmacies. The consulting firm that will oversee the rehabilitation has been identified and selected through a bidding process. In addition, the recruitment process began for hiring of eight additional district pharmacists during the reporting period with the announcement of the vacancies in the local newspapers. The process will be finalized in the initial weeks of the second quarter.

Currently, all eight district pharmacists hired and seconded to the MoH by /SPS are integrated and functioning effectively in their assigned districts. SPS continues it technical supervision and support of the pharmacists in collaboration with PTF. During the reporting period, with TA support of SPS and the PTF, seven of the eight district pharmacists were successfully trained in basic pharmaceutical management for the staff of all health centers in their districts; a total of 190 individuals received training. Training will be carried out by the remaining district pharmacist during the first two weeks of January 2008.
SPS also continued to support the eight hospitals that are in various stages of establishing or strengthening existing DTCs. In collaboration with PTF, SPS organized and conducted a comprehensive one-day workshop on the importance and benefit of DTCs, followed by a four-day training on DTCs for new DTC members from four hospitals; a total of 39 individuals were trained.

Finally, in support of the National University of Rwanda, SPS provided training on basic pharmaceutical management to 55 graduating students from the Faculty of Pharmacy.

SENEGAL—PMI

Overview

Every year, malaria causes 300 to 500 million cases of acute illness resulting in more than a million deaths worldwide of which at least 80 percent occur in sub-Saharan Africa. Senegal is one of the high malaria burden countries in sub-Saharan Africa. The burden of malaria has been intensified by the appearance of chloroquine and sulfadoxine pyrimethamine (SP)-resistant *Plasmodium falciparum* forcing countries to change their first-line therapies for malaria. To address this challenge, WHO recommended that all countries, revising their first-line treatment policies for malaria, should opt for a combination treatment, preferably an ACT.[1] Responding to this need, Senegal is implementing ACT policy with support from different funding mechanisms such the GFATM and the U. S. Government President's Malaria Initiative (PMI).

Senegal was selected as a beneficiary country for the PMI. The overall five-year $1.2 billion initiative intends to rapidly scale up malaria prevention and treatment interventions in 16 African countries which include promotion of insecticide-treated nets, indoor residual spraying, prompt and effective case management of malaria, and intermittent preventive treatment. The goal is to reduce malaria-related mortality by 50 percent after three years of program implementation in targeted countries. It is expected that this malaria mortality reduction will be achieved if each selected country can reach 85 percent coverage of the most vulnerable groups with proven and effective interventions.

Malaria is a major cause of morbidity and mortality in Senegal and a public health priority for the government. The disease is responsible for about one-third of all outpatient consultations and between 20 and 30 percent of mortality in health facilities. In 2004, RPM Plus conducted a study that showed a limited availability of antimalarials at the health facility level with only 44 percent of the visited facilities having SP and 37 percent with AQ. Major pharmaceutical management issues subsequently identified are the limited availability and inappropriate use of stock and inventory management tools, the lack of collaboration and exchange of information between the pharmaceutical distribution system and the public health system, inappropriate quantification methods, and the lack of distribution plan for antimalarials and other commodities.

In January 2006, the National Malaria Control Program (PNLP) procured three million AS/AQ treatments with resources from the GFATM that were distributed to hospitals, health centers, and health posts along with malaria case management training. AS/AQ has also been introduced into the community through the cases de santé (village health huts). AS/AQ is currently available in private pharmacies at a higher price (4,000 Senegal francs [CFA] or USD 8 per treatment). In May 2006, the USG conducted a rapid assessment in preparation for PMI country planning and implementation and subsequently requested the support of MSH/RPM Plus Program to support Senegal PMI COP.

[1] WHO. 2004. Position of WHO's Roll Back Malaria Department on malaria treatment policy

In October 2006, USAID supported the Malaria Action Coalition to resolve bottlenecks in implementation of the GFATM malaria grant. The team, comprised of RPM Plus, WHO/AFRO, and the PNLP, suggested establishing a committee to implement and monitor the recommendations made by the team following a rapid assessment of the pharmaceutical management information system, particularly for ACTs. This committee has been established and began working on implementing recommendations to improve the capacity to quantify the needs of ACTs by central level MoH staff.

SPS will continue to provide support along the same technical lines as RPM Plus. Activities will focus on supporting the drug supply and pharmaceutical management and address the issues related to quantification, storage, and distribution. Contributing to national efforts to fight against malaria, the SPS Program will build on lessons learned and work done by RPM Plus to support implementation of ACTs policies through using the comprehensive approach proposed in the implementation guide *Changing Malaria Treatment Policy to Artemisinin-Based Combinations* prepared by RPM Plus in collaboration with the RBM partnership and the GFATM. This support will contribute to the PMI expected results in the context of the national malaria control policy in Senegal while achieving SPS technical objectives.

Major Activities this Quarter

- Provided technical assistance to the PNLP in conducting formative supervision visits in Thiès region. SPS oversaw the pharmaceutical management aspects in the districts' depots and health centers. It was noted that stock cards were not correctly filled out, severe malaria was not appropriately managed, and monotherapies were available despite their ban.
- SPS met with a variety of MoH (SNIS, Pharmacie Nationale d'Approvisionnement [PNA], PNLP, PNT, DLSI, etc.) and NGO (WHO, USAID, USAID CAs) partners individually to present the concept of the pharmaceutical management supervision guide and share an initial draft for feedback. SPS subsequently held a two-day workshop with these partners and stakeholders in Thiès to review and finalize the guide according to participant comments and discussion. The guide was then field-tested in two regions (Thiès and Kaolack); in each region the guide was administered in one regional medical store, one district depot, one health center pharmacy one health post depot, and one health hut.
- SPS provided support in developing the terms of reference, selecting candidates, and the recruiting external providers (18 providers and 3 supervisors) the PNLP hired to strengthen supervision in the private sector and at the district level.
- SPS participated in the MoH's antimalarial quality surveillance coordination committee meeting. The meeting was held in response to reports regarding the irregular stock levels of adolescent ACT/6+6 in many regional depots and at the central medical store.
- SPS has regularly participated in the PNLP quarterly review meetings (North and Dakar axes) to discuss malaria treatment, IPT, treated net distribution, and ACT management. Participants include district health officials, regional medical team, PNLP, PNA, and partners.

Next Steps

- Initiate pharmaceutical management for antimalarials training activities for health center and health post dispensers to correct the identified weaknesses (poor maintenance of stock cards) and advocate to the MoH to take appropriate action to remove antimalarial monotherapies public sector facilities.
- The field test of the pharmaceutical management supervision guide demonstrated some redundancies, so the guide is being modified for validation by the partners and stakeholders.
- Exchange with the PNLP and other partners the results of the last quarterly review and make suggestions to improve data collection and use.

SENEGAL TB

Overview

In 2004, WHO estimated that the incidence rate for smear-positive tuberculosis cases was 110 per 100,000 inhabitants in Senegal. WHO's DOTS strategy was adopted throughout the country in all health regions, involving 68 diagnosis and treatment centers. Despite this, the case detection rate remains very low (51 percent in 2005). In 2006, the treatment success rate for TB cases registered in five regions supported by USAID was 72 percent. The HIV-TB co-infection is a heavy morbidity burden for the country (15 percent for the HIV/TB co-infection according to the sentry surveillance).

Situational analyses show a particular feature of the Dakar region, which hosts a high percentage of people suffering from TB, has a large number of cases managed centrally. Furthermore, rural areas show great shortcomings in detecting and treating people suffering from TB because of the population's vulnerability and the low rate of access to screening tests and case management services. Recent evaluations by the UNION revealed numerous shortcomings in human resources and screening facilities. Patient adherence to treatment is also an important aspect to be taken into consideration to increase the current treatment success rate.

The Programme National de Lutte contre la tuberculose (PNLT—National Tuberculosis Control Program) has decided to adopt a new therapeutic approach consisting of changing the treatment period from eight to six months. This change will be coupled with the introduction of fixed-dose combinations (FDC). For a successful transition, the PNLT has solicited the support of the MoH's technical partners. The PNLT's goal is to contribute to reducing the TB morbidity and mortality rates in an environment marked by poverty and TB/HIV co-infection, and by reinforcing and expanding the DOTS strategy application throughout the country. The expected impact is the reduction by 2015 of the tuberculosis incidence, by achieving by 2010 a case detection rate of 70 percent and a treatment success rate of 85 percent.

The Central Medical Store (PNA), responsible for procuring essential medicines for the public and non-profit sectors, was responsible to procure the new TB medicines since December 2006. Due to delays in procuring TB medicines, the MoH, through the PNT, requested the GDF's support to get those new products (FDCs) and avoid stock-outs of TB medicines in the country. GDF supplied four FDC medicines to the MoH during the second half of 2007; the GDF medicine delivery coincided with the arrival of the medicines ordered by PNA.

Based on the support RPM Plus provided to PNLT in the past, USAID requested MSH to help the PNLT carry out its activities within the framework of the implementation of the new SPS program.

Many meetings between MSH/SPS, the USAID Mission, the PNT, and their implementing partners, namely Family Health International (FHI), helped to develop a coordinated intervention plan. SPS will be essentially responsible for matters relating to the management of TB medicines

based on the new treatment plan. It will also be charged with adapting and printing management tools in accordance with new data reporting requirements. Furthermore, SPS will support the PNT in collaboration with other partners in the framework of the health care provider trainings, which is an indispensable step for an effective implementation of the new policy in the field.

MSH/SPS will also help in setting up a forum that will be charged with facilitating the coordination between the PNLT and some of its partners to quickly find solutions for certain problems that are very likely to occur in the TB medicine management process.

Major Activities this Quarter

- The SPS Technical Advisor met with the PNT and FHI to discuss and coordinate planned technical assistance and activities with NTP and partners.
- The SPS Technical Advisor gave input on the draft training manual for management of TB drugs with regard to the introduction of four FDCs by the PNT.
- SPS provided funding for the initial distribution of four FDCs anti-TB medicines from the central level to regional medical stores throughout the country.

Constraints to Progress

- A number of PNA staff (regional medical store pharmacists) who were selected as trainers were too busy conducting the annual inventory activities to participate in training.

Next Steps

- Organize a TOT targeted at central level (CMS and NTP) and regional medical store pharmacists on the management of anti-TB medicines.
- Participate in training staff from health center depots and TB treatment centers on the management of anti-TB medicines.
- Advocate at the central level to create a committee to monitor activities related to the management and quality of anti-TB medicines.

TANZANIA—PEPFAR

Overview

The SPS Program in Tanzania received FY07 funds from USAID/Tanzania to continue RPM Plus activities in support of USAID HIV/AIDS and malaria programs. This includes assistance for the scale-up of the ADDO program and integration with other public health interventions such as the Tunajali home-based care/orphan and vulnerable children program in Morogoro, and the provision of subsidized ACT. In addition, SPS program funds in Tanzania are being leveraged with RPM Plus SO3 core funds to integrate child health intervention using the Integrated Management of Childhood Illness (IMCI) approach into the ADDO program.

ADDO scale up and links to community HIV/AIDS palliative care services in Morogoro region is PEPFAR-funded. Its implementation which runs into two phases—first the accreditation of the outlets and then integrating the community HIV/AIDS palliative care services by linking the outlets with the HBC-kits distribution programs in Morogoro region—is in its final stages as only one out of six districts remains. This is expected to be finalized in the first quarter of 2008. The process of linking ADDO with Tunajali community HIV/AIDS palliative care services is underway in collaboration with FHI. A drafted Memorandum of Understanding is being reviewed by the parties and once signed, identified activities will be implemented in Kilombero and Kilosa districts.

The SPS overall program objective is to increase access to and appropriate use of medicines of assured quality. The program aims to contribute to strengthening pharmaceutical management systems to support priority public health service and interventions and expand access of essential medicines.

Major Activities this Quarter

- On accreditation and ADDOs scale-up in Morogoro, SPS, in collaboration with TFDA, provided TA to train 22 Council Food Drug Technical Committee members for Morogoro rural and Mvomero districts and 65 local ward inspectors for Kilombero district, and carried out pre-accreditation inspections of 212 drug outlets in Mvomero and Morogoro Rural. A total of 112 outlets were approved for accreditation and the remaining outlets that did not meet requirement were given extra time to meet TFDA set standards.

- SPS interviewed 300 candidates for the dispensers' course for Mvomero and Moro Rural districts and selected 242. Those selected were enrolled in the ADDO dispensers training course and 240 successfully completed the course and qualified for a dispensing certificate.

- A joint SPS and FHI Tunajali team visited Kilosa district to familiarize each program's activities and finalize the designing of the ADDO HIV/AIDS palliative care services link in Morogoro region. The team held discussions with Kilosa stakeholders and briefed them

about the proposed ADDO/HBC linkage. The Memorandum of Understanding between MSH/SPS and FHI/Tunajali is being reviewed and implementation of agreed activities will begin during first quarter 2008.

- SPS provided technical support to TFDA in July 2007 to finalize the ADDO implementation manual and to review ADDO regulations. The implementation manual will guide ADDO roll out scale-up by local government and other implementing partners. The review of ADDO regulations intends to further delegate TFDA regulatory responsibilities of ADDOs and other medicines-related issues to local councils.

- SPS provided TA to TFDA to develop a draft strategy document on how to scale-up ADDOs in urban settings to guide ADDO roll-out in Morogoro Urban. The draft was presented to TFDA management team for their input and approval process.

- SPS participated in the first Medicines Access Steering Committee Meeting chaired by the MOHSW Chief Medical Officer. MSH/SPS is a permanent member to the Ministry's committee.

- In collaboration with TFDA, NMCP and local authorities SPS conducted a comprehensive supportive supervision in all 10 districts of Ruvuma and Morogoro covering 763 ADDOs. Funding for this activity was leveraged from all components in the ADDO program (HIV/AIDS, malaria, and child health). This supervision achieved the following—
    - Observed the general dispensing practices of ADDO dispensers and adherence of both owners and their dispensers to ADDO general regulations.
    - Followed trained dispensers after training in IMCI and observed implementation of IMCI components at site.
    - Assessed the extent of distribution and availability of ACTs at facility level.
    - Provided instructions at facilities documentation of ACTs' utilization and assessed dispensers dispensing skills and knowledge especially for managing children under age five.
    - Assessed the extent of implementation of safety of medicines reporting (ADR) at ADDO level and exchanged findings with district focal persons.
    - Provided on-site training and supportive supervision to local CHMT members.
    - Collected relevant monitoring and evaluation data for further analysis and result sharing. Detailed supervision report with specific results is being finalized for dissemination.

Major Constraints to Progress

- Although SPS leverage funds and jointly carry out activities for the three components in the ADDO program, implementing many of the key activities is financially demanding and requires extended staff time for field work and providing TA to TFDA, NMCP, and local government authorities. Constrained funding leads to over extending current staff and skipping other vital planned activities which would further strengthen the system.

- SPS continues to experiences delays in activities that have been planned due to unavailability of TFDA staff to travel to the districts or lack of approval for some activities. For instance, the scale-up of ADDO in Morogoro Urban has been delayed for months because TFDA management did not make a strategic decision on how to approach urban settings despite a draft strategy proposal that was prepared by SPS months earlier.

Next Steps

- Finalize all key reports for activities completed in the reporting period (July–December 2007)
- Begin implementation of ADDO-Tunajali intervention activities in Kilosa district.
- Jointly conduct supportive supervision to cover all ADDOs in relation to all three program component
- Start accreditation activities for the remaining Morogoro Urban district

TANZANIA—PMI

Overview

In March 2006, USAID/Tanzania requested the RPM Plus Program to provide technical support for the implementation of the PMI in Tanzania. In the context of the national policies, the SPS/ program activities continue to support ACTs policy implementation through private sector distribution of subsidized ACTs using the ADDO. SPS also supports the Tanzania Food and Drug Administration (TFDA) to strengthen monitoring of medicines safety (pharmacovigilance) systems in the country with regards to monitoring possible adverse drug reactions (ADRs) including those due to ACTs.

Under the Tanzania PMI country program, the SPS strategy focuses on two technical objectives—

- How to improve the supply and quality of antimalarials and related supplies and
- How to improve the management and use of antimalarials achieved through SPS technical assistance provided to NMCP, TFDA, and local (regional and district) government to implement private sector delivery of subsidized ACTs using the ADDOs. Under MOP 2006 and MOP 2007, PMI procured 646,050 of ACTs treatment course which were distributed through 763 ADDOs in the 10 districts of Morogoro and Ruvuma regions which have approximately a population of over 2 million. In PMI's FY 2008, these services would expand to cover other two regions—Mtwara and Rukwa.

Major Activities this Quarter

- Finalized fixing stickers with ADDO logo to all packs for the first consignment of 113,280 treatment doses of subsidized ACTs for ADDOs.
- Participated in a joint planning meeting with John Snow International/DELIVER and ACT distributor on procurement of the second ACT consignment. Received additional 532,770 treatment doses from Novartis in September.
- Dispatched about 50,000 treatment doses of ACTs to Songea and Morogoro distributors for distribution to ADDOs. Distribution to ADDOs started mid-August 2007.
- Conducted sensitization and orientation workshop on ACT policy implementation and distribution through the private sector to 60 community health management team members, 255 ADDO owners, and 345 ADDO dispensers for Morogoro Rural, Mvomero, and Kilosa districts
- Finalized printing and distributed management tools, SOPs for ACT distribution, price indicator sheets, and dosage charts to ADDOs through regional distributors and during supervision visit.
- Provided support to the NMCP, TFDA, and Ministry of Health and Social Welfare (MOHSW) for planning official launch of private sector distribution of PMI-procured ACTs through ADDOs. ACT distribution through ADDO was successfully launched by

the USAID country director and the MOHSW Director of Preventive Services at the MOHSW in Morogoro region.

- Finalized incorporating information related to tracking ACT distribution and use in the overall ADDO supportive supervision checklist and used the checklist during supportive supervision visits.
- In collaboration with TFDA, SPS maintained contact with the pharmacovigilance focal persons in the pilot districts of Ulanga, Kilombero, and Songea Urban and Rural to encourage them to make follow up reporting of ADRs in their respective districts and continued to participate in the pharmacovigilance working group meetings.
- SPS shared experiences and lessons learned in distributing ACTs through private sector (ADDO) during the workshop for developing a strategic plan to improve access of ACTs through the private sector in Uganda.
- In collaboration with TFDA, NMCP, and local authorities, SPS conducted a comprehensive supportive supervision in all 10 districts of Ruvuma and Morogoro covering 763 ADDOs. Funding for this activity was leveraged from all components in the ADDO program (HIV/AIDS, malaria, and child health). This supervision achieved the following—
    - Observed the general dispensing practices (including those for ACTs) of ADDO dispensers and adherence of both owners and their dispensers to ADDO general regulations.
    - Assessed the extent of distribution and availability of ACTs at facility level and documentation and reporting on ACTs' utilization, and dispensing skills and knowledge especially for the management of children under age five.
    - Assessed the extent of implementation of safety of medicines reporting (ADR) at ADDO level and exchanged findings with district focal persons.
    - Provided on-site training and supportive supervision to local community health members.
    - Collected relevant monitoring and evaluation data for further analysis and result sharing. Detailed supervision report with specific results is being finalized for dissemination.

Major Constraints to Progress

- Takeoff for ACT distribution through ADDOs has been slower than anticipated mainly due to concurrent availability of SP and other monotherapies. Other contributing factors are the long distances owners have to travel to regional distributors for ACT refills and meager capital which prevents preventing large stock purchases at one time. Plans are underway to select a few ADDOs at district level to restock ACT and bring them close to other ADDOs in the area.

Next Steps

- Strengthen ACT distribution in the Morogoro and Ruvuma region, and data collection and compilation/analysis
- Expand distribution to cover Rukwa and Mtwara regions if funding is available.

- Carry out supportive supervision to cover all ADDOs in relation to all three program components.
- Implement marketing strategy for ACTs in the private sector in collaboration with PSI.
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