Strengthening Pharmaceutical Systems Programs:
Summary of Activities Conducted in Guangxi Province, China, during
July 2008–September 2011

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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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ABBREVIATIONS AND ACRONYMS

ART  Antiretroviral treatment
ARVs  Antiretrovirals
BOH  Bureau of Health
CDC  Center for Disease Control
MSH  Management Sciences for Health
NCAIDS  National Center for AIDS/STD Control and Prevention
PMTCT  Prevention of mother-to-child-transmission of HIV
RDMA  Regional Development Mission Asia
RPM  Rational Pharmaceutical Management
SOP  Standard operating procedures
SPS  Strengthening Pharmaceutical Systems
ToT  Training of trainers
USAID  US Agency for International Development
WHO  World Health Organization
The Strengthening Pharmaceutical Systems (SPS) Program, funded by the US Agency for International Development (USAID), provided technical support to strengthen pharmaceutical management and systems in China from July 2008 to September 2011. From fiscal year 2008 to 2011, USAID contributed $300,000 to provide technical assistance to the Center for Disease Control (CDC) in Guangxi Province, National Center for AIDS/STD Control and Prevention (NCAIDS). SPS recognizes the opportunity provided by USAID to support pharmaceutical management strengthening in China and appreciates the technical guidance received from the USAID over the life of the project.

At the request of WHO China, the technical assistance was to focus on standardizing and strengthening the pharmaceutical management practices for antiretrovirals (ARVs) in China. During the time the request was made, there was no standardized management practice in place in China, and it was felt that instituting standardized practices would improve efficiency. Guangxi was identified as the province to receive the technical support from SPS.

The initial phase of the project involved an assessment visit in December 2008 to the province to understand ARV management at the provincial, city, county, and facility levels at that time. At the conclusion of the assessment, the recommendation was made to develop a standardized operating procedure for ARVs to uniformly manage the reporting of consumptions, quantifications, supply, distribution, and dispensing practices.

Based on the initial assessment report, the ARV management and operation workflow was determined. SPS developed a first draft on an ARV SOP for provincial, city, county, and facility levels.

In June 2009, SPS and WHO presented the initial drafted SOP manuals, tools, and reporting forms to their counterparts from Guangxi CDC, NCAIDS, and staff from the city and county CDC offices, ART treatment centers, and prevention of mother-to-child-transmission of HIV (PMTCT) sites for review and validation, and solicited input on adaptations needed to the manuals and tools for the Guangxi context.

SPS then revised the draft SOP manuals, tools, and reporting forms based on the comments received; in addition, training materials for a training of trainers (ToT) workshop and a follow-on training workshop on SOP implementation in January 2010 were developed. During this same visit, the revised SOP manuals were also handed over to local stakeholders for piloting.

In November 2010, a follow-up visit was conducted to evaluate the adaptation and implementation of the SOP at the selected sites. Initial findings revealed that, despite the general

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appreciation for having a standardized management practice in place, there is a lack of ownership and commitment to implement the SOP in a comprehensive manner.

This and previous reports capture the detailed descriptions of the work undertaken by SPS. With the limited funding and lack of a country office, the above activities were extended over a 3-year period, from assessment, development, validation, and implementation to the follow-up evaluation phase. Because of the short time period between the implementation and follow-up evaluation phase, the long-term outcome has yet to be concretely measured and hence it is too soon to determine any impact as a result.

Nonetheless, SPS is pleased with the contribution that it made to assist the national partners to develop the first standardized pharmaceutical management procedure for ARVs in China. At the national level, the concepts and practice principles elicited in the Guangxi SOP manuals can be used as guidance documents for the other provinces to develop SOPs.
INTRODUCTION

Purpose

This report illustrates an account of the activities carried out and results achieved during the entire project period spanning July 2008 through September 2011.

Background

The Strengthening Pharmaceutical Systems (SPS) project has received funding from the US Agency for International Development’s (USAID) Regional Development Mission/Asia (RDMA) to provide technical assistance to strengthen pharmaceutical management operations for the HIV program in China. The National Center for AIDS/STD Control and Prevention (NCAIDS), WHO, and SPS decided to start the work in Guangxi Province. In July 2008, SPS staff, WHO, and local stakeholders organized a workshop in Nanning in Guangxi Province to train participants on good practices in pharmaceutical commodity management; a tool was introduced for reviewing the practices of managing antiretrovirals (ARVs) at various levels of the supply chain and usage.

As planned during the July workshop, SPS staff traveled to China in December 2008 to review pharmaceutical management operations at antiretroviral therapy (ART) treatment and distribution sites in Guangxi Province and to work with stakeholders to develop an action plan for strengthening (ARV) pharmaceutical management system.

During the review visit, the SPS/WHO team visited several sites at various levels. The review team identified gaps and recommended measures to strengthen the system. The major recommendations included—

- Review existing manual forms and tools to identify options to streamline, consolidate, and fill gaps
- Develop SOPs to manage ARVs
- Strengthen forecasting methods and develop tools to complement other partner efforts

SPS worked closely with WHO and local stakeholders to review the existing formats and procedures and develop SOPs that included standardized tools for quantification and forecasting ARVs. SPS also helped to pilot the SOPs in a few selected sites in the province. A rapid evaluation was made by a team of local stakeholders, WHO, and SPS. The findings and recommendations of the evaluation are presented in this report.
PROGRAM ACTIVITIES AND RESULTS

Review of Existing ARV Management System in Guangxi Province

As planned during the July workshop, SPS staff traveled to China in December 2008 to review pharmaceutical management operations at ART treatment and distribution sites in Guangxi Province and to work with stakeholders, including WHO and NCAIDS (at the national level) and Guangxi Bureau of Health (BOH) and China Center for Disease Control and Prevention (CDC) to develop an action plan for strengthening ARV pharmaceutical management.

During the review visit, the SPS/WHO team visited five distribution and seven treatment sites at each system level, including two of the three centers in the province that provided ART services to children. Following the site visits, SPS met with stakeholders from Guangxi Province, NCAIDS, and WHO to present key findings and recommendations and to develop a plan of action.

Some of the major concerns observed in the course of review were—

- Absence of SOPS for managing ARVS and controlling inventories at each level
- Limited availability of second-line ARV products
- Frequent stock shortages resulting from problems with procurement that necessitated emergency orders to fill gaps
- Absence of simple tools to assist staff in analyzing data and quantifying needs
- Limited storage conditions at distribution facilities
- Absence of standardized and simple tools (both manual and electronic) to record inventory transactions at all levels and to capture data at the dispensing point
- Inadequate knowledge and skill of personnel responsible for the management of ARVs

In response to the assessment findings, SPS provided an overall list of recommended activities to national stakeholders.

Review of Existing Manual Forms and Tools to Identify Options to Streamline, Consolidate, and Fill Gaps

All the existing formats and written procedures used in the management of ARVs across the supply and service chains were collected and translated into English. Extensive consultation and discussion were held among all the stakeholders and gaps were identified.
Development of SOPs for the Management of Antiretroviral Medicines

SOPs for managing ARVs at provincial, city, county service center, and supply chain stores were drafted. Formats and procedures currently in use in the province were referred to during the drafting process. This was necessary to ensure that the formats and procedure that were working satisfactorily were retained rather than replacing them with new ones.

Each SOP (provincial, city, county, and service-center levels) is developed as an independent and complete reference material for the intended level. Because the use of computers was not uniform across the centers, formats and tools were developed that could be used with or without a computer. Formats for computer were developed in Microsoft Excel and do not require extensive training on computers. Basic operating knowledge of computers is adequate. However, if the tools require modification, a higher level knowledge of Excel is required. Few staff from NCAIDS and provincial CDC were trained to enable them to effect changes if needed.

Strengthening Forecasting Methods and Developing Tools to Complement Other Partner Efforts

Tools for forecasting demand for ARVs were developed. These tools are based on Microsoft Excel and do not require extensive training on computers. Basic operating knowledge of computers is adequate.
VALIDATION OF SOPS

In June 2009, a workshop was organized in Nanning in Guangxi Province where the draft SOPs were presented to the stakeholders. Extensive discussions were held and feedback and recommendations were received. Most of the concerns were related to the language because of the quality of translation from English to Chinese.

The SOPs were generally liked by the stakeholders. There were, however, many suggestions to modify the formats and procedures to suit the Chinese context.

The feedback and recommendations received during the workshop were carefully evaluated and accommodated in the SOPs. SOPs were thus finalized and ready for pilot testing.
In January 2010, two trainings were organized in Nanning in Guangxi Province. The first was training for trainers (ToT). Participants in this training were mostly from national, provincial, and (some efficient) city/county-level stores and health facilities. The participants of ToT were expected to train the users of SOPs during the implementation.

The second training was for end users from city/county stores and service centers. This training was facilitated by the participants of the ToT with guidance from SPS facilitators. This was done to ensure that the ToT participants can train store and facility staff independently when SOPs are implemented.

A group of staff from national and provincial levels were exclusively trained on the Excel-based tools to enable them to change the formulas and layout if needed.

It was decided to pilot test the SOPs at all levels. SOPs were put on pilot testing in 17 sites which included sites from all levels.
POST-PILOTING EVALUATION

In November 2010, two SPS staff traveled to Guangxi Province to review how completely procedures and tools outlined in the SOPs were implemented and to analyze the outcome with respect to knowledge, attitudes, and practices related to the management of ARVs. A team composed of staff from SPS, WHO/China, NCAIDS, and Guangxi CDC conducted semi-structured interviews with the informants. Use of procedures and formats was observed onsite. A technical report 3 was prepared to document the findings of the review.

Major findings were—

- Management and staff at all levels generally appreciated the concept of SOPs, particularly that the procedures and tools recommended in the SOPs are logical and scientific.

- At some sites, the SOPs were not used at all or were partially used. The staff thought some of the formats and procedures were difficult to use and needed some change to suite the Chinese context. Concern was expressed regarding the difficulty in using the documents due to the poor translation from English to Chinese.

- A shortage of skilled staff dedicated to the management of ARVs.

- Some positive changes were reported after using the SOPs.
  - Facilities did not experience any ARV stock-outs in 2010.
  - Staff are very vigilant in stock monitoring and rotation. For example, it was reported that stock expiring within three months is generally returned to the upper level for redistribution.

In general, given the incomplete implementation of the SOPs at the sites we visited and the eight-month lapse between the SOP implementation and the evaluation visit, the full impact associated with the SOP is likely unknown or unobserved.

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RECOMMENDATIONS

Though the SOPs are appreciated by all stakeholders, they are not being implemented as yet beyond piloting in a few sites.

A detailed list of recommendations is presented in the evaluation report. Because the tools and procedures contained in the SOPs are not formally endorsed by provincial authorities, the facility has the option of not using them. The top priorities of BOH of Guangxi Province should be to revisit the SOPs and make necessary changes to suit the local context, formally endorse them, and implement them province-wide. This should not be difficult because the concept and content of the SOPs are generally appreciated by the intended users.
LIST OF DELIVERABLES

Reports


SOP Manuals

Standard Operating Procedures for ARV Management for Guangxi Province of China for Provincial Level

Standard Operating Procedures for ARV Management for Guangxi Province of China for City and County Levels

Standard Operating Procedures for ARV Management for Guangxi Province of China for Facility Level