

SPS Ukraine Associate Award: Final Report

August 27, 2011- December 28, 2012

March 2013



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This report is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00, Associate Award number AID-OAA-LA-10-00003. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries and countries with transitional economies 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

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MSH. 2012. *SPS Ukraine Associate Award: Final Report*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

Key Words

Ukraine, TB, HIV/AIDS, DOTS, ART, MDR-TB, eTB Manager, pharmaceutical management, pharmacovigilance, rational medicines use

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ACKNOWLEDGMENTS

The US Agency for International Development-funded Strengthening Pharmaceutical Systems (SPS) Program would like to thank the many individuals and entities over the course of the project for their collaboration, guidance, and support, including: the USAID/Ukraine Mission, USAID/Washington, Ukrainian Ministry of Health, All Ukrainian Center for TB Control, Ukrainian AIDS Center, Ukrainian Center for Socially Dangerous Disease Control, National Committee for HIV/AIDS and Other Socially Dangerous Diseases, State Service for HIV/AIDS and Other Socially Dangerous Diseases, State Expert Center of the Ministry of Health (SEC), State Administration of Ukraine for Medicinal Products (SAUMP), National Academy of Sciences, F.G. Yanovskiy National Institute of Phthisiatry and Pulmonology, Sanitary Epidemiological Service of Ukraine, and the State Penitentiary Services of Ukraine.

We are also grateful for the collaborative efforts of the World Health Organization/ Ukraine, EURO and Geneva, PATH/Ukraine, Futures Group, the Foundation of Development of Ukraine, as well as the various local government agencies that were partners in our Ukraine activities, in addition to collaborating organizations that may not have been mentioned above.

Special gratitude is offered to the committed staff at national and local levels of the Ministry of Health and other State Services, as well as many non-governmental organizations, who work tirelessly to strengthen pharmaceutical systems, make quality HIV/AIDS and TB pharmaceutical and health services more accessible to Ukraine's citizens, ensure the quality and safety of medicines and other commodities, and promote their appropriate use. It was a privilege for the Project to assist in furthering progress on in this key area.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
DOTS	directly observed treatment (short course)
FDC	fixed dose combination (product)
FDU	Fund for Development of Ukraine
GDF	Global Drug Facility
Global Fund	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GOU	Government of Ukraine
HIV	human immunodeficiency virus
HSCP	HIV/AIDS Service Capacity Project
IPAT	Indicator-based Pharmacovigilance Assessment Tool
M&E	monitoring and evaluation
MDR-TB	multidrug resistant tuberculosis
MIS	management information system
MoH	Ministry of Health
MSF	Médecins Sans Frontières (Doctors without Borders)
MSH	Management Sciences for Health
NGO	nongovernmental organization
PLWHA	People Living With HIV/AIDS
PMIS	pharmaceutical management information system
RPM Plus	Rational Pharmaceutical Management Plus
SAUMP	State Administration of Ukraine for Medicinal Products
SEC	State Expert Center (MoH)
SIAPS	Systems for Improved Access to Pharmaceuticals and Services (Program)
SPS	Strengthening Pharmaceutical Systems (Program)
STbCU	Strengthening Tuberculosis Control in Ukraine (Project)
STG	standard treatment guideline
TA	technical assistance
TB	tuberculosis
TOR	terms of reference
TOT	training of trainers
TWG	technical working group
UAC	Ukrainian AIDS Center
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
USG	United States Government
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

EXECUTIVE SUMMARY

Background

In 2009, at the outset of the Strengthening Pharmaceutical Systems (SPS) Associate Award work in Ukraine, the Ukraine Ministry of Health (MoH) reported that tuberculosis (TB) was the leading cause of death from infectious diseases in the country and that patients with multi drug resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) were increasing in number. The World Health Organization/EURO estimated that Ukraine had the highest burden of TB in the region after the Russian Federation, and nearly 16 percent of new TB patients had MDR-TB, the fourth highest proportion in the world.

Ukraine also was experiencing the most severe HIV/AIDS epidemic in Eastern Europe and Central Asia, with an estimated 350,000 people living with HIV and an adult prevalence rate of 1.1 percent in 2009. Large scale anti-retroviral treatment began under the Global Fund grants, and shifted to MoH in 2009. Barriers to providing TB and HIV/AIDS services, however, included the lack of continuous availability, irrational use, and unassured quality of related medicines and commodities.

In 2008, the MoH requested support from the Strengthening Pharmaceutical Systems (SPS) program implemented by Management Sciences for Health (MSH) to implement the eTB Manager; a web-based program designed to strengthen TB programs and improve program outcomes. From September 2010 through December 2012, SPS collaborated with key stakeholders on implementation of eTB Manager, as one of the focus areas within the following four technical objectives:

1. Improving information systems to improve medicines availability and treatment outcomes
2. Building institutional and human resource capacity to strengthen supply chain management
3. Improving the use of medicines
4. Supporting development of policies and other measures to assure medicines quality and safety

Key Achievements

SPS activities contributed to the four core technical objectives for improving access to and use of essential medicines for TB and HIV/AIDS. The primary focus on pharmaceutical management information systems (PMIS) was on scaling up implementation of the eTB Manager to provide adequate information related to TB case management and product availability. SPS support resulted in adaptation of eTB Manager to the Ukrainian environment, and development of capacity to use the system at national and oblast levels, and initial roll out to rayons. . By December 2012, two thirds of oblasts were entering data into the eTB Manager on a regular basis, with over 50,000 cases entered. SPS Ukraine provided on-site support to oblast and national level TB facilities to reinforce training on the eTB Manager and resolve on-going implementation issues. A core group of users provide ongoing

feedback on the system, and training and other support to their peers. Initial benefits include reinforcement of the need for accurate reporting and recording, and information on facilities that provide TB case management by oblast. In 2012, the eTB Manager obtained official designation as the official national TB electronic registry, and received the security certificate for the eTB Manager, in accordance with Ukrainian law on patient confidentiality and data security.

SPS provided technical assistance to strengthen supply chain management, particularly in quantification of first and second line medicines at national and oblast levels, resulting in noticeable engagement of the MoH counterparts in strengthening procedures and capacity in TB medicines quantification for procurement. SPS also worked with the State Service, TB Center, and the TB Quantification Working Group to develop new quantification instructions, which were approved by the MOH, and trained national and oblast level TB staff to use the new instructions to develop the annual quantification for 2012. With SPS assistance, the MDR-TB Treatment Working Group adapted existing pharmaceutical management tools for supply chain management of second line TB medicines, and supported preparation of sites for receiving and dispensing those medicines to selected patients.

In March 2012, Ukraine received notification that its second application to the GDF for a grant of first line TB medicines, prepared with SPS support, was approved for 2013. Between this new grant and the previous one, Ukraine would receive first line drugs to provide treatment to over 20,000 patients.

SPS, in conjunction with the University of Illinois at Chicago (UIC), worked with the Yanovsky Institute of Phthysiatry and Pulmonology (TB Institute), as well as the State Service, TB Center, WHO, and other key stakeholders to conduct a survey of prescribing practices in TB facilities, and adherence to nationally accepted standard treatment guidelines (STGs) in one oblast. The primary conclusion of the survey was that the vast majority of TB treatment in the oblast did not adhere to official Ukrainian 2010 STGs. Adherence issues included both patient related and prescriber issues. The findings will be used to inform intervention development to support the rational use of TB medicines.

SPS worked closely with the State Expert Centre (SEC) to conduct an assessment of the pharmacovigilance and medicines safety system in Ukraine. Data were collated from document reviews, and from interviews with key informants and experts from 55 health institutions and organizations in Ukraine. Following a detailed analysis, the draft technical report, *Safety of Medicinal Products in Ukraine: Assessment of the Pharmacovigilance System and its Performance*, was developed in June 2012, and finalized in December 2012, at the stakeholder meeting, sponsored by the SEC.

Among the lessons learned throughout this SPS Ukraine Associate Award were the following:

- Reorganization of key MOH counterpart organizations created both opportunities and challenges
- eTB Manager “super- users” facilitated implementation and sustainability
- New legal requirements entail building new partnerships and approaches
- Nationwide implementation of the eTB Manager, a web-based program, can only move as quickly as the last adopters

BACKGROUND

In 2009, at the outset of the Strengthening Pharmaceutical Systems (SPS) Associate Award work in Ukraine, the Ukraine Ministry of Health (MoH) reported that tuberculosis (TB) was the leading cause of death from infectious diseases in the country and that patients with multi drug resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) were increasing in number. The World Health Organization/EURO estimated that Ukraine had the highest burden of TB in the region after the Russian Federation, with 12,000 people dying each year.¹ According to WHO, nearly 16 percent of new TB patients had MDR-TB, the fourth highest proportion in the world.

Ukraine also was experiencing the most severe HIV/AIDS epidemic in Eastern Europe and Central Asia, with an estimated 350,000 people living with HIV and an adult prevalence rate of 1.1 percent in 2009². Large scale anti-retroviral treatment began under the Global Fund grants, and in 2009, the MoH took responsibility for the treatment of patients who were initiated on treatment under Global Fund Round 1 grant. In 2010, according to the MOH, approximately 20,000 patients were on ART, primarily funded through the MoH, with additional patients on treatment supported through the Global Fund Round 6 grant.

To address these and other public health challenges, the MoH was structured to deliver services through vertical systems for HIV and TB. The delivery of HIV preventive and treatment services was provided primarily through a government network of AIDS centers at the national, regional (oblast), district (rayon) and municipal levels. The TB service was comprised of a large network of specialized institutes, dispensaries, hospitals, outpatient clinics, and sanatoria at national, regional, municipal/district, and community levels.

Although most clinicians were trained to provide TB and HIV/AIDS services, the continuous availability and the rational use of related medicines and commodities is not assured. Challenges included procurement delays and unpredictable distribution schedules. Quantification processes were long and unclear, resulting in inappropriate quantities ordered. Anecdotal reports of stock-outs for TB medicines were common, while health professionals and patients expressed concern about the quality of medicines. Irrational use of medicines and prescribing practices that did not conform to standard treatment guidelines (STGs), especially for TB, contributed to increased cases of drug resistance. Other major challenges included weak overall coordination of pharmaceutical management activities and weak medicine monitoring and reporting systems.

In 2008, at USAID's request, SPS collaborated with WHO and the European Commission to evaluate the procurement and supply management of HIV/AIDS- and TB-related medicines and commodities in Ukraine. The findings from the evaluation mirrored the challenges described above, and resulted in a broad set of recommendations for short-, mid-, and long-term system strengthening strategies.

¹ WHO. 2010. *Review of the National Tuberculosis Programme in Ukraine*. Copenhagen: WHO/EURO

² UNAIDS. 2010. *Report on the Global AIDS Epidemic, 2010*. Geneva: UNAIDS

Under field support, SPS participated in an evaluation of the National TB Program in 2010. Findings and recommendations from the evaluation were used to guide the development of the next five-year program for TB control in Ukraine (2012-2017). Ukraine has also benefited from the SPS Program's core and regional activities related to TB, including Global Drug Facility (GDF) monitoring visits to facilitate TB medicine supply, and the participation of MoH representatives in oblast level trainings for TB drug management.

Also in 2008, the MoH requested SPS support to adapt and implement eTB Manager, a web-based program designed to strengthen TB programs and improve program outcomes. This comprehensive information system brings together all elements of the DOTS strategy and provides patient specific and summary information on TB diagnosis, case management, and pharmaceutical management. Adaptation of eTB Manager began under SPS core funding, and continued under SPS Mission field support and this Associate Award.

From 2009-2010, SPS received field support under the Leader Award. The SPS Ukraine program supported two technical objectives: (1) Strengthen the National TB Program by improving its access and utilization to quality information related to TB case and commodity management, (2) Contain the emergence and spread of antimicrobial resistance to TB medicines. SPS assisted the government to continue the adaptation and pilot eTB Manager in selected oblasts. SPS began development of a protocol to evaluate the extent to which prescribers adhere to national standard treatment guidelines for TB to provide a baseline and guidance for intervention development. SPS also coordinated with other USG partners to support the implementation of newly approved standard treatment guidelines for treatment of MDR-TB. Achievements under the Leader Award are included in the SPS LWA Final Report.

Project Objectives

In August 2010, SPS received field support under the SPS Ukraine Associate Award. SPS activities in TB and HIV/AIDS pharmaceutical management focused on four technical objectives:

1. Improving information systems to improve medicines availability and treatment outcomes
2. Building institutional and human resource capacity to strengthen supply chain management
3. Improving the use of medicines
4. Supporting development of policies and other measures to assure medicines quality and safety

ACHIEVEMENTS

OBJECTIVE 1: Improving information systems to improve availability of medicines and treatment outcomes

Activities under this objective fell into two major categories: those related to information systems for improving availability and treatment outcomes for tuberculosis, and those related to TB. Planned activities included the following:

- Expanding implementation of the eTB Manager to ensure adequate information related to TB case management and product availability
- Providing technical assistance in data analysis and reporting, and use of a pharmaceutical management information system (PMIS) for decision-making for program improvement
- Assessing existing PMIS for HIV/AIDS and developing recommendations for strengthening information systems to support effective HIV/AIDS pharmaceutical management

Accomplishments

Information systems for TB: eTB Manager

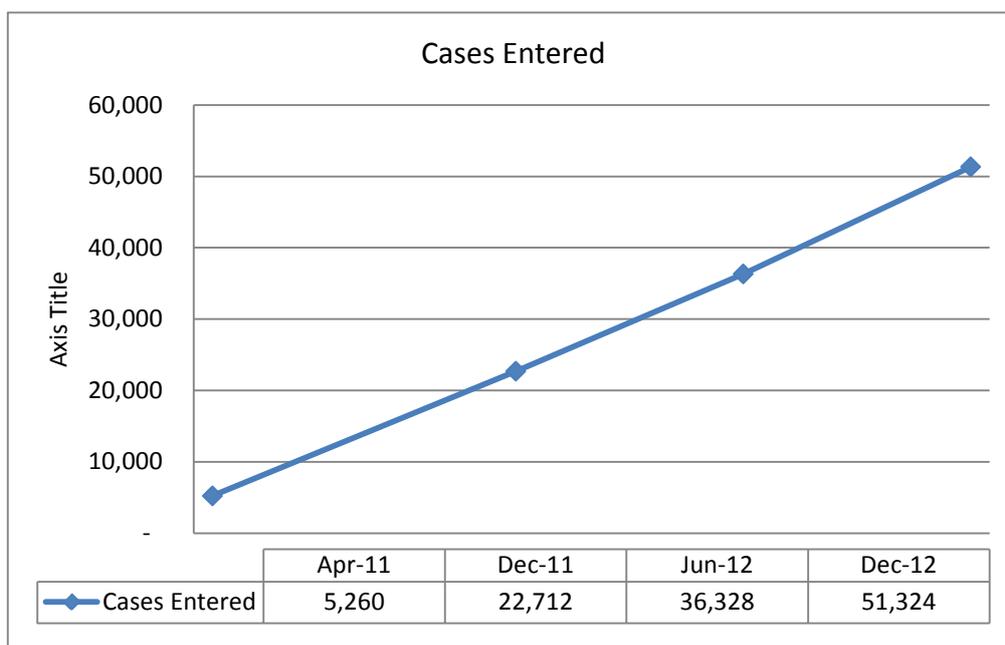
SPS supported the scale up of eTB Manager at the national level and in all 27 oblasts and municipalities, in collaboration with partners to strengthen the collection and use of data for improved TB case management and availability of medicines. The eTB Manager supports the DOTS strategy and provides patient-specific and summary information on TB case management, including diagnosis, treatment, and follow up, as well as pharmaceutical management information. Scale up activities built on the eTB Manager pilot in five oblasts under SPS core, regional bureau, and Leader Award funding.

Benefits to-date include the ability to identify facilities by rayon and oblast that are providing TB case management, something that was not possible without considerable effort prior to 2010, and recognition in a number of oblasts of the importance of complete and accurate recording and reporting in paper and electronic formats. Users in several oblasts have developed the capacity to produce regular and ad hoc reports. This capacity at national level will support decision-making when acritical mass of oblasts are entering complete information on a timely basis.

In 2010, SPS and partners collaborated to learn about the gaps in capacity and resources for implementation of the program, worked to address gaps, and provided post-implementation support. During the period of 2010-12, the initial focus was on refining the software based on user and program feedback, stabilizing the platform to assure continuous access, and training users in data entry and use. The number of oblasts entering data increased from the initial pilot five oblasts to all twenty seven. Users from several oblasts, where data entry was ensured by effective local oversight, were able to produce standardized and ad hoc reports. This set the stage for producing and sharing reports with counterparts at national and local levels, and using this information for programmatic and clinical decision-making, once all oblasts are entering data on a regular basis, and quality of those data is assured.

Implementation of eTB Manager was planned and agreed with the MOH and USAID and formalized in a number of documents. SPS coordinated with other partner organizations, including PATH, Médecins sans Frontières (MSF), and the Fund for Development of Ukraine (FDU) as Round 9 Principal Recipient (PR). To include implementation at the rayon level, the SPS updated and enhanced the previous implementation plan in collaboration with other key counterparts and implementing organizations. The plan allowed unblocking of Global Fund monies for procurement by the PR of computers in identified oblasts, and allowed leveraging of USAID funds for the purchase of computers for use in TB facilities. SPS procured 178 computers for use in TB facilities, while the FDU obtained authorization from the Global Fund to procure an additional 367 computers and approximately 400 internet connections. It is anticipated that these procurements will be finalized in 2013. Periodic meetings among the various partners were held to review necessary areas of support, organizations or persons responsible, and to provide status updates. Such meetings were also useful in dispelling inaccurate information about the process.

SPS trained staff from the MoH, State Penitentiary Services, and other key stakeholders to facilitate use of the program and to develop oblast-specific implementation plans. A total of 343 users from national, oblast, and rayon levels were trained and an additional 190 were trained by their peers in 12 oblasts. Training included basic computer literacy for some users, and introduction to and use of the eTB Manager modules, commensurate with the level of care.



To foster sustainability and reach out for local inputs and feedback, SPS worked with partners to create a pool of “super-users” who can be accessed for future training and support, and finalized training materials and the user manual to allow cascade training and a standardized reference for users. In 2011, SPS Ukraine organized and conducted a training of trainers for 15 of the more experienced users of eTB Manager. Those trained as trainers were subsequently active in providing training to staff at the local within their own oblasts, and to staff from other oblasts. They are now accessible to provide training for new users, as well as collect live

feedback on eTB Manager functionality and user experience. Several super-users were also conducted initial assessments of site readiness and monitoring visits.

As a proxy measure of the rate of implementation, SPS collected information from the National TB Center on the number of cases entered into the database. As of December 31, 2012, more than 50,000 cases were entered in eTB manager. Approximately 2/3 of oblasts were entering data on a regular basis, increasing the number of cases input on a monthly basis.

Based on the same data, the cumulative number of cases entered by oblast is presented in the table below.

Oblast	Apr-11	Dec-11	Jun-12	Aug-12	Dec-12
AR Crimea	17	30	481	613	843
Vinnnytska	15	48	48	48	46
Volynska	12	14	14	31	57
Dnipropetrovska	404	2,629	4,373	4,653	5,802
Donetska	144	3,374	5,941	6,497	8,324
Zhytomyrska	8	821	1,598	1,704	2,090
Zakarpatska	337	916	1,292	1,465	1,699
Zaporizhska	87	88	89	232	1,738
Ivano-Frankivska	90	580	1,030	1,106	1,542
Kirovohradska	14	64	251	253	3057
Kyivska	345	884	2,104	2,363	247
Luhanska	58	502	546	546	545
Lvivska	7	924	1,966	2,160	2,709
Kyiv	31	363	363	363	359
Mykolaivska	546	2,095	3,232	3,419	343
Odeska	641	2,252	3,330	3,844	4,256
Poltavska	8	430	430	430	5,105
Rivnenska	112	644	920	997	430
Sevastopil	138	183	222	290	1,250
Sumska	257	875	1,055	1,089	1,495
Ternopilkska	377	899	1,232	1,314	1,485
Kharkivska	1,078	1,470	2,012	2,085	2,245
Khersonska	73	980	1,508	1,567	1,867
Khmelnyska	223	414	414	429	1,178
Cherkaska	44	451	626	632	756
Chernivetska	8	21	21	21	21
Chernihivska	186	761	1,230	1,423	1,835
Total	5,260	22,712	36,328	39,574	51,324

Following training, SPS staff and trainers provided on-site and remote support to oblast and national level TB facilities to reinforce the training and resolve on-going implementation issues and respond to users' requests. SPS conducted a series of monitoring visits to ensure that the infrastructure and personnel were in place, determine if other barriers to implementation existed, and conduct on-the-job training. Over the course of the program, all 27 oblasts/municipalities had been

visited at least once and the 2012 implementation plan proposed additional visits over the next 18 months.

In August 2012, SPS successfully completed the security system certification process and received the security certificate for the eTB Manager, in accordance with Ukrainian law on patient confidentiality and data security. With certification complete, MoH could proceed with official adoption of eTB Manager. Ensuring that the eTB Manager is implemented fully throughout the country required changes in the Ukrainian TB law. On March 23, 2012, eTB Manager was designated as the official national TB electronic registry. A companion MoH order specified official adoption, authorization, and requirements for use as well as reports to be produced.

Pharmaceutical Management Information System (PMIS) for HIV/AIDS

SPS work with the Ukrainian AIDS Center (UAC) on pharmaceutical management centered on information systems to support ART and training staff on various aspects of HIV/AIDS treatment. SPS conducted an assessment of pharmaceutical management information systems for HIV/AIDS to assist the Ukrainian AIDS Center to develop a comprehensive, evidence-based PMIS strategy for HIV/AIDS, which is a key priority under the Global Fund Round 10 grant. The purpose of the assessment was to evaluate existing PMIS elements of the ART program and identify gaps and potential strategies for optimizing processes and tools to assure timeliness and quality of data needed to manage medicines for HIV/AIDS.

The assessment found that the existing electronic and manual systems at the facility and oblast levels limit the capacity of ART centers to scale up significantly, and to manage the additional increase in patients, medicines, and reporting. The support that the HIV/AIDS program has received from the government as well as multiple Global Fund grants has resulted in improvements in infrastructure and reporting systems, however, there are multiple vertical streams of information, and no common platform for aggregating these data. This has limited the program's ability to quickly process data, and to effectively advocate for funding and staff increases.

Following the assessment, recommendations were developed for central and oblast facility levels to strengthen the PMIS for HIV/AIDS, reduce the burden of data collection and reporting, and support development of a comprehensive HIV/AIDS PMIS strategy. SPS shared the final report with key stakeholders including the State Service, UAC, UNAIDS, the Network, the Alliance, CHAI, FDU, and others who offered comments later incorporated into the report. The need for a comprehensive information system, including pharmaceutical management, was also identified as a priority area in the Global Fund Round 10 HIV grant. The follow-on project will support the government to develop next steps for an HIV/AIDS PMIS as requested.

OBJECTIVE 2: Build institutional and human resource capacity to strengthen supply chain management for TB and HIV medicines and other health commodities

Assessments indicate that management of medicines in most TB and HIV/AIDS facilities in Ukraine is relatively weak, and often medicines are managed by health

care personnel without formal pharmaceutical management training. Lack of standardized approaches to quantification, distribution, and site level recording have also resulted in a broad range of practices, from quite poor to very good. Unpredictability in the procurement cycle and shipments of medicines also resulted in stock outs of critical medicines. Planned SPS activities to strengthen capacity included the following:

- Providing technical assistance and training to support TB and HIV/AIDS quantification of medicines and for development of adequate distribution plans
- Updating or developing pharmaceutical management training materials, and providing training in management of TB medicines

Accomplishments

SPS focused on improving supply chain management at both national and oblast levels. At national level, SPS provided technical assistance through a number of working groups to address policy and operational issues related to standard treatment guidelines and quantification, including development of key steps for rational drug use and drug management for the National MDR-TB Operational plan (2013-2015 years).

SPS provided recommendations to the improve supply chain management of the first and second groups of oblasts designated to receive second line TB medicines. SPS worked with the TB Center Global Fund Project Working Group to develop a new order for MDR-TB treatment guidelines, which included revisions in diagnosis, treatment, infection control, and drug management for MDR-TB. The new order was approved by the MoH. Updated guidelines were intended to allow for procurement of second line TB medicines by the GF PR. The new standard treatment guidelines for TB and MDR-TB also included separate guidelines for pediatric TB.

Quantification of TB and HIV/AIDS medicines is a function that has often been cited as problematic in Ukraine. To work toward a stable, continuous supply of quality TB medicines, SPS assisted the State Service and TB Center to revise official quantification instructions based on new TB standard treatment guidelines, using paper and electronic information systems to inform the calculations. New quantification approaches included building in buffer stock for TB medicines. The new methodology was used to conduct the TB State drug procurement for 2011 and included the eTB Manager as a tool for quantification.

To promote the use of fixed dose combination (FDC) products as standard treatment, SPS, together with the WHO, assisted the TB Center/MoH to submit two applications to the Global Drug Facility (GDF) for first line TB FDCs. Both grants (of approximately one million dollars each) were awarded, providing FDCs for approximately 14,000 patients in 2012, and approximately 16,500 patients in 2013. The TB Center distributed the first shipment of FDC medicines in November 2012 to the following oblasts: Dnipropetrovska, Donetsk, Khersonska, Luhanska, and Sevastopol (city). The distribution to the Penitentiary Services required additional regulatory action, as a non-MoH recipient of those products; SPS also provided support to the working group to make this possible.

The National TB Center and the National Committee on HIV/AIDS and other Socially Dangerous Diseases (later called the State Service) worked with partners to develop the new five year program for TB Control in Ukraine for the years 2012-2017. One area, identified as a gap in the October 2010 evaluation of the TB Program in Ukraine, was the consistent availability of first and second-line TB medicines, and skills in quantification of those medicines. Following a request from the National Committee, SPS provided technical assistance to collect required information and quantify first and second-line TB medicines to estimate the budget required for medicines for inclusion in the five year plan.

In response to a request by the State Service to improve quantification skills at oblast level, SPS trained oblast staff responsible for preparing annual requests from all 27 oblasts and municipalities in 2012, to introduce the new quantification instructions and supported the development of calculations for the annual TB commodity request to be procured by the MOH. SPS staff, together with the TB Center and the quantification working group, developed the training materials and practical exercises in accordance with the new TB quantification instructions. SPS specialists provided support to the working group to calculate the quantity of second line TB medicines, which would be procured using Global Fund grant monies, for nearly 8,000 patients, of whom 1,726 are in the penitentiary system. SPS also tested the new TB quantification instructions in Zakarpatska Oblast.

Under Round 9, the TB Center planned to implement monitoring visits to the following oblasts to track availability and use of second line drugs: Dnipropetrovska, Donetsk, Khersonska, Luhanska, Chernihivska, Poltavska, Lvivska, Odeska, Mykolaivska, Kharkivska, Kyivska, Zaporizhzhska, Kyiv (city), and the AR Crimea, where 720 patients would receive second line TB medicines (SLD).

Training activities were designed to systematically improve the skills of health facility and oblast staff in managing TB medicines, including appropriate quantification, inventory management, adequate storage, and recordkeeping. SPS adapted existing training materials, job aids, and other tools to facilitate adoption of standardized, efficient procedures to improve management of medicines and other commodities. Oblast-level training was designed to emphasize supply chain monitoring and supervision.

SPS provided support to the TB Center and FDU to develop a standardized approach to monitoring supply chain management in these oblasts. The TB Center, together with FDU (the Global Fund PR), visited the TB dispensaries in August 2012 to conduct an evaluation of their capacity to provide diagnosis and treatment for MDR-TB. The main gaps in pharmaceutical management found during these visits included: lack good storage facilities, temperature control, and means of transportation; and inadequate knowledge and practice of pharmacovigilance. In addition, legislation for pharmaceutical practices in hospital facilities was outdated.

To enable sites to receive and manage second line TB medicines, SPS provided pharmaceutical management training sessions for selected oblasts which were scheduled to receive second line TB medicines (Khersonska, Lvivska, Odeska, Mykolaivska, Kyivska, Zaporizhzhska, and Kyiv (city)). Participants in the training were individuals responsible for drug management in their respective institutions.

Over the course of three trainings sessions, 38 persons were trained from TB facilities in the seven regions.

In January and February 2012, SPS Ukraine staff participated in an evaluation of the 2007-2011 MDR-TB project in Donetska oblast, supported by the WHO. The assessment included laboratory services, infection control, the monitoring and evaluation system, treatment and drug management. During this mission, SPS applied the supply chain management checklist and other tools to evaluate the pharmaceutical management practices in Donetsk facilities and provided recommendations in the overall report.

OBJECTIVE 3: Improving the use of medicines

Planned activities included:

- Evaluating TB medicines utilization patterns and dispensing practices and support development of appropriate solutions for continuous improvement

Accomplishments

Various assessments (2008, 2010) and WHO reports have noted a growth in drug resistance for infectious diseases, particularly TB, in Ukraine. One of the contributing factors frequently suggested is the irrational use of medicines, however, little data are available to provide a sense of the order of magnitude of the problem. Under the SPS Leader Award, staff started developing a protocol to survey prescribing practices in TB facilities and to evaluate their adherence to national standard treatment guidelines (STGs). Under the Associate Award, SPS, in conjunction with the University of Illinois at Chicago (UIC), worked with the Yanovsky Institute of Phthysiatry and Pulmonology (TB Institute), as well as the State Service, TB Center, WHO, and other key stakeholders to refine the protocols and prepare for conducting the survey. SPS signed an MOU with the TB Institute for its collaboration, and received the approval from its ethics committee to implement the pilot research. The final instrument was also approved by the UIC institutional review board.

By June 2012, data collection for the survey of TB prescribing practices in one pilot oblast was complete. Data cleaning and analysis were completed with assistance of the UIC, and a draft report and executive summary were prepared by August 2012, providing descriptive data on prescriber and patient adherence to TB standard treatment guidelines (2010). The survey successfully demonstrated that a retrospective study of prescribing practices could be conducted with existing data. The familiarity of TB Institute researchers with national TB treatment guidelines enabled the study to proceed with the required rigor in a relatively short time frame. Survey findings and recommendations suggested that MoH counterparts and their partners, focus on conducting their own structured monitoring of prescribing and developing interventions to support adherence to internationally accepted standards for treatment of TB.

The primary conclusion of the survey was that the vast majority of TB treatment in the oblast did not adhere to official Ukrainian 2010 STGs. Adherence issues included patient related problems, such as missed doses and patient default, as well as prescriber issues. The latter included incorrect classification of patients, incorrect prescribing (selection of first and second-line medicines, length of treatment) and unavailability of medicines. Of the patients known to be HIV positive, less than 25% were known to have received ARVs. The survey also found a disturbing level of XDR-TB among those patients for whom drug resistance testing was performed. The documented treatment success rate was relatively low, and the mortality rather higher, compared with EU countries. Although the findings from the one oblast cannot be generalized to the rest of the country, findings suggest that other oblasts might face similar challenges.

The prescribing survey found numerous discrepancies among data sources in critical data, such as diagnosis, categorization of patients, and length and outcomes of treatment. Although specific oblasts have demonstrated rigorous procedures for ensuring data quality, this pilot survey underscored the need to ensure that such procedures are in place and monitored consistently in all oblasts. To this end, SPS Ukraine and visiting staff conducted an activity startup meeting with the TB Center for eTB Manager data analysis. The basic approach as for TB data quality and data analysis was discussed and 5 pilot regions were selected (Odeska, Zakarpatska, Khersonska, Dnipropetrovska, Chernihivska oblasts) for follow on work.

OBJECTIVE 4: Supporting development of policies and other measures to assure medicines quality and safety

Planned activities included the following:

- Assessing the existing pharmacovigilance system and developing a comprehensive approach for implementation of a national pharmacovigilance system.
- Providing technical assistance to the PSM Working Group or other designated structure to identify solutions to pharmaceutical management challenges in TB and HIV/AIDS

Accomplishments

Pharmacovigilance

The current pharmacovigilance system for medicines in Ukraine focuses primarily on passive surveillance, namely submission by health providers of forms that detail incidents of potential adverse drug reactions and other adverse events. An effective pharmacovigilance system provides a mechanism for ensuring the safe and effective use of medicines by identifying and communicating information broadly about potential medicines-related problems. This is of particular importance in public health problems, such as TB and HIV/AIDS, as adverse drug reactions or other problems may be a frequent cause of non-adherence or interruption in therapy.

SPS, in collaboration with the State Expert Center (SEC) and WHO, adapted a the IPAT tool to the language and context in Ukraine. The IPAT indicators will serve as a baseline, against which to measure future progress. SPS obtained the necessary approvals and authorizations from the SEC and State Administration of Ukraine for Medicinal Products (SAUMP) to conduct the pharmacovigilance assessment. SPS also collected and analyzed the major legislative documents that govern pharmacovigilance and drug safety in Ukraine to identify processes and gaps, which affect the effectiveness of the pharmacovigilance systems. Regions were selected for the study based on the total number and size of hospitals, physicians and degree of participation in pharmacovigilance activities.

**SPS's Indicator-based
Pharmacovigilance Assessment Tool
(IPAT)**

IPAT is a diagnostic assessment of medicines safety systems

- Establishes where a country stands in achieving a functional pharmacovigilance system.
- Supports evidence-based options analysis and development of recommendations reflecting each country's local realities, existing regulatory capacity and priorities, identified system gaps, and resource availability.
- Standardized and indicator-based approach allows the measurement of progress over time.

In December 2011, SPS completed the first phase of data collection focusing on the pharmaceutical industry, health commodities manufacturers, and clinical research organizations. In March 2012, SPS completed phase two of the assessment, focusing on central and regional levels, medical institutions, and medical device companies. Data were collated from document reviews, and from interviews with key informants and experts from 55 health institutions and organizations in Ukraine. Following a detailed analysis, the draft technical report, *Safety of Medicinal Products in Ukraine: Assessment of the Pharmacovigilance System and its Performance*, was developed in June 2012.

In August 2012, the findings of the assessment and recommendations were presented and discussed at a one-day meeting with participants from the MoH, SEC, the SAUMP, the State Service on HIV and Other Socially Dangerous Diseases, the National TB Center, UAC, the WHO, the Public Organization for Patients' Rights Protection, Sanofi, GlaxoSmithKline, an advisor to the Minister of Health/Deputy Prime Minister, as well as other organizations. The Advisor to the Minister noted that the data presented by SPS were timely and informed the meeting participants about the Minister's personal interest to the report results.

A number of organizations and individuals provided their suggested revisions, including patient advocates and the pharmaceutical industry. The SEC recommended that further discussion continue after the dissemination meeting, and offered to hold a broader stakeholder meeting to plan next steps for pharmacovigilance systems strengthening in the following quarter, with support from SIAPS.

In addition to the pharmacovigilance assessment, SPS supported counterpart participation in several international meetings, including the following:

- Cohort monitoring training sponsored by WHO for Commonwealth of Independent States countries, where SPS also provided a presentation on pharmacovigilance.
- Participation of a representative of the MoH State Expert Center's pharmacovigilance unit at the 34th Annual Meeting of Representatives of the National Centers participation in the WHO Programme for International Drug Monitoring to discuss monitoring the safety of medicines and vaccines, including resource limited settings, risk management plans for potential medication errors, and other relevant topics.

Policies for effective PSM

As a follow-up to the recently finalized 2008 PSM Joint Evaluation for HIV/AIDS and TB, in December 2010, SPS co-facilitated with WHO/EURO, a roundtable on access to antimicrobial medicines, drug quality, procurement and supply management, and rational drug use. Participants included various units of the MoH, including the drug regulatory authority, the National Committee, the TB Center, INGOs, NGOs, the pharmaceutical industry, donors, and other stakeholders. The roundtable passed recommendations with the goal of increasing access to and rational use of quality medicines. The three recommendations included the following:

- PSM is a complex process, which requires involvement from a broad range of stakeholders to effectively address challenges
- Is it necessary to ensure transparent and accountable high level country mechanisms as a platform for addressing PSM barriers and other issues
- The 2008 assessment of PSM in HIV/AIDS and TB and the 2010 evaluation of the National TB Program reports should be used as a baseline for developing a plan to improve and monitor progress of PSM in Ukraine

The PSM Working Group required a “champion” and political will to effectively tackle the issues recommended in the 2008 assessment, however, during the transitions within the MoH the PSM Working Group did not have a chairperson to manage meetings and other affairs as needed. Consequently, the working group didn't gain sufficient traction to clarify the group's mandate and future steps and to address the problems identified in the assessment. It was possible, however, to use the working group concept on smaller focused activities to achieve consensus on technical and policy issues.

To contribute to the goal of improved access to and rational use of medicines, SPS Ukraine collaborated and coordinated activities with various governmental and implementing organizations, including the State Service, TB Center, the Global Fund Round 9 Principal Recipient (the FDU), WHO, PATH, HCSP, and the new STbCU Project, among others.

Unlike the PSM working group, it was possible to address other priority issues in a timely fashion through technical working groups. Areas of SPS support to working groups included revision of quantification, standard treatment guidelines for TB, supply chain management, monitoring and evaluation, and taking a leading role for implementation of the eTB Manager. Results of the work of these groups included

the development, submission, and approval of a number of MOH orders and other supporting documents to strengthen pharmaceutical management systems, rational drug use, and medicines safety.

SPS staff also worked closely with the State Service for HIV/AIDS and Other Socially Dangerous Diseases to ensure that there was agreement on activities, joint participation in meetings, trainings and monitoring visits, and to facilitate implementation of planned and continuing SPS activities. Subsequently, the State Service involved SPS in the National Coordination Council and other national level meetings, reflecting an increased interest in and support for pharmaceutical management issues.

In addition to planned supply chain management strengthening activities, at the request of the State Service, SPS, in cooperation with the HIV Capacity Service Project (HCSP), started preparations for an evaluation of supply chain management in TB and HIV/AIDS to better understand the structure and gaps. SPS staff, in close cooperation with the representatives of the Kyiv City AIDS Center and the TB Center, adapted a questionnaire on various components of pharmaceutical management to be self-reported in a selected HIV/AIDS and TB health facilities. The questionnaire was drafted and submitted to the State Service for approval in August 2012, and distribution of the instruments to the oblasts by the State Service took place in September 2012. It was anticipated that the collection and analysis of the data would be completed under SIAPS.

LESSONS LEARNED

Several highlights of key lessons include the following:

- ***Reorganization of key MOH counterpart organizations created both opportunities and challenges.*** Frequent restructuring within the MOH, as well as other units of the Ukrainian government created a number of challenges; in the two years of this project, there were three new Ministers of Health, plus many changes at deputy level and below. This created the need to continually orient new personnel to the goals, objectives, and activities of the projects, and created difficulties in obtaining commitment for and coordinating specific activities, as personnel retained often did not have official status. On the other hand, it also provided an opportunity to engage additional personnel within evolving government structures.
- ***eTB Manager “super- users” facilitated implementation and sustainability.*** The TB Service, in general, is understaffed, and the facilities underfunded. TB facility staff rotation, estimated at 10-15 percent, created a need for frequent eTB Manager or other refresher trainings. The training and incorporation of “super-users” to conduct oblast and rayon level eTB Manager training and to provide feedback addressed this challenge and will foster a sustainable approach.
- ***Relationship building is essential to implementing new activities and approaches.*** As a relatively new partner in HIV/AIDS in Ukraine, it was necessary to devote substantial time to meet with governmental structures

and partners, who had been providing support for many years, to clarify SPS's potential role in supporting pharmaceutical management for HIV/AIDS. Similarly, expectations for full implementation of the eTB Manager were very high, but not all decision-makers understood the complexities involved in introducing some of the adaptations to the program, or in scaling up to rayon level. A continuous transparent effort to engage all stakeholders and keep them informed built support for implementation of the eTB Manager.

- ***Effective coordination enables programs to leverage resources.*** Coordination with other implementing organizations, donors, and the MOH allowed leveraging of their relative resources in support of specific activities. For example, there was considerable interest by the MOH and other partners in implementation of the eTB Manager. SPS leveraged Global Fund resources to support infrastructure needs, including computers and internet connections, as required in some locations to scale up eTB Manager to oblast and rayon levels.
- ***New legal requirements entail building new partnerships and approaches.*** In the beginning of 2012, the Government of Ukraine passed an anti-corruption order requiring certification of all training materials at post-graduate educational academic institutions. The procedures were not yet defined by Dec 2012, but it is likely that this requirement will affect future training activities. It may be necessary to develop relationships with additional academic or training institutions for clearance of materials and/or delivery of training.
- ***Nationwide implementation of the eTB Manager, a web-based program, can only move as quickly as the last adopters.*** Early adopters of the program planned for its implementation in the oblasts, meeting the preconditions with their own resources. Others underestimated the time that it would take to implement, were unable to make human or other resources available, or had other concerns about implementing in their oblast. Assuring that preconditions are met and have administrative support in advance would facilitate implementation.
- ***Evidence-based decision-making relies on quality data.*** Preconditions to the appropriate use of the eTB Manager, and producing reports that can support effective decision-making include the availability of infrastructure, adequate trained personnel and time available for working with the program, availability of accurate, complete, and timely data entry, and an understanding of how the information may be used effectively. Whereas efforts early on in the program were focused on ensuring that the software and web access allowed regular access to the program, ensuring the completeness and accuracy of data entry and paper forms are required for accurate information and effective decision-making. All partners can support data quality assurance, once a standardized approach is developed to facilitate accurate and complete electronic data entry.

- ***There is a need for careful coordination of activities, especially training and visits to the oblasts, given the number of activities planned by the various implementing organizations.*** Partner meetings were initiated by the MoH, implementing organizations and/or the Mission to ensure coordination, especially in site visits and monitoring, so as to reduce the chances of duplication and not overwhelm the staff.
- ***Obtaining cooperation and data are possible despite a highly bureaucratic environment.*** Working with governmental structures frequently requires exchange of official documents and considerable time before activities may commence. On the other hand, meetings or information requests may also occur with short notice, requiring flexibility by staff in juggling activities. Regardless, motivated personnel at all levels have found ways to collaborate to implement innovative approaches. The pharmacovigilance assessment required data from a broad cross-section of key informants and experts. Although it was time-consuming to work through the permissions, the survey team was able to obtain sufficient information to provide a comprehensive view of the pharmacovigilance system.
- ***Some changes require collaboration with other governmental structures, but there isn't a tradition of working across multisectoral lines to resolve issues.*** Although obtaining the GDF grant for first line TB medicines was welcome, for example, there were issues with delivering FDCs to the Penitentiary system, since the TB Center is not authorized to distribute medicines to institutions outside of its system without prior approval.
- ***Efforts in management capacity building are nascent.*** With the frequent organizational and political changes, there has been little attention paid to developing the human resource skills to manage programs. Much effort goes toward firefighting, resulting in frequent ad hoc, last minute requests for information and meetings, rather than regular planning, coupled with extended times for obtaining information or permissions. The GOU has recently expressed openness to piloting new approaches, including health financing, and management.

ANNEX 1: PMP PROGRAM YEARS ONE AND TWO

Result Area	Performance Indicators	Means of Verification	Frequency of Collection	Baseline	PY1 Planned	PY1 Actual	PY2 Planned	PY2 Actual
Project Goal: <i>Improve health outcomes in Ukraine through improved access to and use of essential medicines</i>					Cumulative target	Cumulative target	Cumulative target	Cumulative target
Objective 1: <i>Improve information systems to assure continuous product availability and appropriate treatment outcomes</i>								
Sub-Objective 1.1: <i>Support development and use of Innovative and proven information systems for pharmaceutical management</i>	1.1a: Number of cases entered in eTBM	Monthly eTBM reports	Quarterly	0	5,000	12,215	30,000	51,572
	1.1b: Number of oblasts ³ entering data into the eTBM regularly ⁴	Monthly eTBM reports by oblast	Quarterly	0	7	15	20	20
	1.1c: A strategy for a comprehensive PMIS system for HIV/AIDS is developed	Assessment report Strategy document		Baseline Report	-	-	1	1
	1.1d Number of oblasts generating and submitting one or more of the required reports using eTBM	Reports submitted to the TB Center	Annually	0	2	0	15	0
Sub-Objective 1.2: <i>Strengthen human resource capacity for data analysis and reporting, and the use of pharmaceutical management information for decision making</i>	1.2a: Number of people trained on the use of the eTBM	Training records	Quarterly	0	120	167	350	343
	1.2b: Number of people trained in Training of Trainers (ToT) for eTBM scale up to rayon level	Training reports	Quarterly	0	4	4	15	15

³ The term oblast here refers to the 25 oblasts, plus the two municipalities of Kyiv and Sevastopol

⁴ Regularly here refers to continued increases in cases as evidenced by monthly reports by oblast

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Result Area	Performance Indicators	Means of Verification	Frequency of Collection	Baseline	PY1 Planned	PY1 Actual	PY2 Planned	PY2 Actual
	1.2c: Number of oblasts conducting a cohort analysis ⁵ using data from the eTB Manager	Reports submitted to the TB Center	Annually	0	-	-	0	0
Objective 2: <i>Build institutional and human resource capacity to strengthen the supply chain for TB and HIV/AIDS medicines</i>								
Sub-Objective 2.1: <i>Strengthen supply chain management capacity at national level</i>	2.1a: Number of people trained on use of the new quantification methodology for first and second line TB medicines	Training reports	Annually	0	-	-	54	28 ⁶
	2.1b: Number of grants received in support of the National TB Program with SPS support ⁷	Grants received or unblocked	Annually	0	1	1	2	3 ⁸
Sub-Objective 2.2: <i>Strengthen supply chain management systems at regional (oblast) levels</i>	2.2a: Percent of target facilities that have experienced a stock out of one or more first line TB medicines for 3 or more days	Survey		Baseline report	NA	NA	NA ⁹	NA
	2.2b: Percent of target facilities that have experienced a stock out of one or more ARVs for 3 or more days	Survey		Baseline report	NA	NA	NA ¹⁰	NA

⁵ To conduct the cohort analysis, assume that sufficient cases are entered into the eTB Manager for 2011, and that the oblasts generate standardized reports for submission

⁶ 25 participants and 3 trainers who worked with new TB Quantification instructions in WG

⁷ Includes grants from the Global Drug Facility (GDF) and the Global Fund

⁸ Includes two grants from the GDF and unblocking of Global Fund grant monies

⁹ Since the baseline survey is taking place in year 2, it was not possible to set targets for this period. However, regular collection of this information will allow setting targets for the future

¹⁰ Same

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Result Area	Performance Indicators	Means of Verification	Frequency of Collection	Baseline	PY1 Planned	PY1 Actual	PY2 Planned	PY2 Actual
	2.2c: Number of facilities that monitor drug expiry dates for TB medicines using standardized tools	Monitoring and supervision reports	Annually	0	29	26	173 ¹¹	381 ¹²
	2.2d: Number of persons trained in TB supply chain management	Training records	Annually	0	-	-	65 ¹³	63
Objective 3: Improve the use of TB medicines and other health commodities								
Sub-objective 3.1: Evaluate TB medicine utilization patterns and dispensing practices and support development of appropriate solutions for continuous improvement	3.1a: Percent of target sites that have STGs on site/available ¹⁴	Survey	Annually	0	-	-	75	100 ¹⁵
	3.1b Standard treatment guidelines revised and submitted for approval	Revised guidelines	Annually	0	-	-	yes ¹⁶	2
Sub-Objective 3.2: Assess the existing PV system and develop a comprehensive strategy for a national PV system	3.2a Number of key stakeholders participating in developing a comprehensive pharmacovigilance strategy	Report	Annually	Survey	2	2	5 ¹⁷	7 ¹⁸

¹¹ Based on 13 pilot oblasts to receive second line TB medicines through the Global Fund project, at 5 persons per oblast

¹² TB facilities covered by the GF second line TB drug grant including Dnipropetrovska, Donetsk, Khersonska, Luhanska, Chernihivska, Lvivska, Odeska, Mykolaivska, Kharkivska, Kyivska, Zaporizhska, Kyiv (city), Crimea

¹³ Based on 13 pilot oblasts to receive second line TB medicines through the Global Fund project, at 5 persons per oblast

¹⁴ The pilot survey is being conducted only in one oblast; since prescribing is typically not done at lowest levels, it is anticipated that STGs will be available at oblast and rayon levels

¹⁵ 100% sites have STGs but only 29% of them have adherence to using STGs¹⁵ Planned for TB facilities covered by the GDF first line TB drug grant, including Dnipropetrovska, Donetsk, Khersonska, Luhanska, Sevastopol City, and the Penitentiary Service

¹⁶ Revision of the standard treatment guidelines (STGs) for MDR-TB (MOH Order #600) and unified TB STGs

¹⁷ Anticipated stakeholders include the State Expert Center, State Service for HIV/AIDS and Other Socially Dangerous Diseases, State Service for Medicinal Product Quality, TB Center, Ukrainian AIDS Center. The target in year 2 is set to ensure that a broader set of key stakeholders is engaged in the process

¹⁸ WHO, All Ukrainian Council for patients' rights and safety protection, Hromashevsky Institute of Epidemiology and Infective Diseases, Ukrainian AIDS Center MOH of Ukraine (UAC), State Service MOH of Ukraine, «State Expert Center MOH of Ukraine», State Enterprise (SEC), All-Ukrainian Network of PLWH

SPS Ukraine Associate Award: Project Report

Result Area	Performance Indicators	Means of Verification	Frequency of Collection	Baseline	PY1 Planned	PY1 Actual	PY2 Planned	PY2 Actual
Objective 4: Support accountable and responsive pharmaceutical management policies to improve medicines availability, safety, and quantity	4. Number of PSM national laws, policies, or SOPs updated and submitted for adoption.	National records	Annually	0	1	1	4 ¹⁹	4

¹⁹ Includes MOH Order on revised quantification methodology and instructions, the national new five-year National TB Program (2012-2016), MOH order authorizing/mandating the use of the eTBM, certified e-TBM

ANNEX 2: FINANCIAL REPORT

Strengthening Pharmaceutical Systems (SPS) Program: Ukraine Associate Award Number: AID-OAA-LA-10-00003

On August 27, 2010, Management Sciences for Health was awarded the SPS Ukraine Associate Award under the Leader with Associate Cooperative Agreement GHN-A-00-07-00002-00. The cumulative obligation over the life of the SPS Ukraine associate award was \$2,695,723.

The Fiscal Data chart shows the Associate Award total obligations and cumulative expenditures of US \$2,749,857 through January 31, 2013 by funding source.

Pipeline by Funding Source

Fiscal Data: Ukraine, under LWA Cooperative Agreement GHN-A-00-07-00002-00

Funding Source	Total Obligated	Total Expenditures	Total Remaining
Ukraine-TB	2,245,723	2,204,257	41,466
Ukraine – HIV/AIDS	450,000	402,098	47,902
	\$ 2,695,723	\$ 2,606,355	\$ 89,368