

# Ukraine Tuberculosis Control Partnership Project

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Contract Number GHS-I-00-03-00034-00

Year 2 Annual Report  
(October 1, 2008–September 30, 2009)

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**US Agency for International  
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## **Introduction**

PATH continues to implement the Tuberculosis (TB) Control Partnership project in Ukraine under the USAID IQC TASC 2 contract GHS-I-00-00034-00, Delivery Order Three, started in October 2007. In Year II (October 1, 2008–September 30, 2009), PATH continued to support Ukraine in expanding international standards for TB care and improving the quality of TB services in ten administrative territories of Ukraine—seven regions (oblasts): Khersonska, Zaporizhska, Dnipropetrovska, Donetsk, Odeska, Luganska, Kharkivska, and the Autonomic Republic of Crimea; and two cities, Kyiv and Sevastopol. To ensure sustainability of effective TB-control interventions at national and regional levels, the project has sought to enable the Government of Ukraine (GOU) to make critical, technically sound policy and program decisions to improve TB and TB/HIV control in accordance with international best practices. The project has also intensified efforts to assist the GOU in building adequate capacity of the TB control system to address the growing burdens of multidrug resistant TB (MDR-TB) and extensively resistant TB (XDR-TB). The project continued to help Ukraine’s civil society groups active in the TB and TB/HIV domains to bolster GOU’s commitment to improving TB control, and to catalyze the establishment of GOU-civil society partnerships in monitoring and evaluating the implementation of the National TB Control Plan for 2007–2011.

### **I. Progress toward target indicators**

Per activity 02 of the Detailed Implementation Plan for Year 2 (DIP II), monitoring data of TB Control Partnership project performance have been collected to assess progress toward achieving project targets according to the project monitoring and evaluation plan (PMEP). Selected TB-related epidemiological data are also being collected to better understand the national TB situation and assess Ukraine’s TB control program performance. TB-related epidemiological data, Ukraine National TB Control Program (NTP) and USAID/PATH TB Control Partnership project performance indicators, and associated accomplishments are summarized in Annex 1 (PMEP with Year 1 and Year 2 accomplishments).

#### **TB case notification rates**

Although the notified TB incidence rates (TB case notification rate) at the national level and in each project-target area serve a monitoring function only (not as an indicator for project progress), these data have been used to analyze TB trends in Ukraine. Table 1 below contains the final national- and oblast-level data for 2008 compared to 2007 and 2006.

Over the last three years, reported data suggest a decreasing trend in TB incidence, with the country’s average notified TB incidence rate decreasing by 2.5 percent in 2008 as compared with 2007 (from 79.8 to 77.8 TB cases per 100,000 population, correspondingly, in 2007 and 2008). An annual decrease in the national average TB incidence rate has slowed, compared with a 4.6 percent decline in 2007 (from 83.2 to 79.8 TB cases per 100,000 population, correspondingly, in 2006 and 2007). This decrease, however, may not be sustained if HIV transmission, which has the potential to fuel the TB epidemic, continues at the current rate, which is one of the highest in the world, and if the treatment success rate remains at the same low level combined with a high

default rate. The economic crisis may also negatively influence the TB situation in upcoming years.

Although notified TB incidence rates in project target regions (oblasts) remain substantially higher than the average rate in Ukraine (see Table 1), the average notified TB incidence rate in project oblasts continues to decrease more sharply than in Ukraine as a whole, with a 6.2 percent decline in project regions in 2008 following a 4.2 percent decline in 2007, as compared with 2007 and 2006, correspondingly.

**Table 1. Notified TB incidence rates by project region and average in Ukraine (per 100,000 population)**

Administrative regions and areas (project sites)											
Year	Ukraine	Luganska	Odeska	Dnipropetrovska	Kharkivska	Khersonska	Donetka	Zaporizhska	Crimea	Sevastopol	Kyiv
2006	83.2	111.7	94.6	99.1	84.5	155.7	99.4	89.8	85.0	65.8	52.9
2007	79.8	103.5	87.1	94.1	78.6	151.4	94.7	91.3	85.2	68.4	46.9
2008	77.8	101.4	87.4	92.0	72.4	123.8	91.1	81.9	86.9	67.0	47.4

The Ministry of Health of Ukraine (MOH) disseminated statistical data on the TB situation in the first six months of calendar year 2009. Annual TB epidemiological data for 2009 will become available in March 2010. The semi-annual data continue to indicate a decreasing trend in TB case notification in the majority of regions in Ukraine. As shown in Table 2 below, the average notified TB incidence rate in project regions continues to decrease at a sharper-than-average rate in Ukraine (an average 8.7 percent decline in project regions versus a 5.9 percent decline in Ukraine overall). Among project regions, only Crimea and Dnipropetrovska oblast have shown increased TB case notification.

**Table 2. TB case notification by project regions between January–June, 2009 (compared with the same period of year 2008)**

#	Region	TB case notification				±% as compared with year 2008
		Absolute numbers		Rate per 100,000 population		
		2008	2009	2008	2009	
1	Crimea	803	852	40.8	43.5	+6.6%
2	Dnipropetrovska	1,659	1,714	48.5	50.8	+4.7%
3	Donetska	2,174	2,075	47.6	46.2	-2.9%
4	Zaporizhska	837	669	45.3	36.7	-19.0%
5	Luganska	1,246	1,132	52.4	48.6	-7.3%
6	Odeska	1,118	906	46.9	38.0	-19.0%
7	Kharkivska	1,100	946	39.3	34.2	-13.0%
8	Khersonska	745	619	66.8	56.4	-15.6%
9	Kyiv	646	508	24.1	18.6	-22.8%
10	Sevastopol	121	121	32.1	32.0	.03%
<b>Ukraine</b>		<b>18,860</b>	<b>17,542</b>	<b>40.6</b>	<b>38.2</b>	<b>-5.9%</b>

As shown in Table 3, following the declining TB incidence rate at the national level and in project-target areas, the notified rate of new sputum smear-positive (SS+) TB cases per 100,000 population has also decreased. These data, however, also reflect improvements in laboratory confirmation of TB diagnosis, which has been one of the priorities of the project. The proportion of laboratory-identified SS+ TB cases among all registered new pulmonary TB cases reached 47 percent in project areas in 2008. This is higher than average for Ukraine and represents an approximate 10 percent increase compared 2007 data.

**Table 3. Notification rates of new SS+ TB cases (per 100,000 pop) and their proportion among pulmonary TB (PTB) and all TB cases (\*Luganska oblast's data are not included as PATH started TB-related interventions in this oblast at the end of 2008)**

Region/city	Year					
	2007			2008		
	SS+ TB notification rate	% of SS+ TB among PTB	% of SS+ TB among all TB	SS+ TB notification rate	% of SS+ TB among PTB	% of SS+ TB among all TB
AR Crimea	39.5	48	46	37.3	48	43
Dnipropetrovska oblast	33.0	37	35	30.3	37	33
Donetska oblast	33.9	37	36	37.5	44	41
Zaporizhska oblast	38.5	44	42	36.4	49	44
Kharkivska oblast	32.8	43	42	30.5	47	42
Khersonska oblast	50.6	34	33	44.8	39	36
Kyiv	26.8	60	57	27.3	63	58
Sevastopol	28.1	43	41	29.1	50	43
Odeska oblast	34.1	41	41	36.9	46	42
Average in target areas*	35.3	43	41	34.5	47	42
Ukraine average	31.5	41	39	31.6	44	41

### TB mortality rates

TB mortality rates, together with TB incidence rates and other indicators, also shed important light on the TB situation in Ukraine. Final data on TB mortality at the national level and in each project area in 2008 became available in March 2009 (see table 4). These data include cases of death for which TB was diagnosed before death (primarily registered in medical facilities) and cases with a *post-mortem* TB diagnosis (as part of vital statistics)..

Over the last three years, reported data suggest that TB mortality has stabilized, with the average national TB mortality rate of 22 TB deaths per 100,000 population. Tuberculosis mortality in the majority of project target regions, however, increased on average by approximately 4 percent in 2008, compared with 2007. This increase is likely due to the growing numbers of MDR-TB and TB/HIV cases in the project regions, which are higher than in other regions of Ukraine.

**Table 4. TB mortality rates by region (per 100,000 population)**

Year	Administrative regions and areas (project sites)										
	Ukraine	Luganska	Odeska	Dnipro- petrovska	Khar- kivska	Kherson- ska	Donetska	Zapori- zhska	Crimea	Sevas- topol	Kyiv
2006	22.3	29.2	29.3	29.3	18.2	34.9	31.7	23.1	23.5	20.9	11.7
2007	22.6	27.4	31.0	30.7	17.2	30.7	32.3	22.0	24.5	18.3	11.9
2008	22.4	31.3	33.8	32.3	19.7	25.1	30.6	22.3	23.6	23.0	13.5

### Treatment outcomes

Data on treatment success in patients who started treatment in 2007 (based on cohort analysis results) are reliable only in the oblasts where previous USAID-supported project activities were undertaken. A new national monitoring and evaluation (M&E) system was officially endorsed by an MOH order in 2007. Non-project oblasts, which started analysis of TB-treatment outcomes based on cohort analysis following this order, require training and follow-on supervision to ensure correct analysis of 2007 cohort treatment outcomes. Data from the project sites suggest that treatment success rates in all project areas fall far short of the global target of 85 percent (see Table 5), with the average TB treatment success rate at approximately 54 percent in project areas. This is essentially the same level as in 2008—53 percent. Despite these low rates, the data represent important progress in that they are reliable, thanks to the M&E trainings and regular monitoring visits (supervision) supported by PATH. These data are now used at regular review meetings, along with other indicators, to analyze Ukraine’s TB control efforts.

The project will continue addressing a high proportion of TB patients who interrupted treatment seeking to decrease the average default rate of 13 percent in project regions to a common 5 percent default rate for effective TB control programs. The project works with local health and general administrations to prompt further integration of TB services into primary health care to ensure effective follow up of TB patients at the ambulatory phase of treatment, as well as the availability of social support and incentive programs for TB patients in order to improve treatment outcomes.

**Table 5. Treatment outcomes (based on a cohort analysis) of new, regular TB cases enrolled for treatment in project regions in 2007**

	% Treatment success	% Died	% Failure	% Default	% Transferred
AR Crimea	62.4	9.7	14.2	8.2	5.5
Dnipropetrovska	51.5	16.9	12.1	12.6	6.9
Donetska	58.0	17.4	8.2	9.9	6.5
Zaporizhska	57.5	9.9	14.1	10.8	7.7
Kharkivska	50.8	14.8	16.0	12.9	5.4
Khersonska	46.5	12.7	19.6	13.8	7.3
Kyiv	51.8	9.9	11.9	22.6	3.9
Sevastopol	50.5	11.2	17.8	12.1	8.4

## Performance monitoring and evaluation plan (PMEP) indicators

Expanded training and technical assistance, enhanced access to high-quality TB services at the primary health care level, improved laboratory confirmation of TB cases, and improved treatment practices allowed countrywide directly-observed treatment strategy (DOTS) coverage to increase by 5.8 percent to 40.4 percent in Year 2.

Targeted, effective training was a key reason for this expansion. As reflected in the PMEP, attached as Annex 1, PATH had planned to train at least 1,000 individuals in Year 2 of the project. In fact, PATH exceeded this target, instead training 2,408 people in Stop TB Strategy essential components. Specifically, PATH's training focused on DOTS-based diagnosis, on treatment and monitoring services, and on involving primary health care practitioners, communities, and NGO activists—especially those who are members of local coordination councils—in providing appropriate TB-related services

Progress in the fourth quarter of Year 2 towards achieving project targets established in the Project Monitoring and Evaluation Plan is reflected in Table 6 and in the report narrative and covers indicators that require quarterly reporting (Detailed Implementation Plan Year 2 Activity 02).

**Table 6. Indicators that require quarterly reporting in accordance with the PMEP (progress in the fourth quarter of Year 2)**

<b>PMEP Indicator</b>	<b>Description</b>	<b>#</b>
# 8	Number of people trained in any STOP TB Strategy elements	629
# 9	Number of laboratory review meetings held in the project regions	10
# 10	Number of project regions providing accurate and timely TB surveillance and NTP performance data	9
# 14	Number of laboratories performing quality-assured TB culture and first-line drug susceptibility testing according to international standards	4
# 22	Number of individuals trained to provide clinical prophylaxis and/or treatment of TB in HIV-infected individuals	84
# 25	Number of individuals trained in HIV-related institutional capacity building	0
# 30	Number of individuals trained to provide social support services and in HIV- and TB-related stigma and discrimination reduction	214

## II. Key achievements

### DOTS expansion

In Year 2, PATH staff and Ukrainian TB consultants and trainers provided training courses in Stop TB Strategy components, including DOTS principles and TB program management and evaluation, to a total of 2,408 health care practitioners, representing a two-fold increase over the Year 2 target. This number includes TB, laboratory, and surveillance specialists trained in THE new project region of Odeska oblast. Further training of and technical assistance to primary

health care providers, increased laboratory TB confirmation, and improved TB treatment practices will result in fully covering the Odeska region with high-quality DOTS-based services in Year 3. Also, initial training and technical assistance have been launched in the newly-added project region of Luganska oblast.

As shown in Annexes 2–11, following rollout and refresher training on TB-related interventions in Years 1 and 2, Zaporizhska, Donetska, Khersonska, and Kharkivska regions, as well as Kyiv and Sevastopol cities, are entirely covered by DOTS-based services. A few districts of Dnipropetrovska oblast and the Autonomic Republic of Crimea require further training and technical assistance to establish solid DOTS-based TB control services in all rayons. PATH's activities in Odeska and Luganska oblasts will support the establishment of DOTS TB services in these regions in Years 3 and 4.

PATH and Luganska oblast developed a Memorandum of Understanding (MOU), and a letter recognizing Luganska oblast as a beneficiary of the USAID TB Control Partnership program was also signed by the Luganska Oblast Health Administration. These are key documents that permit the revision of PATH's project registration to include Luganska oblast to the list of registered project regions. This is an essential part of project registration at the Ministry of Economy in accordance with Ukrainian regulations (DIP II activity 01).

### **Laboratory quality assurance**

The TB Control Partnership in Ukraine continued to introduce and facilitate the institutionalization of external laboratory quality assurance procedures into TB and primary health care labs to sustain improved smear microscopy for TB diagnosis.

### **Civil society and international partnerships**

PATH expanded its work with key national civil society partners—the Ukraine-based NGO Ukrainians Against Tuberculosis (UATB) and the National Committee of the Ukrainian Red Cross Society (UCRS)—to bolster advocacy, communication, and community involvement, and to improve TB/HIV service collaboration. The performance of UATB in fulfilling the first 6-month and follow-on 11-month subcontracts with PATH was positively evaluated. UATB has focused its activities at the national and regional levels to reach key policy institutions and providers. In addition, the first 6-month plan of action and a 12-month continuation plan were developed and subcontracts were signed, following USAID consent, with the All-Ukrainian Charitable Organization, Network of Organizations that Provide Support in the Penitentiary System (Prison Support Network), to work with prisoners before and after release to support improved adherence to TB treatment in Zaporizhska and Khersonska oblasts (DIP II activity 1.14 and 1.15).

Following regular communication and implementation of collaborative activities, PATH and the charitable foundation, Development of Ukraine, funded by Rinat Akhmetov, also signed a Memorandum of Understanding (MOU) to strengthen coordination of TB-control activities so as to avoid duplication, combine efforts to provide assistance, and plan complementary interventions.

PATH also continued to work on strengthening international partnerships to support project implementation and to bring internationally-recognized TB and other related technical expertise to Ukrainian TB specialists. Per DIP II activity 1.4 and 2.4, a two-week training course on MDR-TB at the Latvia National Tuberculosis and Lung Diseases Agency in Riga, Latvia, was conducted November 26, 2008 through December 5, 2008. This Agency also serves as the only WHO Collaborating Center for Research and Training in Management of Multidrug Resistant Tuberculosis. The training course in this Center allowed 11 Ukrainian TB specialists from project areas to acquaint themselves with international recommendations for effective MDR-TB case management and to discuss organization of services, diagnosis, treatment, management of adverse effects of drugs, infection control, and other MDR TB-related matters with Latvian specialists who have had first-hand experience in improving MDR TB control in their country.

PATH also developed a scope of work and budget as well as finalized a subcontract with Health Strategies International (HSI) to conduct a TB service-related human resources assessment. This assessment was conducted July 2 through July 25, 2009 and focused primarily on human resource development issues within the TB laboratory network in Ukraine (DIP II activity 1.3). The findings of the pre-assessment mission are summarized in Annex 13.

In addition, PATH worked with Management Sciences in Health (MSH) to finalize the scope of work, budget, and other related documents necessary to establish a subcontract, with USAID/Kyiv consent, to provide technical assistance to national counterparts in TB drug management. An MSH/PATH team assessed current practices in pharmaceutical management in TB control in several regions in Ukraine, the findings from which are summarized in Annex 14.

PATH organized and participated in an assessment of TB/HIV policy and practices in Ukraine led by experts from the WHO Collaborating TB and TB/HIV Training Center in Sondalo, Italy, December 10 to 19, 2008. The team assessed TB/HIV basic regulations, procedures, and practices at the National and oblast levels, including routine TB case detection and referral practices at HIV/AIDS centers and TB/HIV case management practices at TB hospitals in project oblasts. As a result, the assessment team provided recommendations for revisions of TB/HIV practices in accordance with international standards and best practices (see Annex 15 for the TB/HIV assessment report). A baseline training course and training-of-trainers (TOT) on TB/HIV collaborative case management also were conducted for selected TB hospitals and HIV/AIDS center staff from project oblasts.

## **Policy reform**

PATH continued supporting the Committee on HIV and TB within the Ministry of Health (MOH) by raising awareness among key policy makers about global TB strategy and the European regional response to the TB epidemic. PATH is encouraging the Committee to initiate and/or endorse revisions to outdated TB regulations and lead the development of new regulations. PATH also suggested priority actions consistent with international approaches, such as establishing the functions of the National Reference Laboratory. With PATH technical support, statistical forms to monitor TB laboratory investigations and other TB-related practices also were revised and finalized, with accompanying instructions on how to complete them. In addition, Ukraine's first protocol on drug-resistant TB case management, which was developed with PATH technical assistance, was endorsed by the Ministry of Health in December 2008.

### III. Results and project elements

#### General management activities

PATH and Luganska oblast developed a Memorandum of Understanding (MOU) and a letter recognizing Luganska oblast as a partner in the USAID TB Control Partnership program. These documents were signed by the Luganska Oblast Health Administration and are required for the revision of PATH's project registration to include new regions. The required package of documents was submitted to USAID/Kyiv as part of the process of revising the TB Control Partnership project registration at the Ministry of Economy in accordance with Ukrainian regulations (DIP II activity 01).

With USAID's guidance, the annual partner meeting for international and national Ukrainian stakeholders was conducted on February 25, 2009. The project accomplishments in Year 1 were presented, and an implementation plan for Year 2 was discussed with stakeholders (DIP II Activity 03). Participants included key representatives from each project region and included staff from the MOH, the Penitentiary Department of the Ministry of Justice, the National TB and Lung Diseases Research Institute, and the Ukrainian AIDS Center. Also present were national and international NGO and civil-society representatives, including the All-Ukrainian Network of People Living with HIV and AIDS (PLHIV), the Ukrainian Coalition of HIV Service Organizations, Futures Group International, the World Health Organization (WHO), and the Project CTO from USAID/Kyiv. All participants provided suggestions for region-specific training and technical assistance. The areas covered included TB laboratory capacity, DOTS training, MDR-TB prevention and management, TB/HIV collaborative measures, TB services in prisons, TB control monitoring, as well as advocacy, communication, and social mobilization activities.

In the fourth quarter, TB control monitoring data for each project region were summarized to provide an annual analysis of project and NTP accomplishments. Quarterly reports and a DIP for Year 2 were submitted to USAID/Kyiv for approval in due time (DIP II Activity 04 and 05).

#### Result 1

##### **High-quality DOTS services available to 50 percent of the population.**

##### ***DIP Objective 1. Expand DOTS coverage to 50 percent of the population and improve DOTS quality.***

As a result of previous USAID support to PATH and WHO that concluded in 2007, approximately 29 percent of Ukrainians had access to DOTS services in eight regions: Donetska, Dnipropetrovska, Kharkivska, Khersonska, Zaporizhska oblast, the Autonomous Republic of Crimea, and two municipalities, Kyiv and Sevastopol. Previous TB activities were not able to cover all rayons in the target oblasts; therefore, the current project has identified for prioritization both uncovered districts (rayons) and other areas that received initial DOTS training but where DOTS service quality still needs further improvement. Mapping the results of this analysis has helped guide the gradual introduction and/or improvement of DOTS-based services in these regions, as illustrated in Annexes 2–11.

In addition, by expanding DOTS-based services to two additional regions—Odeska and Luganska oblasts, which have a combined population of about five million people—DOTS services will become available to an estimated additional 10 percent of Ukraine’s population during the remaining project term. These additional efforts to complete DOTS coverage within the initial target oblasts (approximately 19 million people), combined with expansion of services to Odeska and Luganska oblasts, will result in high-quality DOTS services being available to 50 percent of the population or 24 million people in Ukraine.

#### *DOTS expansion results to date*

As virtually all TB specialists have been trained in the initial project areas, the primary focus in Years 1 and 2 was on training doctors, nurses, and laboratory staff in the general health care system in those remaining rayons within the initial project regions that had not yet benefited from project interventions. In addition, based on an analysis of TB treatment outcomes and other indicators, PATH confirmed the need to continue supporting improvements in the quality of TB control practices at the specialized TB and general health care levels in existing project regions; therefore, refresher training and technical assistance was provided to TB and primary health care specialists to strengthen the essential components of the DOTS strategy.

As a result of these efforts, countrywide DOTS coverage increased to 34.6 percent in Year 1 and to 40.4 percent in Year 2, thus meeting the target of ensuring that 40 percent of the population had access to high-quality DOTS services by the end of Year 2. This figure represents the sum of the 29 percent baseline coverage plus the additional coverage of 11.4 percent achieved during the first two years of the current project. As shown in Annexes 2-11, Zaporizhska, Donetsk, Khersonska, and Kharkivska regions and Kyiv and Sevastopol are now entirely covered by DOTS-based services. A few districts of Dnipropetrovska oblast and the Autonomous Republic of Crimea require further training and technical assistance to establish solid DOTS-based TB control services, which PATH will undertake in the coming year.

#### *New project regions: Odeska and Luganska oblasts*

In the new project oblast of Odeska, PATH focused on training TB, laboratory, and surveillance specialists. Further training and technical assistance to primary health care providers, increased laboratory TB confirmation, improved treatment practices, correct analyses of TB treatment outcomes, and interventions to improve outcomes all will be essential to ensuring full, high-quality DOTS service availability in Odeska oblast in Year 3.

PATH also launched expansion of the project’s activities in Luganska oblast, making an initial assessment visit to the region on December 10 and 11, 2008. The assessment revealed high TB case notification and mortality rates, low bacteriological confirmation of TB cases, and the absence of laboratory internal and external quality-control procedures. PATH is now planning its technical assistance and training activities to address these issues.

Following the initial assessment visit to Luganska oblast, PATH convened a conference, entitled USAID TB Control Partnership Project Implementation in Ukraine, for Luganska oblast and rayon TB and PHC administrators. The conference described project implementation and international approaches in TB control. Participants included seven rayon health administrators, 15 heads of PHC institutions, 34 chief rayon TB specialists, 11 chief laboratory specialists, one

chief bacteriologist, and the head of Luganska oblast's TB hospital statistical department. PATH also provided initial training for TB laboratory specialists. PATH's activities in Odeska and Luganska oblasts will support the establishment of high-quality DOTS-based TB services in these regions in Year 3 and 4.

### *DOTS training*

During Year 2, PATH staff and Ukrainian TB consultants provided training to a total of 2,408 personnel in both TB and the general health services on Stop TB Strategy components, including DOTS principles and TB program management and evaluation (DIP II, activities 1.1, 1.6 and 1.8; PMEP indicator 8). This number includes 849 TB specialists, 326 laboratory specialists, 82 monitoring and evaluation specialists (25 statisticians and 57 epidemiologists), 255 primary health care providers, 159 infectious disease specialists, 586 nurses, and 83 health administrators representing all project target administrative territories. In some cases, the same individuals participated in multiple trainings, depending on their responsibilities. A breakdown of training activities in Stop TB Strategy elements by the number of specialists trained, the location, and the type of training is presented in Annex 12.

During Year 2, PATH also developed and implemented training in Odeska oblast that focused first on TB, monitoring, and laboratory specialists through three- to five-day training courses on essential DOTS components. Specifically, the training plan included five training courses for TB specialists on DOTS-based TB diagnosis and treatment practices, two training courses on TB case recording and reporting, and three courses on TB microscopy and quality assurance. Selected specialists from Odeska oblast were then trained as trainers on DOTS-based TB case management, TB laboratory testing, and TB/HIV case management so that they can provide follow-on training in the region.

With PATH support, two representatives from project regions participated in the WHO training course on the implementation of the STOP TB Strategy that covered MDR-TB and XDR-TB management, public-private mix [PPM] strategies, infection control, and TB/HIV management. This course was held in Sondalo, Italy, May 4 to 16, 2009 (DIP II activity 1.4). The overall goal of the course was to further develop the necessary skills to plan, implement, and evaluate a national TB control program following the WHO-recommended STOP TB Strategy. In addition, per the DIP II activity 1.4, seven leading Ukrainian TB specialists participated in the European regional conference of the International Union Against TB and Lung Diseases (IUATLD), convened in Dubrovnik, Croatia, in May 2009. Participants also provided input on conducting a workshop on TB-related advocacy, communication, and social mobilization (ACSM) as a part of conference proceedings.

PATH held discussions with NGOs and assessed social-support practices aimed at improving TB treatment completion and confirmed that a significant number of TB patients who receive social support provided by the Ukrainian Red Cross Society (UCRS) or are in need of such support are also HIV-positive. Based on these findings, PATH decided to bolster UCRS involvement in providing TB/HIV services. As a part of improving DOTS services—especially in supporting TB treatment adherence and improving TB/HIV co-infection services (DIP II activities 1.1, 1.13, and 3.9)—69 persons were trained representing UCRS nurses and HIV service NGO activists in providing support to co-infected clients.

The Dnipropetrovsk Medical School, the Donetsk Medical School, and the Kharkiv Postgraduate Academy for Continuous Medical Education have already incorporated modules on DOTS-based TB case management into their regular educational courses on TB (DIP II Activity 1.2). PATH continued collaboration with faculty members from the TB departments of the Kharkiv and Kyiv Postgraduate Academies for Continuous Medical Education and with faculty members of the TB departments of the Donetsk, Dnipropetrovsk, and Odesa undergraduate medical schools to assist in developing training curricula and associated guidelines and materials to help trainers and faculty provide specific training courses (thematic training cycle) on essential TB control components in accordance with international approaches.

Training curricula on TB microscopy and laboratory quality assurance and on interpersonal communication and counseling have been finalized. Two sets of training materials on regular TB case management for TB specialists and for primary health providers as well as training materials on TB case management and program monitoring and evaluation are being developed. PATH will recommend that these curricula be adopted by medical schools and academies for postgraduate continuous medical education, used in medical and nursing schools, and in continuing medical education for TB and primary health care physicians and nurses.

#### *Strengthening political will*

To ensure continuing political support for TB control, PATH has worked with Ukraine's civil-society organizations to promote their engagement in developing and implementing TB control-related advocacy activities. Performance of UATB in fulfilling the first six-month subcontract with PATH was positively evaluated. UATB has focused its activities at the national and regional levels to reach key policy institutions and providers. PATH provided the Ukrainian Red Cross Society and UATB with continuation subcontracts to bolster advocacy, particularly at the regional level, as well as communication, social mobilization, and community involvement in TB control.

Under the follow-on subcontract for Year 2, UATB's accomplishments are as follows:

- Spearheaded the development of a registry of the MOH's TB-related regulatory documents as part of the MOH's advisory group activities on implementing and monitoring Ukraine's National TB Control program, which is supported by PATH.
- Conducted a press conference with representatives of central media to promote advocacy and informational activities in dedication to the World TB day (March 24)
- Encouraged the timely scheduling and provided leadership in developing the agenda for the National Council on TB and HIV.
- Conducted monitoring of organizational and social aspects of TB control in Odeska and Khersonska oblasts, utilizing a unified monitoring tool/questionnaire developed with PATH assistance.
- Worked with the health committee of the Parliament and the Cabinet of Ministers to put TB control on the priority list for receiving humanitarian assistance available for Ukraine.

An important limitation in garnering political support is the lack of awareness among decision makers at all levels about the TB situation, the global TB strategy, and the European regional

response. PATH utilized an advocacy presentation on TB to orient key policy- and decision-makers during the introductory conference in Luganska oblast. An informational manual focusing on the TB situation both globally and in Ukraine and internationally-recommended TB control approaches issued by UATB and PATH were disseminated at this conference to support advocacy and communication efforts.

PATH continued to provide support to the MOH Committee on HIV, TB, and Other Socially Dangerous Diseases. Multiple meetings were held with the former head of the committee, Dr. Petrenko, the current head, Dr. Svetlana Cherenko, and deputy head, Dr. Stelmakh, to discuss strategies for implementing the National TB Program and the Committee's priorities. PATH provided technical assistance to the Committee in conducting an analysis of TB program implementation in 2008, as well as in formulating regulatory documents, including functional responsibilities, regarding the newly-established National Reference Laboratory (NRL). PATH also worked with the Committee and other partners to draft a national TB-related infection control plan (DIP II activity 1.10).

#### *Increasing laboratory capacity and quality*

PATH has undertaken a review of PATH and national counterparts' activities to improve TB laboratory diagnosis and an analysis of the achieved results over the last three years in order to guide further interventions. Although laboratory confirmation of TB cases has improved during the last two years (see Table 3), only 44 percent and 47 percent of all pulmonary TB cases were laboratory-confirmed in 2007 and 2008, respectively. Clinicians continue to rely on X-rays to diagnose TB; thus strengthening the country's laboratory systems is an essential priority for improving TB control in Ukraine. Lack of adequate educational programs on TB laboratory testing at both undergraduate and postgraduate educational institutions limits health care system capacity to detect TB.

Starting in 2005, PATH specialists and partners developed guidelines with standard operating procedures based on international best practices for TB smear microscopy and external quality assurance (EQA), implemented a laboratory quality improvement program, and improved access to basic laboratory equipment and supplies. Training programs on smear microscopy and external quality assurance (EQA) were developed with support from international experts and covered approximately 1,500 laboratory specialists from the project's initial eight target regions. Pre- and post-training tests demonstrated a clear impact of the trainings, revealing a 40 percent increase in knowledge scores. Quality of TB smear microscopy also improved, with a tenfold decrease in the proportion of errors during slide rechecking as part of EQA.

In summary, to increase laboratory confirmation of TB cases, PATH focused on training laboratory specialists, implementing a quality improvement program, and training general practitioners to improve selection of TB suspects within primary health care. As a result, the proportion of laboratory-confirmed, smear-positive TB cases among TB suspects significantly increased at the primary health care level between 2005 and 2008, as shown in Table 7.

**Table 7. Proportion of SS+ TB cases among pulmonary TB suspects revealed at the primary health care level.**

<b>Regions and cities</b>	<b>% 2005</b>	<b>% 2008</b>
Donetska	.01	5.00
Dnipropetrovska	.32	2.40
Kharkovska	.15	5.50
Khersonska	.12	2.51
Sevastopol	.20	5.20
Kyiv	2.19	7.15

These results indicate that training for laboratory specialists has been essential to improving TB laboratory diagnosis in Ukraine. Continuation and expansion of this training throughout the country will remain a key component of the project to further advance TB laboratory diagnosis. PATH specialists, in collaboration with partners, have finalized preparation of high-quality training-of-trainer materials so that on-the-job training can be expanded rapidly and TB laboratory training courses at medical education institutions can be promptly initiated.

Data on the number of TB-microscopy testing and quality-control trainings conducted and on the number of individuals trained in laboratory practices have been summarized in Annex 12. Detailed information on laboratory trainings in smear microscopy and quality control is also provided in Table 8, below (DIP II activity 1.6).

**Table 8. Laboratory training activities in TB Control Partnership Project Year 2 (October 1, 2008 to September 30, 2009)**

<b>Administrative Territory</b>	<b>Title of Training</b>	<b># of Participants and Type of Service</b>	<b>Venue of Training</b>	<b>Date of Training</b>	<b>Trainers</b>
Kyiv	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories.	PHC–48 lab specialists TB Service – 2 lab specialists	Kyiv City Central TB Hospital	May 18-20, 2009 May 25-27, 2009 June 1-3, 2009 June 8-10, 2009 June 15-17	Nataliya Goncharenko
Sevastopol	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories.	PHC–12 lab specialists	Sevastopol City TB Hospital	April 7-9, 2009	Larisa Palkina
Zaporizhska Oblast	Laboratory diagnosis of	PHC–12 lab specialists	Zaporizhska Oblast TB Dispensary	April 13-17, 2009	Nataliya Rokhmanova

<b>Administrative Territory</b>	<b>Title of Training</b>	<b># of Participants and Type of Service</b>	<b>Venue of Training</b>	<b>Date of Training</b>	<b>Trainers</b>
	TB by smear microscopy. Quality assurance of smear microscopy in laboratories.				
Dnipropetrovska oblast	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories	PHC–50 lab specialists TB Service – 4 lab specialists	Dnipropetrovska Oblast TB Dispensary	May 20–22, 2009  May 27-29, 2009  June 3–5, 2009  June 10-12, 2009	Mariya Fonariova
Kharkivska oblast	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories	PHC–6 lab specialists TB Service – 6 lab specialists	Kharkivska oblast TB Dispensary	April 13-17, 2009	Maria Novokhatska
Odeska Oblast	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories	PHC–44 lab specialists TB Service – 2 lab specialists	Odeska Oblast TB Dispensary	March 11-13, 2009 April 8-10, 2009 April 28-20, 2009	Maria Novokhatska
Khersonska Oblast	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories	PHC– 27 lab specialists TB Service – 1 lab specialist	Khersonska Oblast TB Dispensary	June 22-25, 2009  August 25-28, 2009	Luydmyla Talashenko, Irina Alekseyenko
Crimea	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear	TB Service - 4 lab specialists	Odeska Oblast TB Dispensary  Kharkiv Oblast TB Dispensary	March 11-13, 2009  April 13-17, 2009	Maria Novokhatska  Maria Novokhatska

<b>Administrative Territory</b>	<b>Title of Training</b>	<b># of Participants and Type of Service</b>	<b>Venue of Training</b>	<b>Date of Training</b>	<b>Trainers</b>
	microscopy in laboratories				
Luganska Oblast	Laboratory diagnosis of TB by smear microscopy. Quality assurance of smear microscopy in laboratories	TB Service - 8 lab specialists  PHC– 20 lab specialists	Kyiv City Central TB Hospital  Kharkiv Oblast TB Dispensary  Lugansk Oblast TB Dispensary	May 25-27, 2009 June 3-5, 2009 September 28-30, 2009	Oblast TB Dispensary  Maria Novokhatska  Tatyana Ananko Natalia Kudrya Katerina Polovko
Regional (from seven regions)	TOT	TB Service – 11 lab specialists	Yalta, Crimea	July 20-24	Elena Boguslavskaya Katya Gamazina Tamara Ivanenko Elena Kononova
Ukraine National TB Reference Laboratory	Organization and functions of the National TB Reference laboratory, TB laboratory testing	1 TB expert, Barbova A.	TB agency, Riga, Latvia	May 11–16, 2009	Girts Skenders, Head of Latvia TB Reference Laboratory
Regional (from seven regions)	Laboratory diagnosis of MDR-TB.	8 TB experts, TB service lab specialists from 5 sites, including 1 TB service lab specialists from the prison system	TB agency, Riga, Latvia	September, 14-18, 2009	Girts Skenders, Head of Latvia TB Reference Laboratory
Kyiv prison	Ukraine National Reference Laboratory	TB service - 25 lab specialists from the prison system	Ukraine National Reference Laboratory	December 15-19, 2008	Anna Barbova
<b>Subtotal</b>		PHC - 218 lab specialists; TB service - 60 lab specialists			

<b>Administrative Territory</b>	<b>Title of Training</b>	<b># of Participants and Type of Service</b>	<b>Venue of Training</b>	<b>Date of Training</b>	<b>Trainers</b>
<b>Total</b>	<b>24 training courses</b>	<b>289 lab specialists trained</b> (278 from TB and PHC services and 11 potential trainers from 7 sites)			

One five-day training of trainers (TOT) was conducted in July for 11 potential master trainers on modern approaches to laboratory diagnosis of tuberculosis. As a result, five specialists are now ready to roll out training activities and have already conducted laboratory trainings for specialists in Luganska oblast and in Feodosiya.

The training objectives were as follows:

- To familiarize training participants with characteristics of potential trainees.
- To review the existing PATH training curriculum, Modern Approaches in Laboratory Diagnosis of Tuberculosis, and study PATH training materials.
- To adapt the existing training program and agenda to the needs of the TB Control Partnership Project.
- To motivate training participants to apply interactive teaching methods for adult education.
- To enhance training participants' skills to conduct group discussions, role plays, brainstorming, and case studies as well as organize individual and group work during an interactive training event.
- To develop a system of training quality monitoring.

All laboratory specialists dealing with TB detection and diagnosis in Odeska oblast have been trained in TB microscopy and quality control. In addition, the first training on TB smear microscopy and QA took place in Luganska oblast in the fourth quarter.

#### *Laboratory diagnosis of MDR-TB*

Training laboratory specialists in TB culture and TB drug-susceptibility testing (DST) is urgently needed to significantly improve the current practices of performing these tests and enabling improved diagnosis of MDR-TB. PATH organized a special, hands-on training course on TB culture and DST for Ukrainian laboratory specialists at the National Bacteriology Laboratory of the Latvia State Agency for Tuberculosis and Lung Diseases.

In addition, PATH has equipped laboratories in Odeska, Luganska and Zaporizhska oblasts with binocular microscopes and other supplies to ensure efficient functioning of TB testing and to support roll-out of DOTS-related training activities (DIP II activity 1.5).

To fulfill DIP II activities 1.7; 1.9, PATH monitored 16 review meetings (in eight project target areas each six months) and provided technical support to seven extended review meetings to oversee TB control practices, including laboratory testing for TB diagnosis (PMEP indicator 9). Detailed information on the TB-related issues discussed at the supported review meeting is summarized in Table 9 below.

**Table 9. Review meetings supported in project Year 2 and summary of reviewed TB program issues**

<b>Date/Place</b>	<b>Attendees</b>	<b>Topic</b>	<b>Conclusions</b>
January 30, 2009 Kharkiv	46 lab specialists	Coordination Council of Health Department of Kharkivska oblast administration on results of TB service activities in Kharkivska oblast in 2008	<ol style="list-style-type: none"> <li>1. To strengthen control of TB case detection in PHC services.</li> <li>2. To improve the work of TB microscopy centers</li> <li>3. To inform the Health Administration about TB program implementation.</li> </ol>
February 10, 2009 Kharkiv	21 lab specialists	Roundtable meeting of laboratory specialists on the results of TB case detection in general health care facilities— outcomes for 2008	<ol style="list-style-type: none"> <li>1. To improve Internal Quality Control Procedures</li> <li>2. To analyse all smears provided for tests at least once a month.</li> <li>3. To provide all positive smears to the bacteriological lab for rechecking.</li> </ol>
July 4, 2009 Dnipropetrovsk	60 lab specialists	Detection of TB cases in general health care facilities	<ol style="list-style-type: none"> <li>1. Main problems: <ul style="list-style-type: none"> <li>• High percent of poor quality materials (according to data from different labs, saliva may constitute from 18% to 25% of all samples)</li> <li>• Specialists at outpatient clinics &amp; Feldsher-Accoucher Points (FAPs) don't refer patients with pulmonary diseases to labs for testing</li> <li>• Lab specialists performing smear microscopy have no motivation</li> <li>• Some labs have no designated working places for smear microscopy</li> <li>• Existing bio-safety cabinets aren't working effectively &amp; aren't controlled by specialists</li> <li>• Phenol is provided to labs in big packages (uncomfortable to work with, impossible to use till the end of the shelf life)</li> </ul> </li> <li>2. Positive changes: <ul style="list-style-type: none"> <li>• 149 lab specialists trained during project implementation in Dnipropetrovska oblast</li> <li>• Following the oblast health administration's order #360 issued on 12/30/2005, on improvement of smear microscopy for TB diagnosis in oblast medical facilities: <ul style="list-style-type: none"> <li>○ Lab network created</li> <li>○ Sputum collection points organized in</li> </ul> </li> </ul> </li> </ol>

Date/Place	Attendees	Topic	Conclusions
			<p>PHC facilities</p> <ul style="list-style-type: none"> <li>○ Training &amp; reference center on lab quality control to improve TB smear microscopy created</li> <li>○ Trainings for laboratory specialists underway</li> <li>○ Stained smears kept for further control</li> <li>○ Internal &amp; external QC of smear microscopy introduced</li> </ul> <ul style="list-style-type: none"> <li>● EQC is carried out on regular basis at oblast level</li> <li>● Results of EQC are discussed at quarterly meetings.</li> <li>● Due to regular EQC panel testing methods, the number of errors decreased by tenfold (since 2006).</li> <li>● 98% of labs participated in the last EQC &amp; 86% of them had no errors</li> </ul> <p>3. Main tasks:</p> <ul style="list-style-type: none"> <li>● Improve selection of TB suspects &amp; referral of patients to labs</li> <li>● Train medical providers on how to collect sputum</li> <li>● Conduct hands-on trainings for lab specialists</li> </ul>
April 16,.2009 Zaporizhska oblast	30, including 2 lab specialists	Implementation of the oblast TB program; TB situation in Zaporizhska oblast	<ol style="list-style-type: none"> <li>1. To check selection of TB suspects at the PHC level &amp; their sputum testing</li> <li>2. To evaluate reasons for increased level of TB relapses in some districts of Zaporizhska oblast</li> </ol>
March 5–6, 2009 Khersonska oblast	40 including 10 lab specialists	Organization of TB activities at all managerial levels; TB diagnosis & care for TB patients	<ol style="list-style-type: none"> <li>1. Main problems: <ul style="list-style-type: none"> <li>● Staff (age, training, motivation)</li> <li>● Detection of TB cases in general health care facilities is very low (majority of patients are referred to TB dispensaries for testing &amp; diagnosis)</li> <li>● The oblast TB dispensary laboratory is overloaded</li> <li>● The Head of the oblast TB lab has no time to conduct EQC (of 33 labs, only 7 [21%] involved in panel testing» of EQC)</li> <li>● It is necessary to revise the oblast order on conducting EQC</li> </ul> </li> <li>2. Positive changes: <ul style="list-style-type: none"> <li>● Premises of the oblast TB dispensary's lab is renovated &amp; new equipment is installed (Bio-safety cabinets 1-11 class)</li> <li>● New sputum collection points established</li> <li>● Chief oblast lab specialist supports the EQC &amp; is ready to assist in its organization on a regular basis</li> <li>● Specialist trainings are organized (including practice in labs)</li> </ul> </li> </ol>

Date/Place	Attendees	Topic	Conclusions
			3. Main tasks: <ul style="list-style-type: none"> <li>• Improve internal quality control. If necessary, train lab specialists on the standards of smear microscopy</li> <li>• Resolve problem with human resources</li> </ul>
June 18, 2009 Kyiv	28 lab specialists	Roundtable meeting on <ol style="list-style-type: none"> <li>1. Review of trainings for the laboratories of PHC facilities.</li> <li>2. Results of EQC in 1st-level laboratories.</li> <li>3. TB case detection in PHC facilities of Kyiv for 6 months of 2009.</li> </ol>	<ol style="list-style-type: none"> <li>1. 50 specialists from laboratories were trained</li> <li>2. 29 laboratories participated in panel testing</li> <li>3. Total number of mistakes—7 (3 LFP, 4 quantification errors)</li> <li>4. It was proposed in GHCF to improve the work of general physicians regarding patients' selection for smear microscopy</li> </ol>
June 9, 2009 Sevastopol	27, including 10 lab specialists	Monitoring & assessment of diagnosis indicators during TB treatment	<ol style="list-style-type: none"> <li>1. Quality of lab tests for TB diagnosis has been improved. External &amp; internal quality control implemented on a regular basis in Sevastopol.</li> <li>2. Lab specialist's qualifications are high (demonstrated by EQC)</li> <li>3. Improved cooperation between lab services &amp; TB clinicians as a result of trainings, monitoring visits, seminars, &amp; round table meetings</li> </ol>
Total attendees	252, including 177 lab specialists		

PATH will continue promoting the organization of general and laboratory review meetings at least on a semi-annual basis in each project area to analyze results of monitoring visits and oblast TB-control program performance as a tool for sustainable improvement.

The TB Control Partnership Project continued its technical assistance to regional laboratories on EQA implementation and eventual institutionalization to sustain improved smear microscopy for TB diagnosis. Data from target oblasts on EQA results of smear microscopy in 2008 and the first two quarters of 2009 were collected, analyzed, and discussed at the review meetings and were used as a foundation for further laboratory improvement. The regional order on establishment of external and internal control of TB laboratory diagnosis in Donetska oblast was approved to enhance implementation of the regional TB-control program there. In addition, regional orders to implement regular external quality control of TB laboratory diagnosis by smear microscopy have been prepared in the eight project regions. Oblast TB dispensary laboratories serve as regional reference laboratories, executing, among other responsibilities, external quality control for the laboratory network performing TB diagnosis in the region. Currently PATH, the MOH Committee to Combat HIV and TB and Other Socially Dangerous Diseases, and National TB Institute experts are applying their experience gained in pilot regions in preparing an order to institutionalize regular external laboratory quality control of TB diagnosis nationwide.

According to the manual on TB microscopy and quality control of laboratory diagnosis, internal and external quality control of TB laboratory diagnosis should be performed in all medical facilities. This manual was developed in 2006 under the previous USAID/PATH TB-control project. PATH staff and national consultants completed the process of updating the manual to better meet the needs of the new training program on external quality control of TB microscopy. At present, PATH expects MOH approval for the manual and is planning to print and disseminate it to laboratory specialists in the project sites as soon as MOH approves it. It will be a significant step forward in EQA in Ukraine.

Eight project regions conducted external quality control of smear microscopy in January–March of 2009. Of 409 level-I laboratories in these administrative areas, 165 laboratories (41%) participated in proficiency testing using panel-testing methodology as part of laboratory quality control. Of those laboratories, 79 percent had no mistakes in reading the panels and demonstrated high proficiency (see Table 10).

**Table 10. Quarterly report on results of EQA of smear microscopy for TB diagnosis using panel-testing method for level-I laboratories in first quarter of 2009**

#	Oblast	# of level-1 labs	# and % of labs participating in EQA	# and % of labs with no errors in reading 10-smear panels
1	AR Crimea	26	4 / 10%	2 / 50%
2	Dnipropetrovska	52	51 / 98%	44 / 86%
3	Donetska	71	20 / 28%	15 / 75%
4	Zaporizhska	45	11 / 24%	5 / 45%
5	Kharkivska	45	35 / 78%	31 / 89%
6	Khersonska	33	7 / 21%	3 / 43%
7	Kyiv	30	17 / 57%	13 / 76%
8	Sevastopol	9	8 / 89%	8 / 100%
9	Odeska	61	12 / 20%	9 / 75%
10	Luganska	37	N/A	N/A
	<b>Total</b>	<b>409</b>	<b>165 / 45%</b>	<b>130 / 79%</b>

Following a requirement of regularity in implementing EQA, eight project regions conducted EQA of smear microscopy again between April and June, 2009. TB microscopy quality control data were collected and analyzed. Of 405 level-I laboratories in these regions, 175 laboratories (43 percent) participated in proficiency testing using the panel-testing methodology as part of laboratory quality control. Of those laboratories, 92 percent had no mistakes in reading the panels and demonstrated high proficiency (see Table 11).

**Table 11. Quarterly report on results of EQA of smear microscopy for TB diagnosis using panel-testing method for level-I laboratories in the second quarter of 2009.**

#	Oblast	# of level-1 labs	# and % of labs participating in EQA	# and % of labs with no errors in reading 10-smear panels
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1	AR Crimea	25	25 / 100%	25 / 100%
2	Dnipropetrovska	51	10 / 20%	10 / 100%
3	Donetska	71	30 / 42%	21 / 70%
4	Zaporizhska	45	10 / 22%	8 / 80%
5	Kharkivska	45	45 / 100%	38 / 84%
6	Khersonska	33	19 / 58%	14 / 74%
7	Kyiv	30	29 / 96%	23 / 80%
8	Sevastopol	7	7 / 100%	7 / 100%
9	Odeska	61	25 / 41%	15 / 60%
10	Luganska	37	N/A	N/A
	<b>Total</b>	<b>405</b>	<b>175 / 43%</b>	<b>161 / 92%</b>

In summary, the laboratory service is ready and eager to practice in accordance with internationally recommended standards but EQA and regular monitoring must be strengthened. Additional specific training and technical assistance are required to significantly improve implementation of laboratory EQA.

#### *Infection control*

A workshop on current TB-related infection control practices was conducted for 27 chief doctors of prison hospitals on September 26, 2009. As a result, a TB-related infection control strategic plan will be developed as a key element of preventing MDR-TB in prisons.

#### *Human resources assessment*

PATH has signed a subcontract with Health Strategies International (HSI) to conduct a TB service-related human resources (HR) assessment. The first step of this assessment, a pre-assessment mission, was conducted July 2 to 25, 2009 and focused primarily on HR development issues within the TB laboratory network (DIP II activity 1.3). The mission confirmed the extent of HR challenges within the TB network and the urgent need for quantitative evidence on existing HR shortfalls, key HR issues, and the projected cost of meeting HR standards. The key HR issues presented in the report (see Annex 13) have been applied to developing an HR assessment conceptual framework that includes indicators and defined data collection protocols for further quantitative assessment. Much of the quantitative data will be collected through a survey at oblast level, while other quantitative and qualitative information will be gathered during NRL, Level-1 laboratory and training institution site visits. MOH HR and TB champions will also be interviewed and central level data collected.

#### *Strengthening the surveillance system*

With PATH technical support, an advisory working group on effective implementation and monitoring of Ukraine's NTP, which was established by the MOH's March 3, 2008 order #71-adm, finalized the revision of statistical forms and instructions on how to complete them for registering TB cases, monitoring their treatment, and analyzing treatment outcomes.

PATH organized and provided technical assistance to proceedings of the MOH's advisory group on implementation and monitoring of Ukraine's National Tuberculosis Program, which was conducted to modify a data entry module and other software components for further

establishment of the MSH's e-TB Registry in Ukraine. The newly-endorsed Ukrainian MDR-TB forms to be used in the e-system were presented, reviewed, and discussed. The MDR-TB module of the e-TB manager has been adapted according to the new MDR-TB forms in September, 2009.

A plan to implement the e-TB manager program (electronic TB registry developed by MSH) was revised by PATH specialists in order to enhance feasibility of implementation. On May 17 to 22, 2009, PATH staff, four specialists from project-target oblasts, and National TB-control center specialists conducted a working group meeting aimed at validating the TB case management module of the electronic registry (e-TB manager). All necessary software and a draft version of e-TB manager were installed on the National TB control central server.

Two-day training in using the TB case management module of the e-TB manager was conducted for 21 regional and two national TB-control center specialists on June 25 to 26, 2009. The purpose of this training was to:

- Learn the structure and format of the TB case management module and what it allows the user to do.
- Practice using the TB case management module online.
- Understand the parameters for recording TB case management data.

During hands-on sessions, participants discovered the importance of proper management of TB case information, and found some discrepancies in their completed forms. Pilot oblasts and the national TB-control center are ready to begin piloting the system as soon as the new version is released. Recently, the e-TB Manager was again updated, but it still needs to be checked for applicability by oblast TB specialists.

The expansion of M&E training in new project regions followed trainings on basic DOTS components in Quarters 3 and 4 of Project Year 2. A model set of training materials has been revised to reflect trainees' feedback and to expeditiously roll out M&E training courses (DIP II activity 1.8). An M&E training curriculum covered the following topics:

- Epidemiology of TB: basics of epidemiology and main factors influencing the level of TB morbidity
- Monitoring and evaluation main indicators
- Cohort analysis
- Indicators of TB cases detection and treatment outcomes. Analysis and interpretation
- DOTS TB statistical forms and how to complete them
- Monitoring of TB services as a background for proper management. Evaluation of TB-related indicators and decision-making based on the data obtained.
- Supervision (site visits) as a part of monitoring and on-the-job training

M&E trainings are reflected in Annex 12, which summarizes training activities in Project Year 2. PATH specialists, in cooperation with national-level TB specialists (statistical department of the

National Institute of TB and Pulmonary Diseases) conducted monitoring visits to Donetsk (March 16 to 18, 2009), Odeska (March 10 to 11, 2009) and Khersonska (January 25 to 27, 2009) oblasts to assess TB case management. These oblasts' statistical departments of the TB dispensaries established regular procedures for TB data collection, aggregation, and analysis aimed at reducing incorrect registration of TB cases by treatment categories to strengthen TB case management.

During a monitoring visit to Odeska oblast, all TB district coordinators brought their TB statistical journals (TB03 forms) to the oblast TB dispensary's statistical department to verify TB case recording and reporting. A follow-up monitoring visit to Odeska oblast will be important to further improvement of the M&E system and to establish a supervisory team to ensure regular on-the-job assistance.

As presented above in Table 9, PATH staff and national consultants, representatives of the National TB Institute, and the National Reference Laboratory actively participated in a meeting in Khersonska oblast to review the organization of TB-control activities at all managerial levels. The meeting included 40 participants from Khersonska oblast and took place on June 3 to 5, 2009. During the meeting, it was noted that district registries of TB patients have been created. Discrepancies among the program's indicators were presented and discussed, and official data reported by Khersonska oblast to the National TB Institute Center were compared with those presented at the meeting. It was noted that the tendency to have everything at 100 percent is still in place. For example, the sputum conversion indicator was 100 percent in some territories, while treatment results are far from 85 percent treatment success.

PATH supported participation of project oblast representatives at the WHO workshop, Monitoring and evaluation of the TB program, on February 23 to 24, 2009, which addressed annual submission of TB statistical data to WHO, definitions of TB indicators and their criteria, and evaluation of TB programs according to defined indicators. Donetsk, Kherson, and Zaporizhska oblasts presented their oblast TB indicators and discussed them with other participants. PATH staff played a key role in the sessions.

#### *Increasing case detection and case holding*

PATH provided a follow-on subcontract to the National Committee of the Ukrainian Red Cross Society (URCS) to implement the following work:

- Carry out collaborative activities with TB medical facilities to provide DOTS services to patients who choose to receive follow-up TB treatment at the outpatient stage at Red Cross aid stations.
- Work with TB patients who have interrupted their treatment.
- Work with local citizens, housing and municipal services staff, and retired people to provide them with correct information about TB, encourage timely consultations with medical providers, and decrease stigma toward TB patients.
- Establish a URCS M&E group for the project areas that is tasked with developing an M&E tool, analyzing M&E data, and developing an action plan for education and social support services.

URCS will continue working with local authorities to inform them of the project's results and to attract local budget funds to sustain program implementation (DIP Activity 1.13).

#### *Working with prisons and prisoners*

According to its subcontract, URCS continues to provide social support, counseling, and referrals for released prisoners. In addition, the first 6-month plan of action and a 12-month continuation plan were developed and subcontracts were signed, after USAID consent, with the All-Ukrainian Charitable Organization, Network of Organizations that Provide Support in the Penitentiary System (Prison Support Network), to work with prisoners before and after release to support improved adherence to TB treatment in Zaporizhska and Khersonska oblasts (DIP II activity 1.14 and 1.15). This NGO works with prisoners at the pre-release stage (two to three months prior to release) to assure that they receive proper information and counseling, which is anticipated to decrease loss to follow up in the civilian health system once prisoners are released. Members of this NGO network accompany released prisoners to the civil TB system.

#### *Assessment of the drug management system*

PATH has worked with Management Sciences in Health (MSH) to finalize the scope of work, budget, and other related documents. With USAID/Kyiv consent, PATH established a subcontract with MSH to provide technical assistance to national counterparts in TB drug management. Per DIP II activity 1.11 and 1.12, an MSH/PATH team assessed current practices in pharmaceutical management in TB control in Kyiv city, Kharkivska, and Dnipropetrovska oblasts June 17 to July 1, 2009. Findings of this assessment and recommendations for further interventions to be undertaken under the project are summarized in Annex 14. Key results are summarized below.

Ukraine's TB pharmaceutical management systems were performing well in the following areas:

- At the time of the visit, DOTS medicines were available at the point of care, with no reported stock-outs or treatment interruptions
- Standards, orders, and protocols are available and followed as directed for quantification, ordering, receiving, and dispensing medicines and reporting
- Communication and coordination between provincial-, city-, and rayon-level sites is relatively good, with staff working together to redistribute or locally procure medicines as needed when stocks are low
- The MOH has approved and is supportive of implementing the e-TB manager to improve information systems, reporting, and the use of the resulting data for decision-making and program management

Several challenges, however, impede progress toward improving TB treatment and control:

- Uncertainty about the procurement schedule has been a consistent challenge in forecasting annual needs at the local level

- Infrequency of procurements further challenges local medicines and commodities budgeting and forecasting capacity. The short shelf life of costly second-line medicines will necessitate changes to the ordering and receiving schedule.
- Stock-outs, failure to adhere, and other treatment interruptions can result in treatment failure and the rapid development of drug resistance. Although sites visited have not experienced stock-outs recently, other reports have documented sustained stock-outs annually since 2002
- Poor quality of medicines and laboratory commodities can contribute to drug resistance
- Fixed-dose combinations (FDCs) are available in only a few oblasts, and second-line drugs are not currently available through the Green Light Committee (GLC)
- The supply system is not sufficiently responsive to needs of new patients, treatment status and location changes, regimen alterations related to disease status, and changes to guidelines
- Compliance with required reporting is generally accomplished in an inefficient manner, including the use of non-standardized forms, and duplicate information submission (monthly, quarterly, manual, and electronic)
- The collection and submission of data does not, generally, result in analysis and use of these data by local staff for improving their own program management

Programmatic areas of concern with respect to pharmaceutical management for TB are:

#### *Quantification*

- Lead times on procurements are 15–18 months, making forecasting challenging
- Site forecasts are often adjusted to meet budget constraints
- Stock-outs have been avoided because oblast staff monitor city and rayon stock levels to anticipate and troubleshoot shortages
- Oblast-level staff may use local funds to directly procure medicines from local manufacturers to close the supply gap, but this is at the expense of other categories of good and services
- Rayon- or city-level sites may request redistribution from other sites within the oblast to meet the demand for medicines
- Buffer stocks are inconsistently interpreted as part of the quantification calculation

#### *Record keeping and reporting*

- Standard forms monitor the financial aspects of medicines as opposed to medicines or program management
- A wide variety of locally developed (homemade) forms are used to monitor site inventory (expiration, stock balance, received, and issued)

- Staff often hand-copy patient information into journals to consolidate essential information from several reports or patient forms.
- Electronic tools in facilities are generally unavailable for pharmaceutical management, making the process time-intensive and laborious. Usually these are used for accounting, which is not responsible for pharmaceutical management

#### *Inventory management*

- Many sites have inadequate storage space to accommodate an annual supply of medicines at one time
- The option of splitting shipments or more frequent ordering is not available to most sites
- Some staff have insufficient knowledge of or training in comprehensive pharmaceutical management
- Few job aids exist for reference or to serve as checklists

#### *Monitoring and supervision*

- Staff responsible for conducting supervision visits don't have or don't use a pharmaceutical management checklist. It is unclear exactly what they monitor.
- Staff do not use non-financial indicators to monitor the status of medicines and commodities management

#### *Training*

- Training for pharmaceutical management is not available to non-pharmacists and rarely occurs for pharmacists as part of their continuing education

#### *Immediate recommendations*

- Strengthen quantification of anti-TB medicines (first- and second-line) through technical assistance and training
- Review and revise existing instructions for annual quantification to reflect the most recent standard treatment guidelines
- Develop or refine practical record-keeping tools to facilitate data collection, analysis, and reporting relative to medicines; make the tools consistent with and complementary to the e-TB manager
- Work with counterparts to adapt effective pharmaceutical management tools and develop methodology and tools to address gaps in inventory management practices
- Further enhance counterpart capacity to assess and monitor pharmaceutical management practices by including them in site visits to other PATH project focus sites

Given the findings and proposed long- and short-term recommendations, PATH and MSH will convene an options-analysis workshop with stakeholders to review and prioritize issues and

needs, identify and analyze options for addressing them, and develop an action plan to strengthen existing TB and MDR-TB medicines management systems.

## **Result 2**

### **High-quality DOTS-plus (including MDR-TB, XDR-TB, and TB/HIV co-infection) services available to 30 percent of the population**

#### ***DIP Objective 2. Build adequate capacity for rapid implementation of DOTS-plus for MDR/XDR-TB in the project regions***

Ukraine's first protocol on drug-resistant TB case management was endorsed by the Ministry of Health in December 2008 (DIP II activity 2.1). It was developed with PATH technical assistance. Per DIP II activity 2.3, a feasibility assessment regarding the creation of a Ukrainian Center of Excellence for MDR-TB Case Management was conducted by Dr. Vaira Leimane, head of the WHO Collaborative Training Center on MDR-TB Case Management at the Latvia State Agency for Tuberculosis and Lung Disease, and PATH staff. Following this assessment, the Dnipropetrovska oblast TB dispensary and a training center of the TB department of the Dnipropetrovsk Medical University were selected as potential demonstration/training sites for MDR-TB case management. PATH has assisted the Dnipropetrovska oblast TB-related institutions in developing a scope of work and a training plan, as well as in identifying funding mechanisms for establishing an MDR TB Center of Excellence.

PATH continued working on strengthening international partnerships to most effectively implement the TB Control Partnership project and to increase access among Ukrainian TB specialists to internationally-recognized TB and other related technical expertise. Per DIP II activity 1.4 and 2.4, a two-week training course on MDR TB at the Latvia National Tuberculosis and Lung Diseases Agency in Riga, Latvia, was conducted November 26, 2008 to December 5, 2008. This agency also serves as the only WHO Collaborating Center for management of multidrug-resistant tuberculosis. Its training course allowed 11 Ukrainian TB specialists from project target areas to acquaint themselves with international recommendations for effective MDR-TB case management and to discuss organization of services, diagnosis, treatment, and management of adverse effects of drugs, infection control, and other MDR-TB-related matters with Latvian specialists who had first-hand experience in improving MDR TB control.

Per DIP II activity 2.2, Ukrainian experts who participated in the European regional conference of the International Union Against TB and Lung Diseases in Dubrovnik, Croatia, became acquainted with a standardized MDR/XDR-TB assessment tool developed by PATH and other international TB experts. The tool was field-tested in Ukraine, and TB-related data have been collected using the tool in Luganska and Odeska oblasts. These data will be further analyzed to provide an accurate evaluation of the MDR-TB situation and program in these regions. This tool is designed to gather data and develop a situation-analysis report on MDR-TB and XDR-TB at the country/region level. The situation analysis will provide the basis for prioritizing recommendations on MDR-TB and XDR-TB, developing a realistic action plan, and identifying any technical assistance the country needs to help prevent new MDR-TB cases and to diagnose and treat existing cases.

***DIP Objective 3. Provide access to TB/HIV co-infection services to 30 percent of the population***

To identify barriers for effective integration of TB/HIV services in Odeska and Luganska oblasts, PATH reviewed an assessment tool that has been used in other project sites and adjusted it based on the lessons learned. The revised tool was used to identify barriers in client-provider communication and counseling, barriers and motivation for TB/HIV case management, and the roots of stigma. The revised assessment tool includes an initial protocol, a survey based on exit interviews of TB and HIV/AIDS facility clients, and an in-depth interview guide for use with providers (DIP II activity 3.1). The related questionnaires and the protocol were submitted to PATH's Research Ethics Committee and approved.

Competitive bidding among NGOs in Odeska and Luganska oblasts to select two organizations to implement this baseline assessment was completed. Selection criteria were based on NGO experience in conducting assessments in the TB/HIV domain, NGO capacity, and existence of agreements between NGO and TB and HIV/AIDS facilities. Two NGOs (Luganska charitable fund, Step to the Future, and the Odeska NGO, Faith, Hope and Love) were selected based on these criteria as well as their action plans and budgets to implement the assessment. Training on collecting data for the baseline assessment was conducted on June 5, 2009, for 16 interviewers from the selected NGOs. The sub-agreements with selected NGOs currently are being developed.

In collaboration with the HIV/AIDS Service Capacity Project in Ukraine, PATH continues to build the capacity of Oblast Coordination Councils (CC) on TB and HIV/AIDS. With PATH's technical support, the OCs in Zaporizhska and Dnipropetrovska oblasts established oblast-level TB/HIV collaborative task forces (working groups) to review policies and practices and revise existing guidelines to better manage and support TB/HIV co-infected individuals. The collaborative strategic plan for improved TB and HIV systems coordination was developed in Zaporizhska oblast by this collaborative task force. The plan was approved by the Zaporizhska oblast CC (DIP II activity 3.2).

Following strategic plan development, a seminar entitled, Actual Problems of TB/HIV Co-infection, was conducted for 131 medical providers from TB facilities, AIDS centers, and sanitary-epidemiologic (SES) institutions from all districts in Zaporizhska oblast (PMEP indicator 8). This seminar initiated discussions on improved collaborative TB/HIV activities at all levels of care in Zaporizhska oblast. The focus was on essential components of DOTS as well as strategic planning and implementation of collaborative activities for TB/HIV care and social support, international approaches to HIV/TB program management, and existing resources and barriers (DIP II activity 3.9).

PATH provided assistance to establish an *office of trust*, which will render psychosocial support to co-infected patients in Berdyansk, one of the largest cities in Zaporizhska oblast. This office of trust also functions as a center for training in interpersonal communication and counseling for health care providers and NGO activists from this city, serving as a best practice center for other districts in Zaporizhska oblast.

A roundtable to discuss implementation of the TB/HIV collaborative action plan was conducted with project support in Dnipropetrovska oblast. The results of the assessment, Needs of TB/HIV

Co-infected Individuals and Role of NGOs in Addressing Those Needs in Ukraine, which was conducted earlier by PATH, were discussed. As a consequence of this roundtable, a resolution was developed with recommendations to the OC to create and support a working group that will assure proper monitoring and sustainability and consistency of the TB/HIV strategy implementation. In Dnipropetrovska oblast, a collaborative action plan is pending approval (DIP II activity 3.2).

To evaluate TB/HIV policy and routine practice at the national and regional level, identify training needs, and revise existing training curricula, consultants from the WHO Collaborative Center in Tradat, Italy (Sondalo) visited Ukraine. The main findings of the assessment highlighted the following urgent needs:

- Establish coordination between all partners for TB/HIV curricula development
- Develop a training plan and comprehensive training curricula, which will include both TB/HIV program management and TB/HIV case management
- Prepare a pool of trainers to scale up and improve the quality of the existing in-country TB/HIV capacity and establish proper monitoring of TB/HIV case management trainings
- Assure increased access of co-infected individuals to high-quality services (DIP II activity 3.3).

The TB/HIV assessment report is attached as Annex 15. This work will require intensive advocacy efforts to consolidate resources of existing activities funded by the Government of Ukraine and other donors. Based on the results of assessment, a training plan on TB/HIV activities was developed. PATH will support implementation of this training plan.

Following the visit of consultants from the WHO Collaborative Center in Tradat, Italy (Sondalo), PATH convened a roundtable meeting on the development of a TB/HIV educational program in February, 2009. After discussing the needs and challenges specific to Ukraine, a resolution was developed and included the following commitments

1. In partnership with national and international institutions, establish a working group on the development of a TB/HIV curriculum and educational materials to be endorsed by the Ukrainian MOH's Committee for Combating HIV/AIDS, TB, and Other Socially Dangerous Diseases.
2. National and international experts (Ukrainian AIDS/HIV Center, the National TB Institute, Institute of Epidemiology and Infection Diseases, National Medical Academy of Postgraduate Education, WHO, and NGO representatives) should be involved in the working group
3. The main tasks of this working group are to:
  - Develop a curriculum on TB/HIV case management that meets international and national requirements based on the existing TB/HIV treatment curriculum and following recommendations of experts from the WHO Collaborative Center in Tradat, Italy (Sondalo)

- Prepare this curriculum for certification in the institutes of postgraduate continuous medical education
- Identify target groups for trainings on TB/HIV treatment

PATH and the NGO, National Training Center, will provide technical assistance to the working group in developing educational materials on TB/HIV case management. Two working group meetings were conducted, and a draft order regarding the development and implementation of a unified TB/HIV training curriculum was drawn up and submitted to the MOH of Ukraine for approval ((DIP II activity 3.3).

PATH initiated the process of identifying potential trainers for an initial TOT based on their professional experience. In concert with the WHO Collaborative Center in Tradat, Italy (Sondalo), a TB/HIV training course and a TOT course on TB/HIV collaborative case management were conducted for TB/HIV team members selected from appropriate oblast- and district-level staff (DIP II activity 3.4). Training materials on a collaborative approach to TB/HIV case management in Ukraine were developed based on the evaluation results. TB/HIV training included three stages:

*First stage:* A training course (organization of TB/HIV collaborative activities) for 18 TB and infectious disease specialists from eight project-target regions (Kyiv, Sevastopol, Crimea, Dnipropetrovska, Khersonska, Odeska, Zaporizhska, and Donetsk oblasts) held on May 18 to 22, 2009.

*Second stage:* Follow-on training on TB/HIV collaborative activities, a TOT course for the same participants held on June 8 to 12, 2009. During the training, a teach-back approach was used. Participants discussed training topics, delivered presentations, and received recommendations on training content, trainer's role, effective communication, and training techniques.

*Third stage:* Participants carefully studied the TB/HIV training materials. The next TOT course for the same participants was aimed at improving trainers' skills. This training included sessions on interactive techniques and creation of a training agenda and training manual. The course was conducted by PATH trainers on September 7-11, 2009.

Per DIP II activity 3.8, PATH has been working steadily to improve communication and counseling skills among TB providers, including encouraging diagnostic counseling and testing for HIV as part of routine care. In response to growing interest and requests from health care providers and health administrations, PATH has increased the number of trainings on interpersonal communication and counseling. The content of PATH's training courses on communication and counseling was based on baseline exit survey data collected from clients. The training course also takes into account data from focus group discussions with PLHIV regarding TB services, as well as the clear need to improve collaboration and service integration between TB and HIV services. Overall, the course includes the following components:

- Interpersonal communication
- Main steps of effective counseling

- Counseling on TB
- Diagnostic counseling and testing of TB patients for HIV

Since the previous evaluation focused on client satisfaction, PATH developed an additional questionnaire and protocol to assess provider experiences to strengthen this component. Specifically, PATH’s experience in conducting trainings suggests that further understanding of providers’ attitudes towards patients, work conditions, motivation, and opportunities for professional growth would be useful in improving trainings on client-provider interactions, especially as TB and HIV services become more coordinated. PATH expects that the questionnaire results can help to develop additional training sessions with the goal of further supporting providers and reducing stigmatizing attitudes towards patients with TB and TB/HIV.

Per DIP II activity 3.8, PATH conducted trainings on interpersonal communication, diagnostic counseling, and HIV Testing (DCT) for TB providers in the project-target oblasts. A training curriculum was developed, and trainings were conducted as shown in Table 12:

**Table 12. Training courses on interpersonal communication and counseling**

<b>Title</b>	<b>Date</b>	<b>Participants</b>
Training on interpersonal communication and diagnostic counseling of TB/HIV patients	June 3–5, 2009	23
Training on interpersonal communication and diagnostic counseling of TB/HIV patients	June 10–12, 2009	26
Training on interpersonal communication and diagnostic counseling of TB/HIV patients	June 15–17, 2009	19
Training on the improvement of trainer’s skills for TB specialists, infectious disease specialists, psychologists, and social workers from four regions (Dnepropetrovsk, Odeska, Kharkivska oblast, and Crimea)	June 19–22, 2009	15
Training on interpersonal communication and diagnostic counseling in TB/HIV patients	June 24–26, 2009	15
Training on interpersonal communication and diagnostic counseling in TB/HIV patients	June 30–July 2, 2009	25
<b>Total</b>	<b>6 trainings</b>	<b>123</b>

A training agenda and materials for training NGOs and HIV-service organizations were developed at working group meetings on April 11, 2009 and May 4 to 8, 2009 (DIP II activity 3.9). The purpose of the training was to provide information on effective TB/HIV project implementation.

In collaboration with the Ukrainian Coalition of HIV Service Organizations, PATH conducted a training course entitled, Provision of Social Support Services to People with TB/HIV Co-infection, for 21 NGO activists whose organizations have started field-testing the standards of social care and support for TB/HIV patients developed during the first year of the project (DIP II activity 3.6 and 3.7).

Implementation of enhanced standards of social support for TB/HIV patients is now underway. After an assessment of social support programs in May, 2009, a final version of recommended social support programs has been submitted to the Ministry of Labor and Social Policy of Ukraine (DIP II activity 3.5). In addition, per DIP II activity 3.6 and 3.9, an algorithm of granting with education to strengthen the capacity of HIV-service organizations in implementing TB/HIV service-provision grants was developed that, in brief, includes:

- Identification of HIV-service organizations in Zaporizhska, Lugansk, and Dnipropetrovska oblasts for TB/HIV project implementation (TB screening among HIV-positive persons, referral, and other related services)
- Development of training materials
- Development and distribution of brochures among vulnerable groups

Per DIP II activity 3.10, a strategic plan on TB/HIV services improvement in Zaporizhska oblast was also developed, and monthly meetings with participation of TB specialists and infectious diseases specialists were conducted to oversee implementation of TB/HIV coordinated activities according to this plan.

### **Result 3**

#### **Reduced policy, legal, regulatory, fiscal, and attitudinal barriers inhibiting access to TB and TB/HIV co-infection prevention, diagnosis, treatment, and care according to international DOTS-based standards**

##### *DIP Objective 4. Create an enabling environment for DOTS implementation by removing or reducing existing policy and attitudinal barriers*

PATH continued to support the MOH's Committee on HIV and TB in raising awareness among key policy-makers on global TB strategic approaches and the European regional response to the TB epidemic (DIP II activity 4.1). 1). PATH actively participated in proceedings of the MOH's working group, supported by the Capacity Project in Ukraine (HPI), on the development of amendments to the Ukraine law on AIDS prevention and social security of the population.

PATH continued providing technical support to strengthen activities of the regional coordination councils in guiding and monitoring TB/HIV collaborative activities at local and regional levels in the project target oblasts. To bolster political commitment to overcoming barriers to implementing effective TB and TB/HIV strategies at the oblast level in accordance with international recommendations and best practices, the PATH team met with the head of health administration, key TB specialists, and other members of the Odeska Oblast Coordination Council on December 10 and 11, 2008 (DIP II activity 4.4). A TB advocacy presentation was delivered to Odeska oblast CC's members (DIP II activity 4.6). Also, the PATH team met with the heads of health administrations, key TB specialists and members of the Coordination Councils during visits to Luganska, Zaporizhska, and Dnipropetrovska oblasts, as well as in Kyiv and Sevastopol.

As a PATH subcontractor under its TB Control Partnership project in Ukraine, UATB participated in meetings of the MOH's working group established to provide support in improving Ukrainian legislation and regulatory documents on TB control (DIP Activity 4.2).

#### **iv. Performance problems during the reporting period and variance from the annual implementation plan and PMEP**

Decreasing national and local budgets may potentially impede implementation of TB-control interventions initiated by the project activities.

#### **v. Budget and expenditures**

In the fourth quarter of Year 2, PATH has spent \$603,912 for Result 1, \$26,511 for MDR TB-related activities, and \$244,814 for TB/HIV activities to fulfill Result 2; and \$35,742 for Result 3—totaling \$910,979 as of September 30, 2009.

In summary, as of September 30, 2009, PATH has spent \$4,083,112 in Year 1 and 2. The remaining \$ 104,887 of the total obligated for Year 1 and 2 funds of \$ 4,188,000 will be utilized in the first quarter of project Year 3 to pay outstanding project Year 2 invoices from subcontractors (HSI, MSH, etc) that were not submitted by the date of this report.

#### **vi. Key activities planned in Year 2 and estimated expenditures for each result**

PATH plans to intensify training activities and technical assistance in Odeska and Luganska oblasts to roll out DOTS services. Monitoring review meetings will enable analysis of project oblast TB-program performance and the development of site-specific plans for improvement. The Autonomous Republic of Crimea will become a priority region for enhancing MDR-TB case management. Training focused on MDR-TB and TB/HIV case management will be underway in the coming year. Key activities will be implemented in accordance with the Year 3 Detailed Implementation Plan (October 1, 2009 to September 30, 2010).

Within the current obligated funding of \$2,408,506 for Year 3, PATH is planning to spend \$928,711 for Result 1, \$142,959 for MDR TB-related activities and \$568,660 for TB/HIV activities to fulfill Result 2, and \$285,918 for Result 3. It is also planned to spend \$482,258 for TB-related activities in Crimea.

## Annex 1

**TB Control in Ukraine (IQC TASC 2)  
Contract number GHS-I-00-00034-00  
Project performance monitoring and evaluation plan**

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
1	TB incidence rate at the national level and in each project area (oblast level)	NTP data  Oblast TB program data	Reported nationally (85 TB cases per 100,000 population in 2005) and is calculated for each region.	No target for this impact indicator—it will serve a monitoring function and for further calculation of TB surveillance and NTP performance indicators.  <b>Year I (2007-2008)</b> - TB incidence (TB case notification) rate at the national level in 2007  <b>Year II (2008-2009)</b> – TB notification rate at the national level in 2008  <b>Year III (2009-2010)</b> - TB notification rate at the national level in 2009	<b>Year I</b> <b>79.8 TB cases per 100,000 population</b>  <b>Year II</b> <b>77.8 TB cases per 100,000 population</b>	An increase in reported TB incidence may indicate improved TB diagnosis and case registration rather than worsening of the TB situation.  <b>Year I</b> TB incidence rate in each project area is provided below in table 1  <b>Year II</b> TB incidence rate in each project area is provided below in table 1  TB incidence (case notification ) rate for 2009 will become available in March 2010.	Annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
2 AI	DOTS-based TB case detection rate at the national level and in project regions	WHO estimates  NTP data  Oblast TB program data	DOTS-based TB detection rate for cases registered in 2006 is a baseline indicator for the project Not available for sub national regions.	At or approaching 70% case detection by 2011 in project regions (project goal).  <b>Year I</b> (2007-2008) – DOTS-based TB detection rate for cases registered in 2006  <b>Year II</b> (2008-2009)– DOTS-based TB detection rate for cases registered in 2007  <b>Year III</b> (2009-2010)– DOTS-based TB detection rate for cases registered in 2008	  <b>Year I - 65%</b>  <b>Year II – 55%</b> <b>Estimated TB detection rate of new SS+ TB cases</b>	.WHO estimates of detection rates are available for TB cases notified in countries two years earlier.	annually
3 AI	TB treatment outcomes by a cohort analysis: - Treatment success · Treatment failure · Default · Died · Transferred	NTP data Oblast TB program data	Available for project regions.  Data on treatment success rates in patients who started treatment in 2006 (based on results of cohort analysis) are reliable only in the oblasts that have been covered previously by project activities. Oblasts that started analysis of TB treatment effectiveness based on a cohort analysis as part of the new M&E system - introduced in 2007 – need training and TA. A reliable	At or approaching 85% treatment success by 2011 in project regions (project goal).  <b>Year I</b> (2007-2008) – treatment results for patients who started treatment in 2006  <b>Year II</b> (2008-2009)–TB treatment results for patients who started treatment in 2007  <b>Year III</b> (2009-2010)–TB treatment results for patients who started treatment in 2008	  <b>Year I – 54.4%</b> <b>(average for project regions)</b>  <b>Year II – 54%</b> <b>(average for project regions)</b>  TB treatment outcomes of patients who started treatment in 2006 and 2007 in each project-target areas, stratified by a cohort analysis into: Treatment success	Note that per the cohort analysis final annual results are available in 12-15 months after the fourth cohort in a year is closed which will allow, for example, reporting treatment success in 2009 for 2007 cohorts (patients who started treatment in 2007)  2008 cohort data are in progress and will be available in March 2010.	annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
			overall rate in Ukraine are yet to be calculated.		<ul style="list-style-type: none"> <li>· Treatment failure</li> <li>· Default</li> <li>· Died</li> <li>· Transferred</li> </ul> are provided below in table 3 and 4.		
<b>4.</b> <b>AI</b>	DOTS coverage	NTP data  Project data	29%	50%  <b>Year I</b> (2007-2008) – 35%  <b>Year II</b> (2008-2009) – 40%  <b>Year III</b> (2009-2010) – 46%	<b>Year I - 35%</b>  <b>Year II – 41%</b>	<p>29% represents a proportion of the country population living in areas within the initial 8 administrative areas where WHO and PATH introduced DOTS-based TB control services.</p> <p>In Year II, coverage by improved DOTS services will be expanded primarily in the initial 8 administrative areas. In the new oblasts, administrative and training activities will trigger the improvement of DOTS practices to then significantly increase coverage in these regions (plus 10% of the population) in year III and IV.</p>	annually
<b>5</b> <b>AI</b>	Case notification rate in new sputum smear positive pulmonary TB cases	NTP data  Oblast TB program data	Not available nationally, but can be calculated for the current project regions using the available data.	No target for this indicator—it will serve a monitoring function and for further calculation of TB surveillance and NTP performance indicators.  <b>Year I</b> (2007-2008) – TB notification rate in new sputum smear positive pulmonary TB cases reported in 2007	<b>Year I - 35.3 (35.2 including Lugansk)</b>	Data collection system is not standardized throughout the country yet. Project regions will be able to monitor these data, however. While seeking a decrease in case notification rate, a temporary increase in reported new sputum smear positive pulmonary TB cases will	annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
				<p><b>Year II</b> (2008-2009) – TB notification rate in new sputum smear positive pulmonary TB cases reported in 2008</p> <p><b>Year III</b> (2009-2010) – TB notification rate in new sputum smear positive pulmonary TB cases reported in 2009</p>	<p><b>Year II – 34.5 SS+ TB cases per 100,000 population (average for project regions)</b> Case notification rate in new SS+ TB cases in each project area is provided below in table 4</p> <p><b>National average in 2007 - 31.5 2008 – 31.6 SS+ TB cases per 100 000 population.</b></p>	most probably indicate improved TB diagnosis by microscopy and culture and enhanced case registration rather than worsening of the TB situation and delayed TB detection..	
<b>6 AI</b>	TB microscopy laboratory coverage: Average population per TB microscopy unit	NTP data  Oblast TB program data	In the current project regions, there is one Level I lab per 68,000 population, in addition to many Level II labs performing smear microscopy.	Adequate coverage - one quality Level I laboratory per approximately 70 - 100,000 population, taking into account the need to ensure coverage of remote areas.	<p><b>Year I and Year II – There is one Level I Lab per 55,000 population</b> TB microscopy laboratory coverage in each project area is provided below in table 5</p> <p>Having the decreasing population, the number of Level I laboratories was not decreased by health administrations. Further work is needed to analyze the workload with microscopy testing.</p>	The objective is to decrease the number of labs so that the workload is sufficient to maintain quality while ensuring coverage (especially for remote areas).	annually
<b>7 AI</b>	Proportion of TB laboratories with less than 5% error on sputum	Laboratory External Quality Assurance	Two laboratories in the current project regions functioning at	More than 70% of laboratories in the project regions with <5% error on	<b>Year I - Performed</b> EQA procedures, non-representative		annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
	smear microscopy	(EQA) records	this level of proficiency.	smear results.  <b>Year II</b> – 20% of laboratories in the project regions with <5% error on smear results.  <b>Year III</b> – 50% of laboratories in the project regions with <5% error on smear results.	smear results.  <b>Year II</b> – 43 % of laboratories in pilot regions took part in the last round of EQA and <b>92 %</b> of them pass it with error level less then 5%.		
Project Data							
<b>8. AI</b>	Number of people trained in any Stop TB Strategy elements	Project records	7,000 from all DOTS efforts (PATH and WHO).	10,000  <b>Year I</b> (2007-2008) – 600  <b>Year II</b> (2008-2009) – 1000	<b>Year I - 1,124</b> Previously established infrastructure for training, especially for primary health care providers, was the main reason that the project was able to exceed its Stop TB Strategy training targets.  <b>Year II - 2408</b>	Cumulative total as a result of additional training through this project only	quarterly

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
				<b>Year III</b> (2009-2010) – 800			
<b>9.</b>	Number of laboratory review meetings held in project regions	Project records	Not done currently	<p><b>Year I</b> (2007-2008) - At least 24 lab review meetings held in the initial eight project regions</p> <p><b>Year II</b> (2008-2009) – at least 18 lab review meetings held in 9 project areas (semi-annually)</p> <p><b>Year III</b> (2009-2010) – at least 20 lab review meetings held in 10 project areas (semi-annually)</p>	<p><b>Year I - 10</b></p> <p><b>Year II – PATH</b> monitored 16 review meetings (in 8 project areas each 6 months) and provided technical support to conveying extended 7 laboratory review meetings.</p>	Financial and time constraints may most probably allow conducting lab review meetings by oblast TB specialists semi-annually	Quarterly
<b>10.</b>	Number of project regions providing accurate and timely TB surveillance and NTP performance data	Project records	Analysis of accuracy and timeliness is not conducted currently	<p><b>Year I</b> (2007-2008) - Eight current project regions provide accurate and timely TB data for annual data collection and analysis</p> <p><b>Year II</b> (2008-2009) – nine project areas provide accurate and timely TB data for annual data collection and analysis</p> <p><b>Year III</b> (2009-2010) – ten project areas provide accurate and timely TB data for annual data collection and analysis</p>	<p><b>Year I – 8</b> regions provide data in a timely manner, but accuracy needs to be addressed in further trainings (findings of supervision visits)</p> <p><b>Year II - 9</b> regions provide data in a timely manner, but accuracy needs to be addressed in further trainings and supervision visits</p>		quarterly

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
11	Proportion of new TB cases diagnosed with MDR-TB	NTP data Oblast TB program data	No accurate data available.	No target for this indicator—it will serve a monitoring function only. No measurable effect on MDR-TB prevalence can be achieved during the project period.  <b>Year II</b> (2008-2009) – data reported in 2008  <b>Year III</b> (2009-2010) – data reported in 2009	<b>Year I - There is no reliable data on MDR-TB.</b> To date, there are reliable data only in Donetsk oblast. National NTP reported 11% of MDR-TB among new TB cases, however, this data are not supported by reliable MDR-TB testing. <b>Year II - There is no reliable data on MDR-TB.</b> The implementation of temporal MDR-TB recording and reporting forms has been launched in 2009.	Although DST occurs in many areas, there is no quality assurance and results are not accurate. Tracking will help identify sites for intervention to improve accuracy of results, rather than measuring true MDR-TB incidence.	annually
12	Proportion of MDR-TB cases diagnosed as XDR-TB	Laboratory data Oblast TB program data	No data available.	High-quality data available for at least 2 project regions. No measurable effect on XDR-TB prevalence can be achieved during the project period  <b>Year II</b> – preparation in progress  <b>Year III</b> – preparation in progress	<b>Year I - There is no reliable data on XDR-TB.</b>  <b>Year II - There is no reliable data on XDR-TB.</b>	No in-country capacity for second-line drug susceptibility testing exists. PATH will work with the two labs capable of accurate first line DST to increase their capacity.	annually
13	Number of DOTS-Plus projects operating in project areas	Project records Oblast TB program data	Donetska Oblast is operating one DOTS Plus pilot project from 2007 with support	2 additional pilot sites supported by the project.	<b>Year I – 1 MDR TB case management program operates in Donetsk oblast with</b>		annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
			from WHO.	<p><b>Year II</b> (2008-2009) – preparation in progress</p> <p><b>Year III</b> (2009-2010) – Crimea, Zaporozhska and Dnipropetrovska oblasts</p>	<p>WHO support</p> <p><b>Year II – 1</b> MDR TB case management program operates in Donetsk oblast with WHO support</p>		
14	Number of laboratories performing quality assured TB culture and first-line drug susceptibility testing (DST) according to international standards	Laboratory EQA records Laboratory TA reports Laboratory supervision records	1 (Donetska only)	5	<p><b>Year I</b> – Laboratory of the Donetsk Oblast TB Hospital only</p> <p><b>Year II</b> – 4 laboratories</p>		Quarterly
15	TB/HIV co-infection service coverage	AIDS Center records Oblast TB program data Project data	No data available	30% of the population countrywide have access to both TB and HIV services through improved referral, diagnosis and treatment	<p><b>Year I</b> – TB/HIV services including HIV service NGOs and multidisciplinary teams were established &amp; supported in three pilot sites: Gorlovka, Mariupol and Dniprodzerjinsk. Referral pathways were designed, tested and implemented. This work will be expanded to other sites in the next years.</p> <p><b>Year II</b> – Zaporozhie</p>		annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
					region 100% of the population, Kherson region 10%, Kharkov region 10%, Odessa region 10%, Dnepropetrovsk region 10%		
				<b>Year III</b> (2009-2010) – 20% of population			
<b>16 AI</b>	Number of HIV-infected clients attending HIV care/treatment services that are receiving treatment for TB disease	AIDS Center records Oblast TB program data Project data	No regular data available.	Recording of and provision of services to at least 300 TB/HIV cases on TB treatment will be cross-checked in AIDS and TB centers annually  <b>Year I</b> (2007-2008) - to cross-check 300 TB/HIV cases at TB and HIV AIDS centers  <b>Year II</b> (2008–2009) recording of 300 TB/HIV cases will be cross-checked in TB and AIDS centers  <b>Year III</b> (2009–2010) recording of 300 TB/HIV cases will be cross-checked in TB and AIDS centers	<b>Year I</b> - 300 TB/HIV cases were cross-checked in TB and AIDS centers  <b>Year II</b> - 346	Reflecting the number of recorded TB/HIV patients, the indicator will serve primarily a monitoring function.	annually
<b>17 PI</b>	Cumulative number of individuals provided with HIV-related palliative care including TB/HIV	AIDS Center records TB/HIV pilot project data TB program data HIV/AIDS Capacity Project data	No data available.	30,000 through this project (this indicator may require revision in discussion with USAID/Kyiv Mission).  <b>Year II</b> (2008-2009) –350 TB/HIV cases receiving palliative care in health	<b>Year I</b> - 350 TB/HIV cases  <b>Year II</b> – 346 TB/HIV cases	This project will focus on TB/HIV-related palliative care only. Other palliative care will be provided through the HIV/AIDS Capacity Project. Data collection will require coordination with that project to avoid double counting.	annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
				facilities in project areas which employ health professionals who were trained under the project (5,000 HIV cases in project area)  <b>Year III</b> (2009-2010) – 400 TB/HIV cases (15,000 HIV cases in project area)	(12,747 HIV cases)	The National AIDS Center started implementation of a patients tracking e-system in April 2008 and will be able to provide relevant precise data since April 2009. These data are currently under analysis.	
<b>18 PI</b>	Number and proportion of registered TB patients who received HIV counseling and testing and received their test results	Oblast TB program data TB facility records	To be collected for project regions through review of existing TB data.	85 % of all registered TB patients by 2011.  <b>Year II</b> (2008-2009) – at least 60% of registered TB patients in 9 oblasts receive quality counseling  <b>Year III</b> (2009-2010) – at least 75% of registered TB patients in 9 oblasts receive quality counseling	<b>Year I – 9000 (60%)</b> A preliminary data suggest that 1522 patients in Dnepropetrovsk Oblast which corresponds to 64% and 2210 patients in Kherson oblast (65%) received HIV counseling, testing and received test results.  <b>Year II –11,349</b>  Revised recording and reporting TB forms track this information. These data are not yet available nationwide.		annually
<b>19</b>	Proportion of registered HIV-positive individuals who receive screening for TB	AIDS Center records	Data not available.	100% of registered HIV positive individuals in project regions will receive an initial screening for TB by 2011.	<b>Year I –</b> The National AIDS Center started implementation of a patients tracking e-	Project will also introduce TB screening tool for use at each client visit, but this is too difficult to measure	annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
				<p><b>Year II</b> (2008-2009) – at least 50% of HIV-positive individuals in Donetsk, Zaporizhska, Khersonska, Kharkivska, Dnipropetrovska oblasts, Kyiv and Sevastopol cities</p> <p><b>Year III</b> (2009-2010) – at least 65% of HIV-positive individuals in Donetsk, Zaporizhska, Khersonska, Kharkivska, Dnipropetrovska oblasts, Kyiv and Sevastopol cities</p>	<p>system in April 2008 and will be able to provide relevant precise data in 2009. These data are currently being analyzed.</p> <p><b>Year II</b> – 46% of new HIV cases - according to project target regions</p>	<p>project wide and will be tracked as part of supervision.</p>	
<b>20.</b>	Number of HIV service organizations participating in TB symptom screening of clients	Project records	No data	<p>At least 16 organizations in pilot regions</p> <p><b>Year I</b>- at least 3 organizations</p> <p><b>Year II</b> (2008-2009) – additional 5 organizations</p> <p><b>Year III</b> (2009-2010) – additional 6 organizations</p>	<p><b>Year I – 6</b></p> <p><b>Year II – 18</b></p>		annually
<b>21 PI</b>	Number of service outlets providing voluntary HIV counseling and testing	AIDS Center data TB program data Health facility records	Data not available.	<p><b>Year II</b> (2008-2009) – 24 (cumulative)</p> <p><b>Year III</b> (2008-2009) – 12</p>	<p><b>Year I - 16</b> (initial Oblast TB and HIV Centers, 2 Kiev City dispensaries)</p> <p><b>Year II - 39</b></p>	<p>Because of the current HIV screening requirements in Ukraine, this indicator will also include facilities that provide provider-initiated counseling and testing and diagnostic counseling and testing.</p>	annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
				outlets			
22	Number of individuals trained to provide clinical prophylaxis and/or treatment for TB to HIV-infected individuals	Project records	None (through project activities).	By the end of the project – 265  <b>Year I</b> (2007-2008) – 30 <b>Year II</b> (2008-2009) – 100 <b>Year III</b> (2009-2010) - 50	<b>Year I – 47</b> <b>Year II - 119</b>	This indicator was added as training in TB/HIV clinical management is an objective of this project.	Quarterly
23	Cumulative number of service outlets providing clinical prophylaxis or treatment services for Tuberculosis for HIV-infected individuals	Project records	Data not available.	28  <b>Year I</b> (2007-2008) – 16  <b>Year II</b> (2008-2009) – 24  <b>Year III</b> (2009-2010) - 14	<b>Year I - 16</b> id HIV Centers, 2 Kiev City dispensaries)  <b>Year II - 39</b>		annually
24 <b>PI</b>	Number of local organizations provided with TA for HIV-related institutional capacity building	Project records	Data not available.	20 organizations  <b>Year II</b> (2008-2009) – 5  <b>Year III</b> (2009-2010) - 10	<b>Year I – 7</b>  <b>Year II - 15</b>	Most of this work will occur through GFATM and HIV/AIDS Capacity Project—this project will provide training to staff so that organizations can engage effectively in HIV-related activities.	annually
25 <b>PI</b>	Number of individuals trained in HIV-related institutional capacity building	Project records	Data not available	80 individuals  <b>Year II</b> (2008-2009) – at least 30 persons  <b>Year III</b> (2009-2010) – additional 40 persons	<b>Year I – 28</b>  <b>Year II -137</b>	As above.	Quarterly
26 <b>PI</b>	Number of civil society organizations provided with TA for	Project records	<5	16 At least 2 organizations per project region will be active	<b>Year I - 6 (Odessa 1</b>	This combines two suggested indicators, since organizations will	annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
	participating in TB control, TB/HIV and HIV advocacy and /or policy development activities			in TB control, TB/HIV and HIV advocacy and policy development on a consistent basis  <b>Year II</b> (2008-2009) – 5 organizations  <b>Year III</b> (2009-2010) – additional 8	+ <b>Dnipropetrovsk 1 + Zaporizhia 3 + Kiev 1</b>  <b>Year II - 15</b>	receive both TB and HIV-related support.	
<b>27 PI</b>	Number of individuals trained in HIV-related policy development	Project records	Data not available	32 At least 2 persons from each local NGOs (2 organizations per project region) which will be active in TB control, TB/HIV and HIV advocacy and policy development on a consistent basis  <b>Year II</b> (2008-2009) – the number will be discussed with partner organizations  <b>Year III</b> (2009-2010) - 16	<b>Year I – 8</b>  <b>Year II - 36</b>	This effort will be done in coordination with stakeholder organizations involved in HIV-related TA: HIV Alliance, Constella Futures and others	annually
<b>28.</b>	Number of medical and nursing school incorporating DOTS training into their curriculum	Project record	One medical and one nursing school in Dnepropetrovsk region	At least 8 medical educational institutions  <b>Year II</b> (2008-2009) – an additional medical school	<b>Year I</b> – One medical school in Dnepropetrovsk region  <b>Year II</b> – 3 Medical Educational Institutions (Medical School in Dnepropetrovsk, Medical School in Donetsk, Postgraduate Academy for Continuous Medical		annually

#*	Indicator	Data source(s)	Baseline value(s)	Target value	Actual value	Comments	Timing/ status
				Year III (2009-2010) – 3 additional medical schools	Education in Kharkov)		
29	Number of identified obsolete policies, laws, or regulations that have been canceled, replaced, or revised to comply with international standards	Constella Futures documents Policy review	~18	The identified priority documents are in compliance with international standards.  Year II (2008-2009) – 3 priority documents  Year III (2009-2010) – 5 documents	Year I – 2  Year II – 6 (cumulative)	This is a revision of a suggested indicator. The total number of documents in need of revision to be determined by the Constella Futures review, which is soon to be completed.	annually
30 PI	Number of individuals trained to provide social support services and in HIV- and TB related stigma and discrimination reduction	Project records	700	1,900  Year I (2007-2008) – TOT  Year II (2008-2009) – follow on trainings to 400 participants  Year III (2009-2010) – additional 600	Year I – 31  Year II - 373	Stigma reduction training will be incorporated into other broader trainings.	quarterly
31	Number of Individuals trained in TB and HIV-related policy development	Project records	None (through project activities).	80  Year II (2008-2009) –24 persons  Year III (2009-2010) – additional 40 persons	Year I – 12  Year II - 36	This combines two suggested indicators, since individuals will receive both TB and HIV-related support.	annually
32	Number of project regions with local advocacy plans	Oblast data Project records	None.	10  Year II – 3 regions  Year III – additional 4 regions	Year I – 3  Year II – 6 (cumulative)	This replaces a suggested indicator.	annually

\* AI—Agency indicator; PI—PEPFAR indicator

**Table 1. TB incidence rates by region (per 100,000 population)**

	Administrative regions and areas (project sites)										
Year	Ukraine	Luganska	Odeska	Dnipro- petrovska	Khar- kivska	Kherson- ska	Donetska	Zapori- zhska	Crimea	Sevas- topol	Kyiv
2006	83.2	111.7	94.6	99.1	84.5	155.7	99.4	89.8	85.0	65.8	52.9
2007	79.8	103.5	87.1	94.1	78.6	151.4	94.7	91.3	85.2	68.4	46.9
2008	77.8	101.4	87.4	92.0	72.4	123.8	91.1	81.9	86.9	67.0	47.4

**Table 2. TB treatment outcomes (2006 cohort),**

Oblasts	% Treatment success	% Died	% Failure	% Default	% Transferred
AR Crimea	70.4	9.4	9.8	5.9	4.5
Dnipropetrovska	49.9	13.9	16.5	13.9	5.6
Donetska	58.4	16.2	9.3	11.7	4.5
Zaporizhska	63.1	11.5	10.6	7.5	7.2
Kharkivska	53.1	14.6	13.9	11.5	6.9
Khersonska	44.0	13.8	21.3	14.9	6.0
Kyiv	47.6	11.5	15.5	19.3	6.1
Sevastopol	48.1	13.2	17.0	15.1	6.6
Odeska	54.9	12.9	18.7	10.4	3.1
<b>Average</b>	<b>54.4</b>				

**Table 3. New regular treatment outcomes in project-target areas (2007 cohort)**

	<b>% Treatment success</b>	<b>% Died</b>	<b>% Failure</b>	<b>% Default</b>	<b>% Transferred</b>
AR Crimea	62.4	9.7	14.2	8.2	5.5
Dnipropetrovska	51.5	16.9	12.1	12.6	6.9
Donetska	58.0	17.4	8.2	9.9	6.5
Zaporizhska	57.5	9.9	14.1	10.8	7.7
Kharkivska	50.8	14.8	16.0	12.9	5.4
Khersonska	46.5	12.7	19.6	13.8	7.3
Kyiv	51.8	9.9	11.9	22.6	3.9
Sevastopol	50.5	11.2	17.8	12.1	8.4
<b>Average in project areas</b>	<b>54.0</b>				

**Table 4. Case notification rate in new SS+ TB cases per 100 000 population**

<b>Region</b>	<b>2007</b>	<b>2008</b>
AR Crimea	39.5	37.3
Dnipropetrovska	33.0	30.3
Donetska	33.9	37.5
Zaporizhska	38.5	36.4
Luganska	34.4	33.7
Odeska	34.1	36.9
Kharkivska	32.8	30.5
Khersonska	50.6	44.8
Kyiv	26.8	27.3
Sevastopol	28.1	29.1
<b>Average</b>	<b>35.2</b>	<b>34.4</b>

**Table 5. Average population per TB microscopy unit, 2008**

<b>Oblasts</b>	<b>Population per Level I lab</b>	<b>Population per Level II lab</b>	<b>Population per Level III lab</b>
AR Crimea	75,964	658,357	1,975,070
Dnipropetrovska	66,228	573,978	3,443,866
Donetska	64,930	329,289	4,610,039
Zaporizhska	41,339	620,081	930,121
Kharkivska	58,612	468,897	1,406,690
Khersonska	34,092	281,257	1,125,026
Kyiv	88,397	883,972	2,651,917
Sevastopol	41,901		377,109
Odessa	18,924	596,102	1,192,204
<b>Average</b>	<b>54,487</b>		

## Annex 2

DOTS coverage October 2007 - September 2009



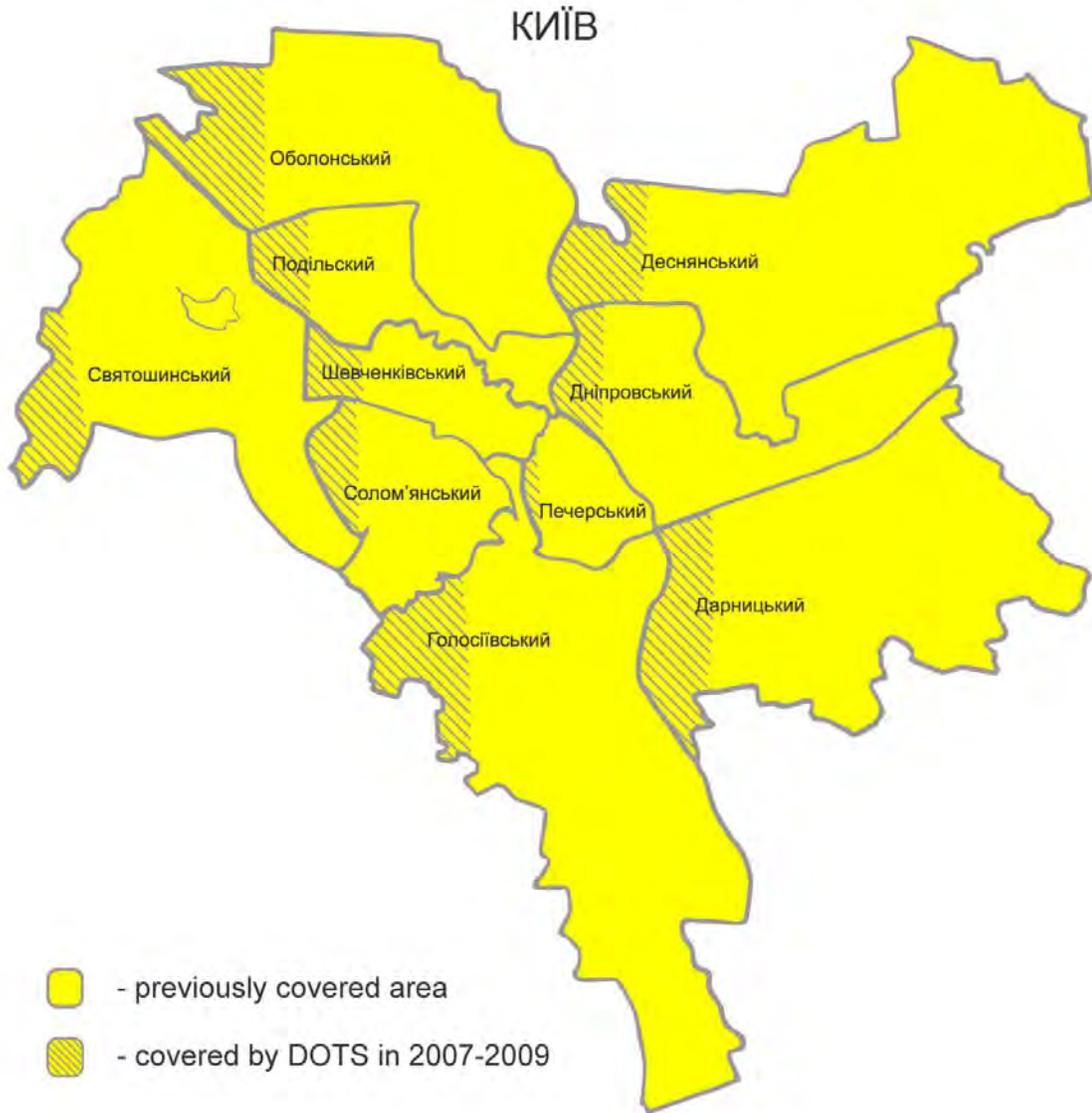
# Annex 3

DOTS coverage October 2007 - September 2009



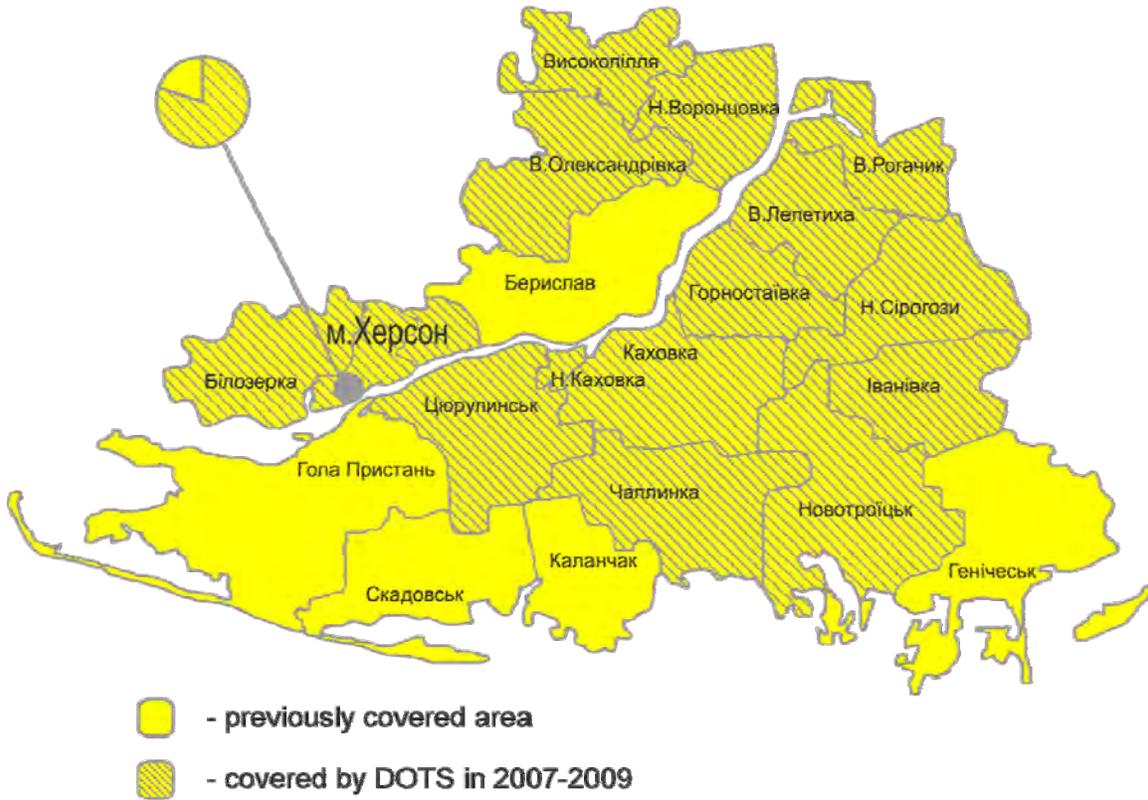
# Annex 4

DOTS coverage October 2007 - September 2009



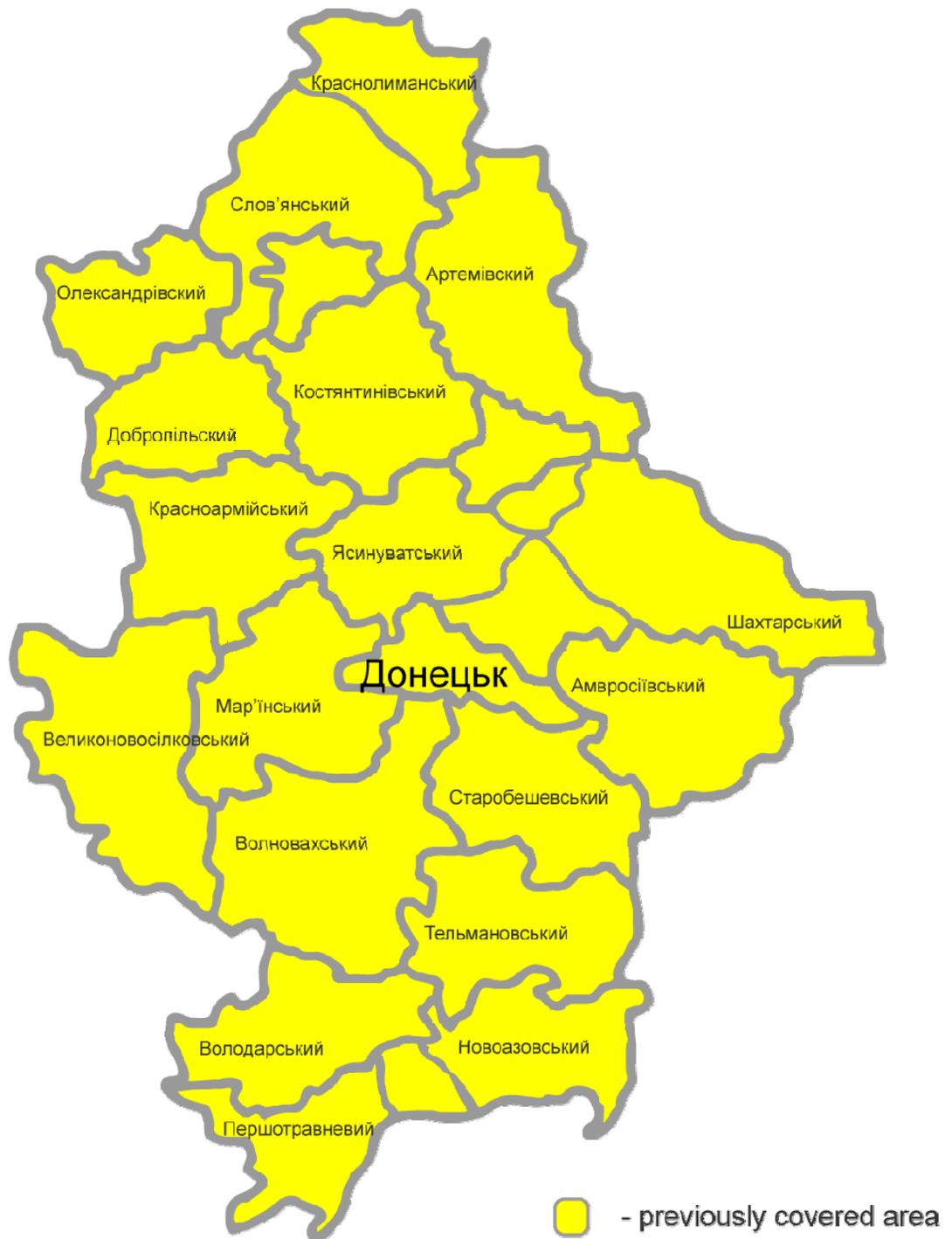
# Annex 5

DOTS coverage October 2007 - September 2009



## Annex 6

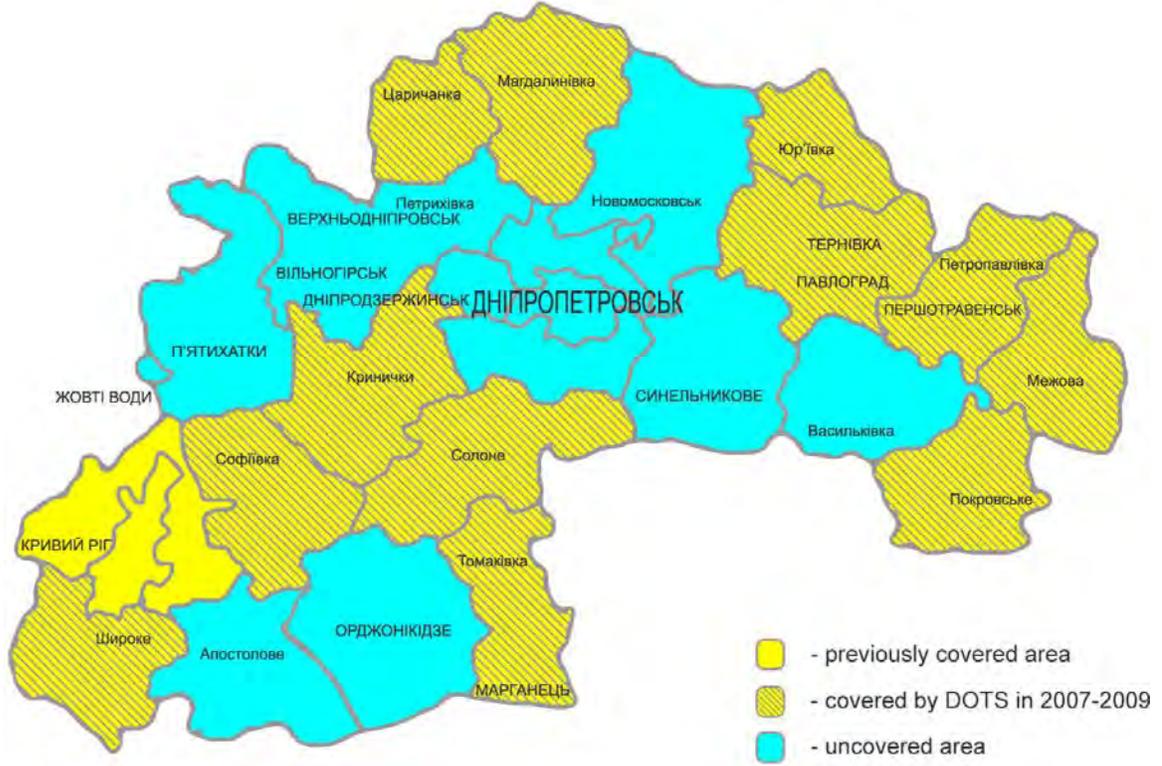
DOTS coverage October 2007 - September 2009





# Annex 8

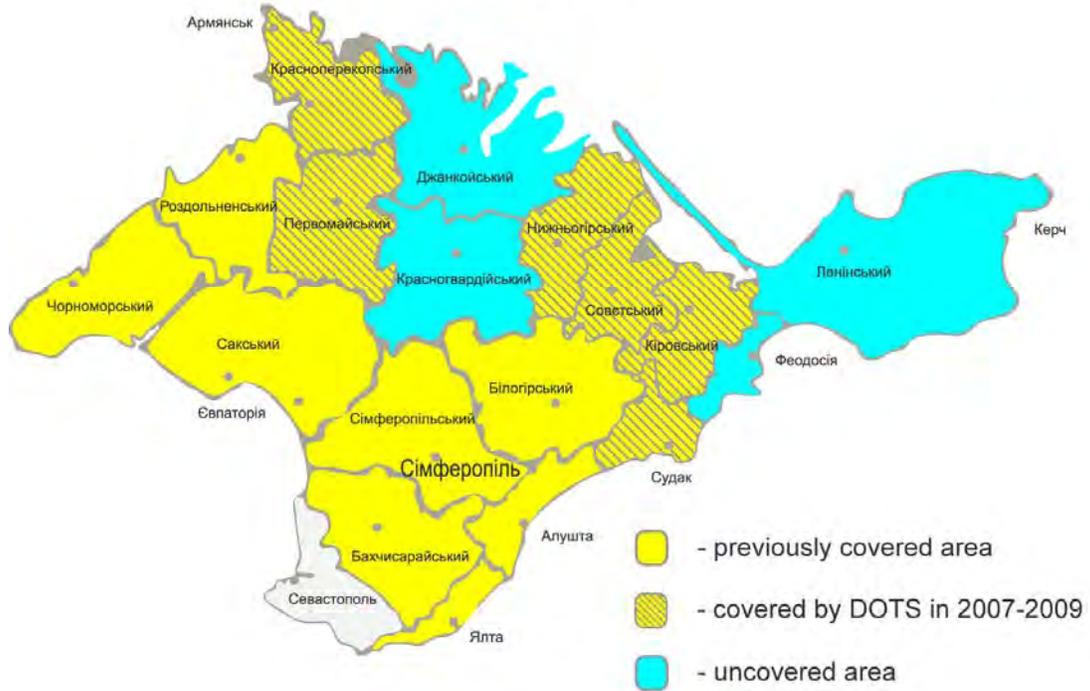
DOTS coverage October 2007 - September 2009



# Annex 9

DOTS coverage October 2007 - September 2009

## КРИМ



## Annex 10

DOTS coverage October 2007 - September 2009



# Annex 11

DOTS coverage October 2007 - September 2009



**Annex 12. Training activities of the TB Control Partnership Project,  
Year 2  
(October 1, 2008–September 30, 2009)**

<b>Sites</b>	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>
	<b>Number and type of trained specialists:</b>	<b>Number and type of trained specialists:</b>	<b>Number and type of trained specialists:</b>	<b>Number and type of trained specialists:</b>
<b>Dnipro petrovska Oblast</b>	1 training on MDR TB treatment – 1 TB specialist		4 Lab trainings – 54 Lab specialists (PHC). 2 TB/HIV TOT (Kiev) – 1 TB specialist. 1 TB/HIV training – 2 Red Cross representatives.	1 Lab ToT (Yalta) – 1 Lab specialist 1 Lab ToT (Riga) – 2 Lab specialists 1 TB/HIV training for NGOs – 1 RC representative MDR TB workshop (Riga)-2 TB specialists
<b>Donetska Oblast</b>	1 M&E training – 1 statistician	3 M&E trainings – 46 TB specialists (2 persons from Dnepropetrovsk oblast)	2 TB/HIV TOT (Kiev)– 1 TB specialist. 1 TB/HIV TOT (Odessa) – 1 TB specialist. 1 TB/HIV training – 1 Red Cross representative.	1DOTS TOT(Odessa) – 3 TB specialists. 1 Lab ToT (Yalta) – 1 Lab specialist 1 TB/HIV training – 9 TB specialists, 5 infection disease specialists 1 TB/HIV training for NGOs – 1 RC representative MDR TB workshop (Riga)- 1 TB specialist
<b>Kharkovska Oblast</b>	1 training on MDR TB treatment – 2 TB specialists. 1 M&E training – 1 statistician	1 DOTS training - 21 PHC providers, 9 nurses. 1 M&E training – 5 TB specialists, 10 nurses. 1 Lab training – 21 Lab specialists (TB institutions)	5 DOTS trainings – 43 PHC providers, 1 TB specialist, 1 infection diseases specialist, 105 nurses. 1 MDR TB training – 40 TB specialists. 1 Lab training – 12 Lab specialists (PHC). 1 TB/HIV TOT (Odessa) – 1 TB specialist, 1 statistician. 1 TB/HIV training – 1 Red Cross representative.	2 DOTS trainings – 28 PHC providers, 34 nurses. 1 Lab ToT (Yalta) – 2 Lab specialists 1 Lab ToT (Riga) – 2 Lab specialists 2 TB/HIV trainings – 21 TB specialists, 8 infection diseases specialists, 11 epidemiologists 1 TB/HIV training for NGOs – 1 RC representative MDR TB workshop (Riga)-1 TB specialist

<b>Khersonska Oblast</b>	<p>1 DOTS training – 23 nurses and 2 lab specialists.</p> <p>1 M&amp;E training – 1 TB specialist</p>	<p>6 DOTS trainings – 9 PHC providers, 32 nurses, 56 TB specialists.</p> <p>4 M&amp;E trainings – 27 TB specialists, 30 nurses.</p>	<p>3 DOTS trainings – 19 PHC providers, 1 infection diseases specialist, 3 epidemiologists, 45 nurses.</p> <p>2 MDR TB trainings – 44 TB specialists, 2 statisticians.</p> <p>1 Lab training – 16 Lab specialists (PHC).</p> <p>2 TB/HIV TOT (Kiev) – 1 TB specialist, 1 infection diseases specialist.</p> <p>1 TB/HIV – 2 Red Cross representatives.</p> <p>1 seminar for oblast health administrators – 47 participants.</p>	<p>4 DOTS trainings – 15 PHC providers, 2 infection diseases specialists, 3 epidemiologists, 1 mental diseases specialist, 1 lab specialist, 72 nurses.</p> <p>1 Lab training – 12 Lab specialists (PHC).</p> <p>1 TB/HIV training for NGOs – 2 RC representatives</p>
<b>Kyiv</b>	<p>1 training on MDR TB treatment – 5 TB specialists.</p> <p>1 M&amp;E training – 2 statisticians</p>	<p>1 TB/HIV Work Groups meeting – 3 TB specialists, 2 statisticians, 3 infection disease specialists, 22 NGO's representatives</p>	<p>5 Lab trainings – 50 Lab specialists (PHC).</p> <p>1 training on TB control program management (Riga) - 2 TB specialists.</p> <p>2 TB/HIV TOT (Kiev) – 3 TB specialists, 3 infection diseases specialists.</p>	<p>1 TB/HIV training for NGOs – 3 RC representatives; 4 NGO representatives</p> <p>MDR TB workshop (Riga)-5 TB specialists</p> <p>WHO-KNCV TB Programme Management training (Riga)- 3 TB specialists</p>
<b>Luganska Oblast</b>		<p>The Conference for Lugansk Oblast Health Administrators “USAID TB Control Partnership Project Implementation in Ukraine” – 15 PHC providers, 34 TB specialists, 11 Lab specialists, 7 Lugansk oblast</p>	<p>7 Lab specialists (TB institutions), 8 Lab specialists (PHC) - Lab trainings in Kharkov &amp; Kiev.</p> <p>5 NGO's representatives, 1 TB specialist– 1 TB/HIV training (Kiev).</p> <p>1 TB/HIV – 1 Red Cross representative.</p>	<p>1DOTS TOT(Odessa) – 1 TB specialist, 1 Lab specialist.</p> <p>1Lab training – 14 Lab specialists</p> <p>1 Lab ToT (Yalta) – 2 Lab specialists</p> <p>1 Lab ToT (Riga) – 1 Lab specialist</p> <p>1 TB/HIV training for NGOs – 1 RC representative</p> <p>WHO-KNCV TB Programme Management training</p>

		health administrators, 1 bacteriologist, 1 statistician		(Riga)-1 TB specialist
<b>Odeska Oblast</b>		1 DOTS training - 18 TB specialists 1 Lab training – 14 Lab specialists (PHC)	2 DOTS trainings – 40 TB specialists. 2 Lab trainings – 15 Lab specialists (PHC), 15 Lab specialists (TB institutions). 2 M&E trainings – 35 TB specialists, 2 statisticians. 2 TB/HIV TOT (Kiev) – 1 infection diseases specialist. 10 NGO’s representatives, 1 infection diseases specialist, 2 nurses – 1 TB/HIV training (Kiev). 1 TB/HIV TOT (Odessa) – 5 TB specialists, 1 infection diseases specialist, 1 epidemiologist, 1 NGO’s representative. 1 TB/HIV – 1 Red Cross representative.	1DOTS TOT (Odessa) – 10 TB specialists, 1 Lab specialist. 2 DOTS trainings – 37 TB specialists 1 Lab ToT (Yalta) – 2 Lab specialists 1 TB/HIV training for NGOs – 1 RC representative MDR TB workshop (Riga)-1 TB specialist
<b>Sevastopol</b>	1 training on MDR TB treatment – 1 TB specialist		1 M&E training – 11 TB specialists, 8 statisticians, 1 nurse. Round Table – 27 health administrators. 1 Lab training – 12 Lab specialists (PHC). 2 TB/HIV TOT (Kiev) – 1 TB specialist. 1 TB/HIV – 1 Red Cross representative	1 Lab ToT (Riga) – 1 Lab specialist 1 TB/HIV training for NGOs – 1 RC representative
<b>Crimea</b>			3 Lab specialists (TB institutions) – Lab training in Kharkov. 2 TB/HIV TOT (Kiev) – 2 TB specialists. 1 TB/HIV – 1 Red Cross representative.	1DOTS TOT(Odessa) – 4 TB specialists. 1 Lab ToT (Yalta) – 1 Lab specialist 1 Lab ToT (Riga) – 1 Lab specialist 1 TB/HIV training for

				NGOs – 1 RC representative
<b>Zaporizhska Oblast</b>	<p>1 DOTS training - 4 PHC providers and 14 nurses</p> <p>1 training on MDR TB treatment – 2 TB specialists</p> <p>1 TB/HIV training – 54 TB specialists, 76 infectionists, 1 PHC provider</p>	<p>4 DOTS training - 47 PHC providers and 68 nurses.</p> <p>1 TB/HIV TOT training – 5 TB specialists, 9 nurses, 1 psychologist.</p> <p>8 TB/HIV Work Groups meetings – 4 TB specialists, 1 statistician, 3 infection disease specialists, 3 NGO's representatives</p>	<p>9 DOTS trainings – 39 PHC providers, 92 TB specialists, 6 statisticians, 47 nurses.</p> <p>1 Lab training – 12 Lab specialists (PHC).</p> <p>2 TB/HIV TOT (Kiev) – 4 TB specialists.</p> <p>5 TB/HIV trainings Zaporizhzhya) - 62 TB specialists, 16 infection diseases specialists, 30 epidemiologists.</p> <p>1 TB/HIV – 1 Red Cross representative</p>	<p>1 DOTS training – 13 PHC providers, 1 TB specialist, 16 nurses.</p> <p>1 Lab ToT (Yalta) – 2 Lab specialists</p> <p>1 Lab ToT (Riga) – 1 Lab specialist</p> <p>9 TB/HIV trainings (Zaporizhzhya) – 70 Nurses; 93 TB specialists; 11 infection disease specialists; 8 epidemiologists; 3 statisticians</p> <p>1 TB/HIV training for NGOs – 1 RC representative</p> <p>TB/HIV Coordination Council workshop- 40 TB specialists; 24 infection disease specialists</p> <p>2 TB/HIV Work Group meetings – 2 TB specialists, 1 statistician, 1 infection disease specialist, 1 epidemiologist</p> <p>MDR TB workshop (Riga)-2 TB specialists</p>
<b>Penitentiary System</b>	1 Laboratory training – 25 Lab specialists			
<b>Total trainings</b>	<b>6</b>	<b>33</b>	<b>58</b>	32
<b>DOTS</b>		<b>12</b>	<b>19</b>	10
<b>MDR TB</b>			<b>3</b>	1
<b>M&amp;E</b>		<b>8</b>	<b>3</b>	
<b>LAB</b>		<b>2</b>	<b>15</b>	4
<b>TB/HIV</b>		<b>1</b>	<b>10</b>	14
<b>TB/HIV WG meetings</b>		<b>9</b>	<b>8</b>	2
<b>The Conference</b>		<b>1</b>		

<b>for Luganska Oblast Health Administrators</b>				
<b>WHO KNCV TB Control Programme management training</b>				1
<b>Total number of trained specialists:</b>	5 PHC providers	<b>92 PHC providers</b>	<b>101 PHC providers</b>	<b>57 PHC providers</b>
	66 TB specialists	<b>198 TB specialists</b>	<b>348 TB specialists</b>	<b>237 TB specialists</b>
	37 Nurses	<b>158 Nurses</b>	<b>199 Nurses</b>	<b>192 Nurses</b>
	27 Lab specialists	<b>46 Lab specialists</b>	<b>205 Lab specialists</b>	<b>48 Lab specialists</b>
	4 Statisticians	<b>4 Statisticians</b>	<b>13 Statisticians</b>	<b>4 Statisticians</b>
	76 Infectionists	<b>7 Infectionists</b>	<b>25 Infectionists</b>	<b>51 Infectionists</b>
			<b>34 epidemiologists</b>	<b>23 epidemiologists</b>
		<b>25 NGO's representatives</b>	<b>27 NGO's representatives</b>	<b>17 NGO's representatives</b>
		<b>1 psychologist</b>		
		<b>7 health administrators</b>	<b>74 health administrators</b>	
<b>Total number of persons trained</b>	<b>215</b>	<b>538</b>	<b>1026</b>	<b>629</b>

\*In the Conference for Lugansk Oblast Health Administrators “USAID TB Control Partnership Project Implementation in Ukraine” took part the heads of 7 Lugansk oblast health administrations, 15 heads of the Lugansk oblast PHC institutions, 34 chief district TB specialists, 11 chief district laboratory specialists, 1 chief bacteriologist, 1 head of the statistic department of the Luganska oblast TB Hospital.

**TRIP REPORT FOR THE PRE-ASSESSMENT MISSION**

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**FOR THE UKRAINIAN TB LABORATORY NETWORK**  
**HUMAN RESOURCE ASSESSMENT**

PREPARED BY:

ANNE MARTIN-STAPLE, PHD

HEALTH STRATEGIES INTERNATIONAL, LLC

JULY 2 –JULY 25 2009

## **Human Resource (HR) Pre-Assessment of the Ukrainian TB Laboratory Network**

### **INTRODUCTION**

PATH has been working on TB in Ukraine since 2001 and is currently in a 4-year Task Order (TO3) through the USAID Mission in Kyiv. This sub-contract is supporting laboratory strengthening by carrying out a human resource (HR) assessment that was included into the TO3 work plan for Year 2.

There is a critical shortfall of qualified staff within the Ukrainian TB laboratory network particularly at lower levels. To remedy this crisis, the MOH and the Global Fund Round 9 TB proposal have requested a TB HR assessment to support a feasible action plan. The assessment will include the laboratory network within the ten PATH pilot sites and incorporate all levels of TB laboratories including the recently implemented National Reference Laboratory (NRL). The objectives of the assessment include:

- Comprehensive HR assessment of laboratories at all levels with a focus on local levels;
- Identify key issues related to workforce shortfall including staff demographics, recruitment, retention and training/education;
- Carry out a costing analysis for staffing for a national reference laboratory;
- Provide a national laboratory agenda including feasible and action oriented recommendations regarding cost-effective strategies for building laboratory HR capacity;
- Improve laboratory HR planning collaboration with other stakeholders including the HIV/AIDS program.

This was the first HSI visit to Ukraine that was carried out to meet stakeholders and collect information about the Ukraine TB laboratory infra-structure including HR issues related to the workforce shortfall. This report is a HSI sub-contract deliverable requirement to provide a detailed work plan for the follow-on assessment.

### **BACKGROUND**

The incidence of TB in Ukraine is estimated to be 102/100000 with an estimated case detection rate at 55% of new smear positives (WHO Global TB Report 2009). There has been much recent documentation of the Ukrainian TB network strengths and the challenges that must be achieved to reach the government goals to sustain a quality assured network under leadership of a strong National Reference Laboratory and increase case detection rates to 70%” as well as meet the increasing challenges of Multi drug resistant (MDR) and intensive drug resistant (XDR). Many of the challenges facing the TB network are a symptom of broader global recession and Ukrainian economic constraints resulting in a 24% reduction in health system budgets and a freeze on health sector capital investment and lowered spending for infra-structural maintenance. Political and policy challenges has constrained aggressive health sector reform or health systems strengthening programs that are taking place in most of Ukraine’s neighboring countries. These system-wide shortcomings have trickled down to the TB network that is in critical need of increased resourcing and re-structuring. There have been several government documents and external assessments reporting the fragmentation and inefficiencies of the TB system including the lack of a fully operational NRL and a significant human resource shortfall.

*TB Laboratory Infra-structure:* The Ukrainian TB network consists of almost 2000 laboratories spread throughout the country amongst 24 Oblasts (Provinces), several Rayons (Districts), one Republic (Crimean) and two main cities (Kyiv and Sevastopol). The laboratories are divided into three levels that together carry out all TB diagnosis and patient referrals including microscopy, culture examination and drug susceptibility testing (DST) . These include:

- Level 1: Smear laboratories incorporated into PHC facilities and responsible for TB microscopy;
- Level II : Culture laboratories responsible for microscopy and culture;
- Level III: DST laboratories performing microscopy, culture and DST along with tasks of supervision, training and External Quality Assurance (EQA) of the entire network.

External assessments that have detailed the inefficiencies of the current structure promote a more consolidated and downsized network primarily by reducing the overall number of TB laboratories by half including a two-thirds reduction of Level 1 laboratories that would allow improved allocative efficiencies especially at higher level laboratories. Table 1 below shows the level of laboratory reductions proposed (WHO Report: 2009):

	2009	2010-2011
Level 1	1837	460
Level 2	109	90
Level 3	47	27

**Table 1: Current and proposed number of laboratories by level**

Table 2 below shows the impact of these reductions on the number of laboratories within the ten PATH pilot sites that will be the focus of the HR assessment.

**Table 2: Current and proposed number of laboratories by level within PATH pilot sites**

HR Assessment Units of Observation	Level 1		Level 2		Level 3		TOTAL	
	Current	Projected	Current	Projected	Current	Projected	Current	Projected
1. AR Crimea	26	17	3	2	1	1	30	20
2. Dnipropetrovska	52	35	6	3	1	1	59	39
3. Donetska	71	47	14	7	1	1	86	55
4. Zaporizhska	45	30	3	1	2	1	50	32
5. Kharkivska	48	32	6	3	2	1	56	36
6. Khersonska	33	22	4	2	1	1	38	25
7. Kyiv	30	20	3	2	1	1	34	23
8. Sevastopol	9	6	0	0	1	1	10	7
9. Odessa	126	84	4	2	2	1	132	87
10. Luganska	37	25	6	3	1	1	44	29
TOTAL	477	318	49	25	13	10	539	353

*Financing:* The Ukrainian health sector and TB laboratory network are co-financed between the centralized MoH and regional Oblasts. The MoH procures and distributes to TB laboratories all supplies (including drugs) and equipment whilst Oblasts are responsible for most capital and operating costs including staff payroll and other compensation. Oblast budgets are based on input parameters such as population size (Level 1 labs) and number of beds (Levels 2 and 3 labs). Facilities develop annual budgets including employee payroll that are submitted to the Oblast offices where they are finalized and approved. All employees are assigned to a specific “category” (1-12) and pay scale that is determined by cadre, years of employment and continuing education points. Categories are based on the rigid civil service payroll system that does not allow staff compensation re-allocations or changes without Oblast approval.

***Description of the Activities:***

This mission was useful in developing the HR assessment methods and work plan (See Annexes A and B). Copious documents, government “orders”, external assessments and routine data forms were collected and reviewed that will inform the assessment protocols. Several meetings were carried out with

the PATH project field office staff, MoH staff and leadership from the NRL and Academy of Medical Sciences. Laboratories within two Oblasts, Zaporizhzhia and Dnipropetrovsk, were toured and interviews carried out with the leadership and other staff from Levels 1,2 and 3 laboratories. MoH staff members reviewed the government commitment and increasing policy initiatives carried out by the MoH to meet TB Programme national and international goals. During the site visits, consistent and detailed HR issues were raised and discussed with all levels of staff laboratory heads, specialists, nurses and technicians. Visits to Levels 2 and 3 TB laboratories in Dnipropetrovsk were particularly helpful in identifying data routinely collected and available at Oblast level.

### **Findings:**

This is a timely opportunity to develop an HR assessment and promote improved TB laboratory HR capacity. The government recognizes that HR constraints are one of the most challenging aspects to meeting government TB control goals. The government is highly engaged in addressing these challenges as evidenced by recent policies and the 2009 GF Round 9 TB proposal highlighting new and sustained initiatives. In 2008, the MOH established an HR department to address the growing health sector HR crisis with a focus on ensuring an optimal supply of qualified personnel in rural health care facilities including TB laboratories. It has initiated improvements for HR planning and training for the overall health sector and TB specific workforce and recently mandated the National TB Control Center to coordinate efforts to improve the recruitment and availability of a sufficiently qualified workforce. At regional level, there is a MOH plan to deploy TB coordinators to improve the harmonization of TB efforts at lower levels. Steps have also been taken to increase staffing recruitment and productivity outcomes through redesigning job definitions and promoting task shifting and improved workforce harmonization with NGOs and other civil society organizations.

This pre-assessment visit provided opportunity to confirm the key TB control system strengths to be considered in the HR assessment including:

**Policy Environment and commitment:** The WHO 2009 assessment noted the Ukrainian political commitment to TB laboratories as a key strength. The MoH has initiated several TB laboratory capacity building policy initiatives within the last decade and has illustrated its commitment to meeting international TB diagnostic standards including staffing requirements. In 2008, an MoH “order” regulating principles of workforce distribution was revised as well as other plans promoting acceleration of HR planning and training agendas.

**National Reference Laboratory (NRL):** The NRL was implemented in May 2009 and the WHO 2009 assessment noted its leadership and physical assets as a key strength to ensure that it will become fully operationalized and sustained to support the TB network.

**Academic Preparation:** Ukraine’s education system is known worldwide for its quality with a stable number of higher education institutions (roughly 900) and among the highest rank of higher education students (including PhD candidates) in the world. It has a strong medical university system with 17 medical universities and is well positioned to train an ample supply of TB laboratory professionals. It was reported that overall academic preparation for TB laboratory staff is strong in Ukraine and that there were adequate numbers of doctor and laboratory technician graduates. Key HR challenges were not perceived to be pre-service education but issues related to the recruitment, retention and practical in-service training of staff.

**Continuing Education:** The health system in Ukraine has a well established continuing education program linked to civil service re-certification and staff “category” upgrading. All staff in TB laboratories are required to attend an approved continuing education every five years for roughly one month.

**Improving work conditions:** The recent 2009 WHO assessment found “substantial” improvement in working conditions in TB laboratories with increased use of modern equipment, a higher level of bio-hazard control, and strengthened quality of methods used. This is in sharp contrast to the WHO 2006 assessment and other reports where safety measures were found to be inadequate with some laboratories reporting occupational TB disease cases during the last years.

Despite these advances, many HR challenges remain within the TB network that reflect broader health system weaknesses including the lack of a national HR development or strategic plan or clear resource

commitments to raising HR supply and competencies to meet health sector need. Over the past decade, the health sector HR supply has decreased in large part due to the high attrition of existing staff. HR morale and productivity is low with inefficient task distribution and increasing workloads that are often unproductive. The following are key challenges identified within the TB laboratory network during the pre-assessment visits:

**Staff supply:** There has been much reporting of TB laboratory HR shortfall although little quantitative evidence exists. The staffing standards established in 1995 and updated in 2000 in MOH regulatory Order #33 are not met in most laboratories, especially at Level 1, and, have not kept pace with increasing workloads or competing private sector labor markets. Staffing shortages is reported for all cadres with almost 80% of students trained in Kyiv on TB-related tasks over recent years having left TB work and with a TB Specialist vacancy rate of 40%. HR shortfall is often attributed to high attrition amongst younger staff driving understaffed laboratories and a “graying” or imbalance of older, less trained staff. MOH recruitment efforts and hiring policies are not keeping pace with the exodus of these workers and has not developed effective incentives to retain highly competent and dedicated staff

**Deployment:** HR shortages are most prevalent in rural, lower level TB laboratories where recruitment and retention incentives are weakest. There is little deployment planning at the MOH and although there are MoH regulations for improving HR distribution, no operational plan has been implemented. Opportunities to improve deployment, such as mandating “free” students to work in TB laboratories, may not be optimally enforced

**Retention:** Ukraine is not suffering from an absolute shortage of health workers but rather the brain drain and migration of health workers, particularly younger staff, to other sectors or careers. Working in the TB sector has become unattractive to young professionals and laboratories are viewed to be a low prestige, unrewarding and dangerous occupation. Three key retention issues consistently raised in interviews include:

- **Compensation:** TB laboratory staff have “category” assignments and salary levels that are some of the lowest in the health industry. There is also little opportunity to compensate for low salaries with other income such as patient gratuities or bonuses. Salary levels are not competitive with other labor markets including the private sector and do not compare favorably with other labor careers such as teachers or even cleaners. As discussed above, salary levels are rigidly fixed within cadre categories with increases unlikely given the current political and economic climate.
- **Working Conditions:** Working environments that are unsafe are given as a key reason for high rates of attrition. Although the most recent WHO 2009 assessment reports significant advances, there remains evidence that some laboratories do not meet requirements for understanding TB infection control and ensuring well maintained and updated biosafety equipment and procedures. While staffing levels are at best stabilized, workloads in TB laboratories are increasing without additional staff compensation or other incentives. The “general sputum analysis” policy, increased demand for TB-HIV and drug resistance testing, over use of DSTs as well as increasing patient loads each contribute to decreasing staff morale.
- **Career Development:** It was reported that Ukrainian TB laboratory staff, particularly within certain cadres, lack opportunity to advance resulting in compensation inequities. Several interviewees noted, for example, that micro biologists may become TB laboratory heads but, unlike other staff, are ineligible to earn continuing education “points” and increase salary levels.

**Training and education:** The 2006 WHO assessment concluded that staff of Level 1 TB laboratories failed to demonstrate adequate performance resulting in poor outcomes and ineffective processes. During interviews, low staff competency was attributed to the lack of systematic and standardized TB pre- and continuing education and on-site internships for TB laboratory staff. Although the higher education system in Ukraine is generally well respected, several interviewees commented that an inadequate amount of time is allotted for TB training with little or no practical skill development, that TB curriculums are outdated and there is not ample in-service training opportunities outside the re-certification process. Several reported concern that the MoH may not have the resources, infrastructure or commitment to sustain the excellent post graduate and continuing education training provided by the USAID PATH project. The four key areas of concern include:

- **Outdated curriculums:** Regular education mechanisms (including post-graduate education) have difficulty adapting to rapidly changing treatment approaches such as MDR and TB-HIV

skills as well as comprehensive training on quality assurance and laboratory innovations. All pre- and post graduate curriculums require review to ensure that they are up-to-date and meet international standards.

- **Indirect cost of training:** Increased use of cascading training models and on-site training is required to reduce the travel and replacement costs for students attending off-site courses.
- **Lack of standard system:** TB laboratory training programs need to strive toward a more acceptable and standardized certification process and a training curricula for all institutions and continuing education.
- **Lack of training to improve work safety:** The 2006 WHO assessment reported that :“there is urgent need for training in infection control for all lab staff including technical assistants and technicians.” It was repeatedly stated that little attention in pre- and in-service training is given to work safety issues and “ even elementary bio-safe mode of work and behaviour is often ignored”.

**Improving staff efficiency:** Several examples were provided throughout the site visits regarding opportunities to improve staff productivity including the use of international diagnostic algorithms or TB case-finding, increased supervision and monitoring of laboratory efficiency; carrying out one DST rather than the current standard of three; and, reducing unnecessary case referrals from Level 1 to Levels 2 and 3 laboratories.

### **National Reference Laboratory (NRL)**

The NRL was visited and two meetings held with the head of the laboratory. The laboratory was implemented in May 2009 although it is not yet fully functioning. It is currently placed within the Yanovsky TB institute and is well equipped and employs five staff including the head of the laboratory. All necessary equipment has been procured from the national budget and through the World Bank loan. The NRL agreed with the Supra National Reference Laboratory (SNRL) in Riga, Latvia to collaborate on training for NRL staff including (to be hired) six specialists on quality assurance and rapid testing for MDR-TB. There is a plan to move the laboratory in 2010 and recruit additional staff to fully implement NRL operations. A key issue raised during the meetings was the challenges of confirming approved staff establishments with the MoH and recruiting highly competent staff with the current non-competitive salary scales. The following table shows the recommended NRL staffing levels

**Table 3: NRL Current and Projected Staff (WHO 2009 Assessment Report)**

Current No. by Cadre	Projected No. by Cadre
Head of NRL	1
Medical Doctors	5
Lab Techs	6
Cleaning	2
Nurses	0

### **Conclusions:**

This report is a briefing of the first HSI visit to Ukraine that provided substantial confirmation of the level of HR challenges within the TB network and the urgent need for quantitative evidence about the level of HR shortfall, key HR issues and the projected cost of meeting HR standards. The key HR issues presented in this briefing have been applied to developing the HR assessment conceptual framework including indicators that will define data collection protocols. Much of the quantitative data will be collected through a survey at Olbast level whilst other quantitative and qualitative information will be gathered during NRL, Level 1 laboratory and training institution site visits. MoH HR and TB champions will also be interviewed and central level data collected.

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- Anna Barbova – MD, PhD Head of Bacteriological Laboratory, F.G. Yanovsky Institute of Phthiology and Pulmonology and NRL
- Field visits:
  - Zaporichzka oblast and capital city – Vasylivka Central District Hospital
    - Valeriy Sapa - Head MD
    - Natalya Voloshina - Head of Lab (Level 1)
    - Olga Shumeiko - Deputy head of polyclinic
    - Vera Dmitrievna – Lab Tech
    - Natalia Rochmanova – Head of Lab (Level 1)
    - Mariya Michailovna Ionareva – Head Doctor (Level 3)
  - Dnipropetrovsk Oblast and Dniprodzerzhynsk City - Dnipropetrovsk TB hospital
    - Oleg Tatsenko Head Doctor (Level 2)
    - D. Yatsenko Oleg Fedorovicy – Head Doctor (Level 2)
    - Irince Stepanovnes - Economist

**Annex A: Human Resource Assessment Methodology**

**I. Conceptual Framework :**

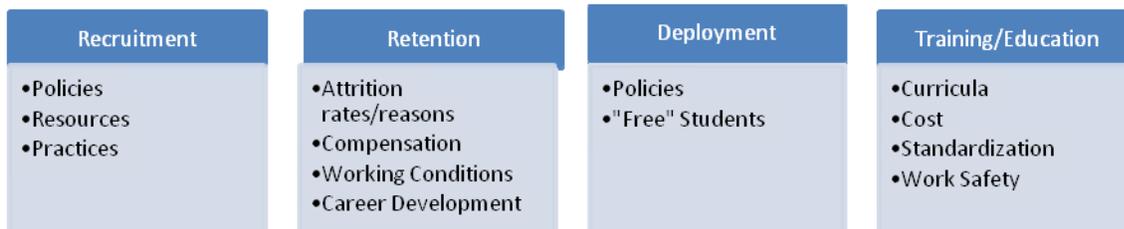
The HR Assessment will include all TB laboratory levels and focus on providing quantitative evidence of HR shortfall and other issues including demographics, recruitment and retention, and training/education. The issues identified throughout the HSI visit and summarized in this report will form the framework for the assessment as illustrated below

**HR ASSESSMENT CONCEPTUAL FRAMEWORK:**

**Quantifying HR Supply:**



**Factors Driving Supply:**



**Costing**



## II. Data Collection

- A. Unit of Analysis: Data collection for the HR assessment will be carried out at two levels :
- Oblast for levels 2 and 3 labs
  - Polyclinics for level 1 labs

In addition, information and data will be collected during site visits to the NRL, a sample of training institutions and the MOH will be and laboratory for Level 1.

- B. Secondary Data: Data will be collected at Oblast level for:
- HR Supply
  - Attrition rates
  - Policies (recruitment and deployment)
  - Practices (recruitment i.e., bonuses/housing)
  - Compensation i.e., bonuses,
  - Career Development
  - Output and outcome

Data will be collected from each of the ten oblasts applying an Excel data collection worksheet (See Annex C):

Step 1: A field office staff member will meet with each Oblast CCM Chairperson-Vice Governor and Medical Heads to confirm participation

Step 2: A one-day training session with Oblast staff will be carried out by the field office staff member to orient them to the study and data collection protocol.

Step 3: Field office staff and HSI consultant conduct follow-up Oblast visits to review collected data for completion and reliability.

Step 4: A sample of Level 1 labs will be site visited by a field office staff and HSI consultant to carry out data collection interviews and focus groups and develop a case study

Step 5: Training institutions will be site visited by a field office staff to collect curricula information

### C. Primary Data

- Unstructured interviews will be carried out at the MoH by field office staff to assess the HR policy and political environment and to collect central data on TB laboratory HR budgets and expenditure. :
- The NRL will be site visited for two days to collect data on current and project staffing
- Level 1 laboratories: Data will be collected directly from a sample of Level 1 TB laboratories because they are not distinct labs with dedicated staff so it will be necessary to quantify proportion of level of effort (LOE) for TB lab work. The following will be carried out:
  - Rapid (two days) time and motion study in a sample (No. = 2) of Level 1 labs in three Oblast s (3 oblasts x 2 x 2 = 12 days). Data will be collected on the percent of time each staff member works on TB activities and levels of output i.e., # of smears times view per smear sputum microscopy.
  - Structured interviews will be carried out with laboratory heads and laboratory technician focus groups to collect data on: attrition, working conditions, recruitment and retention practices , career development opportunities, and output and outcome i.e. # of smears and cultures, # false positive or false negative

- d. A sample of training institutions will be visited to collect data on curriculums i.e. amount of TB, information on DOTS, TB/HIV, PAL, CMT and level of standardization between training institutions.

## **Annex B: Workplan**

**Annex C: Data Collection Excel Worksheet**

## **Review of Pharmaceutical Management for Tuberculosis in Selected Oblasts of Eastern Ukraine**

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September 2009



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## **Key Words**

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## ACRONYMS

ADR	adverse drug reactions
CPM	Center for Pharmaceutical Management
DOE	Department of Economics
DOTS	directly-observed therapy short-course
DST	drug sensitivity testing
E	ethambutol
FDC	fixed-dose combination
GDF	Global Drug Facility
GLC	Green Light Committee
GMP	good manufacturing practices
GOU	Government of Ukraine
INH	isoniazid
KRU	Control Revision Department
MDR-TB	multi-drug resistant tuberculosis
MIS	management information system
MOF	ministry of finance
MOH	ministry of health
MSH	Management Sciences for Health
PATH	Program for Appropriate Technology in Health
PMIS	pharmaceutical management information systems
PSM	procurement and supply management
R	rifampicin
RFP	request for proposal
SBU	State Security Service
SOP	standard operating procedures
SPS	Strengthening Pharmaceutical Systems Program
STG	standard treatment guidelines
TB	tuberculosis
TRC	Technical Review Committee
UAH	Ukrainian Hryvnia
USAID	United States Agency for International Development
WHO	World Health Organization
Z	pyrazinamide

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Sincere gratitude is offered to the following oblast, city and rayon TB treatment centers visited for their assistance during the review:

- Kyiv City TB Hospital #1
- Kharkiv Oblast TB Dispensary
- Nova Vodolaha Rayon Polyclinic
- Dnipropetrovsk Oblast Hospital for TB and Other Lung Diseases
- Dniprodzerzhynsk City TB Hospital

## EXECUTIVE SUMMARY

### *Key Objectives of the Visit*

The MSH/PATH team of Olya Duzey, Sharri Hollist and Olena Kononova (PATH) visited Ukraine from June 17 through July 1, 2009 to learn about pharmaceutical management operations in TB facilities in PATH focus oblasts. The specific objectives of the visit were to:

- Understand the general roles and operations of each type of TB treatment facility within the TB control program in the context of pharmaceutical management practices
- Map the flow of anti-TB medicines through the supply system including the processes of procurement, quantification, distribution and dispensing
- Understand the roles and responsibilities of staff at each level in managing medicines for the TB facility
- Identify standards, protocols and tools used for procuring anti-TB medicines, managing inventories, recording medicines transfers, dispensing, and reporting data

### *Sites Visited*

Location	Unit	Level
Kyiv City	Kyiv City TB Hospital #1	City
Kharkiv	Kharkiv Oblast TB Dispensary	Oblast
Kharkiv Rayon	Nova Vodolaha Rayon Polyclinic	Rayon
Dnipropetrovsk	Dnipropetrovsk Oblast TB Hospital	Oblast
Dniprodzerzhynsk	Dniprodzerzhynsk City TB Hospital	City

The review of previous assessment documents and discussions with national level MOH staff, PATH, and dispensary staff on the site visits were very useful in identifying a number of issues challenging effective management of anti-TB medicines and other commodities in Ukraine. These may not be representative of all Ukrainian oblasts, but, in combination with previous assessment, they suggest a number of issues in pharmaceutical management for TB. These issues and challenges are detailed below, followed by recommendations for next steps. A number of these issues may be addressed through this project, however, other central-level issues are much broader, and may require collaboration with other organizations and donors in collaboration with the MOH and require policy changes, or other longer term actions.

### ***Key Strengths***

Ukraine's TB pharmaceutical management systems were performing well in the following areas:

- At the time of the visit, DOTS medicines were available at the point of care, with no reported stock outs or treatment interruptions
- Standards, orders, and protocols are available and followed as directed for quantification; ordering; receiving and dispensing medicines; and reporting
- Communication and coordination between provincial, city, and rayon level sites is relatively good with staff working together to redistribute or locally procure medicines as needed when stocks are low
- The MOH has approved and is supportive of implementation of the eTB Manager to improve information systems, reporting, and the use of the resulting data for decision making and program management

### ***Key Challenges in TB and MDR-TB Control and Treatment***

Several challenges, however, impede progress to improving TB treatment and control:

- Uncertainty about the procurement schedule has been the source of consistent challenges in forecasting annual needs at the local level
- Infrequency of procurements further challenges local medicines and commodities budgeting and forecasting capacity. The short shelf-life of costly second line medicines will necessitate changes to the ordering and receiving schedule.
- Stock outs, failure to adhere, and other treatment interruptions can result in treatment failure and the rapid development of drug resistance. Although sites visited have not experienced stock outs recently, other reports have documented sustained stock outs annually, since 2002
- Poor quality of medicines and laboratory commodities can contribute to drug resistance
- FDCs are available in only a few oblasts, and second line drugs are not currently available through the GLC
- The supply system is not sufficiently responsive to needs of new patients, treatment status and location changes, regimen alterations related to disease status, and changes to guidelines
- Compliance with required reporting is generally accomplished in an inefficient manner, including the use of non-standardized forms, duplicate information submission (monthly, quarterly, manual, electronic)
- The collection and submission of data does not, generally, result in analysis and use of these data by local staff for improving their own program management

### ***Key Issues***

Programmatic areas of concern with respect to pharmaceutical management for TB are:

- *Quantification*
  - Lead times on procurements are 15-18 months making forecasting challenging
  - Site forecasts are often adjusted to meet budget constraints

- Stockouts have been avoided because oblast staff monitor city and rayon stock levels to anticipate and troubleshoot shortages
- Oblast level staff use may local funds to directly procure medicines from local manufacturers to close supply gap, but this is at the expense of other categories of good and services
- Rayon or city level sites may request redistribution from other sites within the oblast to meet medicines demand
- Buffer stocks are inconsistently interpreted as part of quantification calculation
- *Record keeping and reporting*
  - Standard forms monitor the financial aspects of medicines as opposed to medicines or program management
  - A wide variety of locally developed (home-made) forms are used to monitor site inventory (expiration, stock balance, received, issued)
  - Staff often hand copy patient information into journals to consolidate essential information from several reports or patient forms.
  - Electronic tools in facilities are generally unavailable for pharmaceutical management, making the process time intensive and laborious; usually these are used for accounting, which is not responsible for pharmaceutical management
- *Inventory Management*
  - Many sites have inadequate storage space to accommodate an annual supply of medicines at one time
  - The option of splitting shipments or more frequent ordering is not available to most sites
  - Some staff have insufficient knowledge of or training in comprehensive pharmaceutical management
  - Few job aids exist for reference, or to serve as checklists
- *Monitoring and Supervision*
  - Staff responsible for conducting supervision visits don't have or don't use a pharmaceutical management checklist; it is unclear exactly what they monitor
  - Staff do not use non-financial indicators to monitor the status of medicines and commodities management
- *Training*
  - Training for pharmaceutical management is not available to non-pharmacists, and rarely occurs for pharmacists as part of their continuing education

## ***Strengthening TB and MDR-TB Pharmaceutical Management in Ukraine***

### **Immediate Recommendations**

- Strengthen quantification of anti-TB medicines (first and second line) through technical assistance and training
- Review and revise existing instructions for annual quantification to reflect the most recent standard treatment guidelines
- Develop or refine practical record keeping tools to facilitate data collection, analysis, and reporting relative to medicines; make the tools consistent with and complementary to the eTB Manager
- Work with counterparts to adapt effective pharmaceutical management tools, and develop methodology and tools to address gaps in inventory management practices
- Further enhance counterpart capacity to assess and monitor pharmaceutical management practices by including them in site visits to other PATH project focus sites

### ***Action Plan and Next Steps***

Given the findings and proposed long and short term recommendations in this report, PATH and MSH/CPM will work with stakeholders in an options analysis workshop to review and prioritize issues and needs, identify and analyze options for addressing them, and develop an action plan to strengthen existing TB and MDR-TB medicines management systems.

## **BACKGROUND**

TB stakeholders in Ukraine have hosted several assessment and technical assistance missions in recent years. Given frequent changes in administration, organizational structure, and policies within the TB treatment and control system, however, many of documents available are dated. For the purposes of this document review, therefore, only recent reports (2008-2009) were analyzed for situational context for the review of TB sites in Eastern Ukraine. These included two reports of the GDF Mission to Ukraine, the joint WHO/USAID/EU evaluation report, “Procurement and Supply Management for HIV/AIDS and TB in Ukraine,” and trip reports from the MSH Strengthening Pharmaceutical Systems (SPS) Program on adaptation and implementation of the eTB Manager in Ukraine. Pertinent general program information, mission objectives, findings and recommendations are described in this section. For the purposes of this report, the focus was on information relevant specifically to management of anti-TB medicines.

In January 2008, GDF commissioned a first year direct procurement monitoring mission for Ukraine. Management Sciences for Health’s Strengthening Pharmaceutical Systems Program (MSH/SPS) participated in conducting the pharmaceutical management portion of the review. In addition to the standard objectives, specific mission objectives were to follow up on previously known challenges in program and pharmaceutical management:

- Clarify drug registration and custom clearance procedures and assess how these procedures can cause difficulties and delays for importation of drugs through the GDF
- Clarify national drug policy and its role in drug importation delays
- Analyze Ukrainian preparation to receive a GDF grant, support importation, properly store, distribute and use drugs
- Calculate drug needs for the second year of GDF support
- Provide all information necessary to determine country preparedness for future shipments

Based on recommendations from several evaluations of procurement and supply management (PSM) in Ukraine between 2003 and 2007, and in response to conditions precedent for its Global Fund grant for HIV/AIDS, the Government of Ukraine (GOU) requested an independent international evaluation of its quality assurance, procurement, and supply systems for HIV/AIDS and TB medicines and commodities. Compliant to that request, in July 2008, WHO/EURO, the European Commission Delegation in Ukraine, USAID Regional Mission, and Management Sciences for Health through the Grant Management Solutions (GMS) Program, conducted a joint evaluation mission to assess the procurement and supply management of HIV/AIDS and TB medicines and related commodities in Ukraine.

The stated objective of the Joint PSM mission was to assess all components of PSM in Ukraine for HIV and TB programs from the central level to the end user including:

- Regulatory aspects, including marketing authorization of HIV and TB medicines and commodities in the country, licensing of pharmaceutical manufacturers, wholesalers, retail and hospital pharmacies; drug quality standards; and pharmaceutical inspection
- Product selection, quantification and planning requirements

- Procurement legislation, regulations, financing, processes and quality assurance
- Receipt, stock management, storage and distribution
- Pharmaceutical management information systems (PMIS)
- Reporting, monitoring & evaluation

Although the objectives of the GDF Mission and the joint evaluation team were somewhat different in scope, the findings relative to pharmaceutical management were consistent and complementary, and both identified a number of strengths and weaknesses in pharmaceutical management for TB in Ukraine.

### ***Strengths identified by the GDF Mission***

The team identified a number of positive steps that have been taken by the Ukrainian government and MOH to facilitate availability of products provided by the GDF. These include the following:

- In 2007 the Ukrainian Parliament passed a law on the “National TB Control Program 2007-2011”, which requires adherence to directly observed therapy short-course (DOTS) in DOTS implementing regions
- DOTS has been approved as a national TB control strategy and has been adopted in regions of technical partner and donor focus (WHO, USAID, PATH)
- The National Centre for Tuberculosis was established as the national level coordinating body for TB control; it is a part of the Ministry of Health (MOH) Committee on HIV/AIDS and other Socially Dangerous Diseases
- Established treatment regimens generally follow WHO guidelines
- Centralized data collection is being developed by the National Centre for TB; information is collected at the oblast level and submitted
- The nationwide medicines distributor, UkrVaccina, has skilled personnel, good storage facilities and the capacity to rapidly distribute medicines
- In-country technical assistance is available to the TB program through WHO/Ukraine and a USAID-funded project implemented by PATH
- Government funding for the procurement of TB medicines is adequate for current needs

### ***Challenges***

The team also identified challenges that remain to effective TB control in Ukraine. These include the following:

- Ukraine has high disease rates of drug sensitive TB (83.5 per 100,000) and MDR-TB among newly detected cases (15.6%) and previously treated smear positive patients (41%)
- HIV prevalence among TB patients is high, at 8%, with a 2006 survey showing much higher rates of co-infection in Donetsk, such as the prison population (21.9%),
- Despite adequate funding levels, procurement practices lack transparency
- GDF medicines are procured for only five oblasts and prices for locally procured medicines are high
- There is low DOTS coverage nationally and in DOTS areas not all elements of DOTS are implemented, often replaced by traditional Soviet era treatment approaches

- There is low involvement of primary health care facilities in TB control
- Recording and report systems are not in sync with WHO guidelines used nationally
- Reports from oblasts levels are not always submitted to the national level in a timely manner and are sometimes inaccurate
- The list of centrally procured TB medicines, especially for MDR-TB, includes drugs and unique drug formulations not recommended by WHO
- Drug selection does not seem to be rational and evidence based, and does not leave any medicines in reserve to treat extensively drug-resistant TB (XDR-TB)

### ***Recommendations***

The GDF Mission report recommended the following:

- Strengthen quantification of needs for 2009
  - Collect pipeline data on what and how many drugs have been procured for each of the recipient oblasts when available
  - Calculate the average monthly consumption to establish when the stock must be replenished, taking into account buffer stocks (clarify allowable levels with the MOH and other ministries and agencies)
  - Adjust to national budget and procurement cycles
  - Establish the date when the GDF drugs will be needed
  - Take into account the GDF lead time; an average of 6 months plus 2 months for customs clearance, Pharmaceutical Committee quality control, and distribution
- Establish a mechanism for regular reporting of medicines pipeline and stock levels
- Develop a policy for building a buffer stock of TB medicines, and keeping it at the central level (UkrVaccina)
- Draft a policy for procurement from international sources (GDF, GLC) and present to the MOH and other pertinent government agencies
- Develop/clarify the mandate for the National TB Centre, defining its role as a national center responsible for all programmatic management issues and coordination of TB control in Ukraine and share responsibilities with the Committee on HIV
- Develop and implement a management information system (MIS) for TB<sup>1</sup>
- Establish a national formulary to limit and optimize the number of medicines used for TB, since overuse of second line medicines may lead to increased resistance since medicines use control and enforcement is weak
- Quantify financial needs and existing gaps for program management and laboratories
- Promote and disseminate protocols for the diagnosis and treatment of MDR-TB developed by WHO in 2006<sup>2,3</sup>

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<sup>1</sup> In 2008, Ukraine initiated a program to implement an electronic management information system for TB control (e-TB Manager) to fulfill the legal mandate to develop a national computer register for TB patients. The development and implementation of the tool is in progress with an anticipated completion date in 2011.

<sup>2</sup> Zagorsky, A and A Salakaia. 2008. *The Global Drug Facility Mission to Ukraine January 21-25, 2008: Executive Summary and Supporting Documents.*

<sup>3</sup> Zagorsky, A and A Salakaia. 2008. *The Global Drug Facility First Year In-Country Monitoring Checklist for Ukraine.*



## ***PSM of HIV/AIDS and TB Medicines and Related Commodities in Ukraine***

### ***Key Findings and Recommendations***

The evaluation report provided findings on all of the components of PSM listed in the objectives, including drug selection, quantification, procurement, distribution and inventory management, pharmaceutical management information systems, and monitoring and evaluation. In addition, the report provided findings and recommendations on overarching issues, such as government commitment to change, conflicts of interest, human resource capacity constraints, and policy and regulatory issues that may support or hinder strengthening of PSM for HIV/AIDS and TB.

In general, the evaluation team concluded that the current MOH PSM systems do not meet internationally recognized standards for drug regulation, selection, procurement, or supply chain management. Although efforts have been made to strengthen the PSM system, there is much to be done. There is also considerable concern about the quality of the medicines procured, and the unpredictability of procurement and delivery of these medicines to sites.

### ***Pharmaceutical regulation***

In the US, the EU, and other countries, one may generally assume that, if a drug is registered in that country, the quality of that drug is assured. This is not necessarily the case in Ukraine. The drug regulatory system is fragmented, there is a lack of coordination among the component institutions, and drug marketing authorizations are inconsistent, with numerous questionable expedited approvals. The problem of drug quality is compounded, when the drug procurement process uses only drug registration as a guarantee of quality without any other independently verifiable measure. TB facility staff routinely complain of the quality of the drug products that they receive.

Recommendations for improvement in drug regulatory processes include short-, mid, and long-term actions, including:

- Implementing steps to achieving drug regulatory standards and procedures consistent with those of the EU
- Conducting a review of products registered under requirements not meeting international standards
- Achieving international GMP standards for all products marketed in Ukraine
- Developing user-friendly adverse drug reporting and other elements of a pharmacovigilance system

In the longer term, the team recommended review and restructuring of the component organizations of the drug regulatory authority to provide a harmonized and coordinated approach to all medicinal products and across all regulatory functions.

### ***Product selection, forecasting, and planning***

As noted in the GDF report, Ukraine has adopted standard treatment guidelines (STGs) for the treatment of TB. As of 2008, STGs are also available for MDR-TB. For the most part, the STGs follow WHO recommendations, but they have been adapted “to the Ukrainian context,” which

results in the use of non-standard regimens, excessive use of second line medicines, and the use of non-standard formulations of medicines. This is cause for concern, as it contributes toward further increases in drug resistant HIV and TB, and results in an inefficient use of resources.

Quantification of anti-TB medicines, as with ARVs and other medicines for HIV/AIDS, is conducted annually, approximately 12 to 18 months prior to their delivery to sites. Skills in quantification vary, although there are instructions on the necessary calculations. The most problematic is the understanding of and inclusion of buffer stock in calculations, and the projected lead times for delivery.

Recommendations for improving selection and quantification processes included revising STGs to be fully in accordance with WHO recommendations, implementing a system for monitoring prescribing practices, and building more capacity in quantification at oblast level and below.

### *Procurement*

The process of procurement has been the subject of a number of assessments and reports, including the “Master Plan for Reform and Combating Corruption in the Procurement System of Ukraine,” (USAID/TIBA, 2007), but action in addressing deficiencies has been slow. Officials in the MOH are guided by numerous laws, regulations, orders, and other documents, but these are not codified into an easy to access guide. Current laws and regulations do not allow inclusion of adequate drug quality specifications in procurement documents, nor evaluation of past supplier performance. Drug suppliers have exploited this gap by suing to set aside decisions that exclude them. This has resulted in a protracted procurement cycle in a litigious atmosphere, where the incentives for transparency and drug quality are skewed toward the suppliers, rather than toward consistent availability of medicines of assured quality.

One positive that was noted by the team was the decision to conduct a tender for the entire set of first line anti-TB medicines for 2009, rather than conducting them individually. The expectation is that, by procuring all of the necessary products for one year at one, there will be less disruption in availability of those products.

The team provided a number of short- and long-term recommendations. The report recommends that the MOH build on its efforts in good governance to make the procurement process more transparent and efficient, and so that it is consistent with international standards for procurement. Also recommended are implementation of high level oversight for procurement, development of a supplier performance monitoring system, and use of historical and international pricing data to ensure competitive pricing for pharmaceuticals.

### *Receipt, storage, distribution*

As also noted in the GDF Mission report, there is adequate capacity in supply chain management at national level meet the needs of the TB and HIV/AIDS programs. The joint team noted that there are differences in service levels for medicines that are procured with Global Fund grant monies, and those, procured with GOU budgetary funds. The biggest difference is that the supplier stores and distributes stock on a periodic basis and has modified its information systems

to accommodate Global Fund reporting requirements, whereas UkrVaccina, the distributor for medicines for the TB program does not routinely do this. This may be partly explained by the higher fees that are paid by the Global Fund PRs for procurement, storage and distribution.

Procedures for receiving medicines are well documented at oblast and site levels. Storage capacity and conditions, however, are quite variable. Some sites do not have sufficient storage space for an annual shipment of medicines, and oblast facilities often bear the brunt of the increased work load associated with receiving products for the rayons and other facilities. Site staff indicated that there is often little if any notice that products will be delivered, resulting in disruptions to operations at site level, when the products do arrive.

Recommendations for improvements included revising procedures to introduce periodic deliveries of medicines in response to their needs, implementing improvements in stock conditions (space, temperature levels, records), and strengthening human resource capacity for inventory management.

#### *Monitoring and reporting in PSM*

As already noted in the GDF Mission report, there is a need to improve information systems, reporting, and the use of data for decision-making for TB control. The joint team found that staff were overwhelmed with the amount of paperwork required for managing medicines. However, they did not analyze nor use the information at site level that they were submitting for improving their operations. The frequency of reporting and duplication in reported information for multiple recipients was inefficient, and did not reward accuracy and timeliness.

Recommendations included improving pharmaceutical management information systems to consolidate forms, reduce duplication, and provide timely feedback. Some of these were starting to be addressed at the time of the visit through the PATH TB program and through SPS (below).

#### *Overarching issues*

A number of assessments and reports have been received by the MOH, with insufficient action to assure transparency of the drug selection and procurement processes. The findings and recommendations of the joint evaluation team were consistent with previous findings, although additional recommendations included the following:

- a clear separation and definition of responsibilities for all aspects of procurement and supply management to minimize potential conflict of interest and to ensure availability of products of assured quality
- implementation of a conflict of interest policy for all persons involved in PSM
- review and revision of policy or regulations to support transparent procurement procedures, according to international norms, particularly addressing issues of criteria for quality of medicines
- addressing duplication, fragmentation and inefficiency in drug regulatory processes

- Strengthen national and oblast level human resource capacity to implement pharmaceutical management practices for HIV/AIDS and TB

*MSH eTB Manager*

MSH developed, under the Strengthening Pharmaceutical Systems project, the eTB Manager as a comprehensive web-based tool for programmatic management of TB and drug-resistant TB. This tool integrates all relevant aspects required for national TB program management functions at different levels (e.g., cases, medicines, and other TB commodities) into a web-based tool and provides key information for decision making and epidemiological surveillance where interventions are needed.

Under the SPS Program, MSH began working with the Ukrainian MOH to adapt and pilot the eTB Manager for use in Ukraine. PATH is providing support for implementation of the eTB Manager in its focus regions. The MOH has approved a work plan for implementation of the tool. To-date the eTB Manager has been adapted and translated into Ukrainian, and, has been transferred onto the MOH server. It is anticipated that use of the eTB Manager will provide real-time data on patients, allow tracking of patients with sensitive and MDR TB, provide information needed for quantification of TB medicines, and streamline reporting procedures.

## **SITE VISITS TO TB FACILITIES**

As part of the USAID-funded Population, Health, and Nutrition Technical Assistance and Support Contract (TASC-2) for the tuberculosis sector, PATH is working in partnership with the GOU and civil society at national and local levels to improve prevention, detection, and treatment of TB and TB-HIV co-infection in Ukraine. MSH/CPM works as a partner with PATH, to address pharmaceutical management issues for TB and MDR-TB. In June 2009, CPM traveled to oblast, city and rayon level facilities in Eastern Ukraine to review pharmaceutical management policies and practices including the selection, procurement, distribution, use, management support and policy and legal framework for TB and MDR-TB medicines.

### ***Objectives of TB Treatment and Site Visits***

- Map the general flow of TB medicines through the supply system including the processes of procurement, quantification, distribution, and dispensing
- Understand the roles and responsibilities of staff at each level in managing medicines for the TB Program
- Identify forms, tools, policies, and procedures used for procuring TB medicines, managing inventories, recording medicine transfers, dispensing, and reporting data

### ***Methodology***

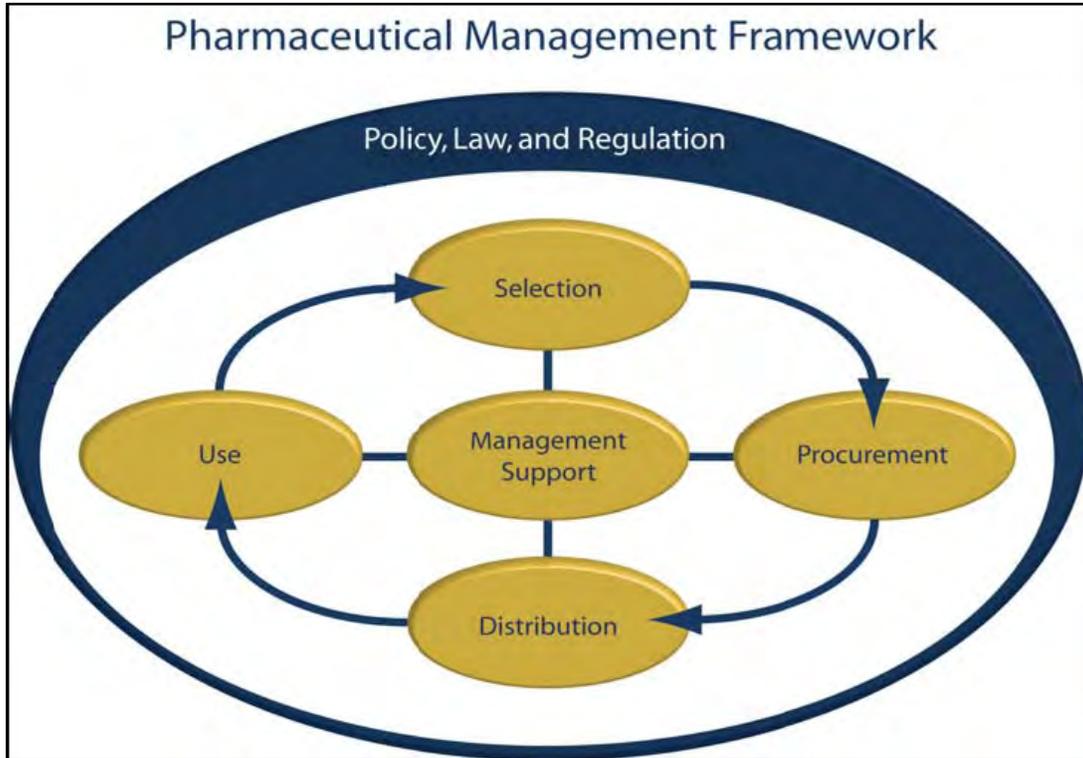
The MSH/PATH team conducted semi-structured interviews with key informants, observed operations, and reviewed available records to prepare this report. In addition, background information included the *First Year In-Country Monitoring Checklist* by the GDF and the *Procurement and Supply Management of HIV/AIDS and Tuberculosis Medicines and Related Commodities in Ukraine* and are outlined in the Background section of this report. A list of the persons interviewed is also included in Annex 1.

Sites visited as part of the review are identified by location, name and system level in the table below.

<b>Location</b>	<b>Unit</b>	<b>Level</b>
Kyiv City	Kyiv City TB Hospital #1	City
Kharkiv	Kharkiv Oblast TB Dispensary	Oblast
Kharkiv Rayon	Nova Vodolaha Rayon Polyclinic	Rayon
Dnipropetrovsk	Dnipropetrovsk Oblast TB Hospital	Oblast
Dniprodzerzhynsk	Dniprodzerzhynsk City TB Hospital	City

The framework used to organize the data collection and report on findings and recommendations is the MSH Pharmaceutical Management Framework (Figure 1). Managing pharmaceuticals, including anti-tubercular medicines, in any setting (public or private sector) and at any level (local, provincial, or national) follows a well-recognized cycle of selection, procurement, distribution, and use. The functions of management support, including the pharmaceutical management information system, and monitoring, and evaluation, are integral to effective functioning of the cycle. The cycle is supported by policies, laws, and regulations.

**Figure 1. Pharmaceutical Management Cycle**



\*Management Sciences for Health. 2003. *Managing Drug Supply*, 2<sup>nd</sup> ed. New Hartford, CT: Kumarian Press

Accordingly, the key considerations reported on in this report include:

- Policies and guidelines: the regulations (nakaz, prykaz, polozhennia) that govern pharmaceutical management of TB medicines at the facility level
- Selection: TB and MDR-TB regimens recommended and used at the facility level (if documented and different from WHO recommendations)
- Procurement: procedures for forecasting needs and procuring anti-TB medicines from the central level and from other partners as determined by the facility
- Distribution: procedures for quantifying needs and requisitioning at the local level, and receiving, storing, and issuing TB medicines including record keeping and inventory control methods
- Use: dispensing, counseling, and rational use of TB medicines

- Pharmaceutical management information system (if applicable)
- Program management: monitoring and supervision, and human resources

The key findings and recommendations from the visits to TB treatment and distribution sites are presented in this section of the report.

### ***Caveats and Limitations***

The purpose of the team visits was to identify and understand the existing forms and systems for managing anti-tubercular medicines and other commodities. Since only five facilities in 2 oblasts and one municipality were visited, the findings represent those facilities visited, but may not be representative of facilities in other oblasts, due to potential differences in human resource capacity, local funding, infrastructure, or other factors. As a result, the team observed and inventoried processes used and records kept, but did not assess the quality of operations and record-keeping.

### **Key Findings**

#### *General Information*

Despite numerous policies, laws and regulations on TB treatment and control, oblast and rayon level facilities are given some liberties concerning pharmaceutical management practices. Distribution, procurement, and other practices, therefore, often differed among facilities visited. The following are **common characteristics** of the TB program related to pharmaceutical management documented during this visit:

- Each oblast has an oblast and/or city-level TB hospital/dispensary, which serves as a referral center for rayon polyclinics and is responsible for the in-patient care and treatment of all TB patients in the oblast for the duration of the intensive phase of treatment
- Suspected TB patients may be diagnosed at the rayon level, if laboratory facilities available on the premises of the referring center, however the diagnosis is confirmed at oblast level
- DOTS based outpatient care is provided at the closest treatment center to the patients' home for the continuation phase. The oblast TB hospital is responsible for coordinating treatment with local polyclinics for TB patients released from prison.
- There is no effective tracking (follow up) mechanism for contacting and returning to therapy patients that do not come to the polyclinic for treatment as expected.
- Primary care facilities at the rayon level are polyclinics with a minimal number of beds dedicated to TB patient use. Each polyclinic is, however, staffed with a TB Specialist, who is involved in TB medicines management including quantification, ordering, stock keeping, reporting and recording and dispensing.
- The Chief Physician/Director, and the Deputy Director for Treatment are involved in decisions regarding quantification, ordering, local procurement, and reporting

- Monthly meetings for TB Specialists within the oblast provide a forum for experience sharing with a focus on patient case management, pharmaceutical management issues may also be discussed there (drug availability, impending shortages, redistribution)
- In general, the TB control program is staffed by inadequate numbers of mostly older (near or past retirement age) health professionals. Frequently, a large percentage of positions are unfilled.
- Until 2001, all medicines were procured at the local (oblast or rayon) level. Experience with local procurement provided mixed results. In 1999, a decision was made to re-establish centralized procurement
- Health personnel responsible for managing anti-TB medicines and other commodities are rarely pharmacists. Most are nurses, who have not participated in any systematic pharmaceutical management training
- Medicines managers at local level facilities each developed and used a set of homemade forms to track medicines, most often for receiving, storing, dispensing, quantification, and tracking inventory movements internally and among other facilities.

There were also several **notable differences** among facility operations:

- The appearance of forms varies from site to site; some are computerized, while most are handwritten journals
- Distribution mechanisms varied between sites. Whereas some oblasts required that rayon and municipal facilities pick-up medicines from a central oblast depot, others distributed medicines to the sites based on order requests.
- Oblasts store anti-TB medicines and other commodities differently, some at an off-site warehouse, some at the hospital storeroom, with periodic distribution to dispensing clinics, and some distributed immediately to local level dispensaries. Storage capacity varied greatly among sites.
- Local funding levels available for supporting the TB program, staff and other needs varied significantly, depending upon the economic health of the local area (village, city, rayon, or oblast) and corresponding local budgets. There is also an expectation that the Chief Physician will seek additional funding from donors and other non-MOH sources; this varies, as well.
- The ability to attract new staff varied considerably. Some facilities near medical and nursing schools had more success in recruitment of certain cadres of new staff easier relative to other sites without close proximity. Physician recruitment and retention was problematic everywhere.
- Propensity to support and promote staff training was high in some areas where international donors and technical assistance organizations had designated training facilities, and lower in other areas.

### *Policies and Guidelines*

There are no standard operating procedure guidelines (SOPs) either at national or local levels. Instead standard orders, created at the national level and issued to oblast and rayon levels, strictly govern TB treatment and control procedures. At the facilities visited, staff are well familiar with the MOH Orders that govern various aspects of management of the TB Control Program. The

most frequently used official documents for pharmaceutical management documented at the time of the visit included the following. Please note that this list is not exhaustive, only a summary of those, mentioned at sites visited.

#### National Level Guidelines

- Order #61: Summary report of the number of patients by category
- Order # 136 (March 2003): Reports that site bookkeepers are required to fill-out and file
- Order #318 (2006): *Implementation of DOTS Strategy* including the duties of medical providers
- Order #361: Quantification procedures for first line anti-TB medicines
- Act #375: Describe staff roles and responsibilities within MOH facilities
- Order #384 (June 2006): *The Order on the Approval of Protocols for Providing Medical Care for Patients with Tuberculosis*
- Order #385 (June 2006): *The Order on the Approval of Instructions on Providing Medical Care to Patients with Tuberculosis*
- Order #419 (March 2009): *Ministry of Justice Order on Treatment of the Homeless*
- Order # 513: *Formulary of medicines used for pulmonary diseases*
- Order #600 (October 2008): *Standards of Treatment for MDR-XDR TB*
- *Act of Transfer of Drugs or Drug Receipt*
- Order #693 (December 2005): Recording and reporting forms for TB control

#### Local Level Treatment Protocol Guidelines

- Order #601: *Kharkiv Oblast Protocol on the Implementation of DOTS*
- *Dniprodzerzhynsk City Memo to Improve the Social and Medical Assistance to Co-infected Patients* (April 2008)
- *Dniprodzerzhynsk Local Protocol of Cooperation to Provide Assistance to TB/HIV Patients* (April 2008)

As described later in this report, each year when medicines are received, oblasts are required to draft an order for the distribution of medicines within the oblast. Kharkiv Oblast Order #379 (June 2009), for example, is the most recent order for the oblast which outlines the distribution plan (site, drug, quantity) for the year.

#### *Selection*

First line TB medicines were available at each of the facilities reviewed in the following doses—

- Isoniazid (INH) 100mg, 300mg
- Rifampicin (R)150mg
- Pyrazinamide (Z) 500mg
- Ethambutol (E) 400mg
- Streptomycin (S)1g (with vials of water for injection)

The doses for INH, E and S are consistent with WHO recommendations. The 100mg doses of INH are used for pediatric household contacts of index TB cases as per WHO recommendations.

The dosage for pyrazinamide of 500mg exceeds the standard WHO recommended dose for pyrazinamide. Rifampicin, however, is not recommended for single formulation distribution given high resistance rates.

There is flexibility allowed in national level protocols for treatment of Category I patients. Only Dniprodzerzhynsk City TB Hospital elected to follow the WHO recommended treatment regimen precisely.

Fixed-dose combination (FDC) medicines were available only in Dnipropetrovsk Oblast TB Hospital in 4-FDC (HRZE), 3-FDC (HRE) and 2-FDC (HR) combinations through the GDF. GDF provides medicines to five other areas, which were not part of this review: Donetsk Oblast, Odessa Oblast, Sevastopol municipality, and two sites within the prison system. Sites visited expressed an interest in acquiring GDF medicines because of quality assurance concerns with existing medicines supplies and a belief that FDCs use would improve patient adherence.

The rayon and municipal sites do not carry second line medicines as MDR-TB patients are treated only at the oblast level or at MDR-TB specific facilities. Three of the oblast level sites visited had some second-line medicines in stock, though with some variability in the variety of medicines, making the selection process and rationale unclear.

Adverse drug reaction (ADR) medicines are not routinely available outside of the oblast hospital. Within the hospital, departments keep ADRs with other emergency care medicines used to treat non-TB related conditions. Lists of ADRs procured were not documented or provided during this review. At rayon level facilities, the TB specialist can provide a prescription for ADR medicines, but the patient is responsible for acquiring the medicines.

### *Procurement*

#### Quantification and Forecasting

Quantification is done annually, beginning with a preliminary estimate on or around April of each year for the following year. Estimates are morbidity based with 10% addition for growth as per guidelines (Order # 361). This amount, less anticipated stock balance at the end of the year, is reported as the requested order amount. Reported actual buffer stock levels range from 10-50% based on funding availability.

In most sites quantification is done by the TB specialist or pharmacist. In others, quantification procedures are more extensive and a collaboration among the treatment director or chief doctor and the pharmacy store staff. Estimates are reviewed and approved by the head of the facility as well as the local health administration before being sent to the oblast level. Sites use standards, guidelines, information and formulae from Orders # 360, 361, 384 and 600, to calculate medicines estimates though methods vary widely between sites. Although Order 361 provides instructions on quantification, more recent guidelines include several medicines that aren't included in Order 361. These drugs must be manually entered, and can be subject to differing calculations or error. The oblast TB facility collates information and provides a comprehensive calculation and report to the MOH/Department of Economics (DOE).

The actual amount of medicines ordered is a result of the difference between the amount the oblast quantifies and national budget availability. The MOH/DOE collates quantification information from the oblasts and municipalities (Kyiv and Sevastopil). The Ministry of Economics (MOE) then provides the MOH/DOE with the budget allocation for the following year. On or around September, sites receive an amended budget and adjusted quantification figures.

The Ukrainian Control Revision Department (KRU), an auditing body that closely monitors budget expenditures, implements severe penalties for holding stocks over the level necessary, considering it inappropriate use of budgetary funds. Sites, therefore, maintain low or no buffer stocks to avoid non-compliance issues. Instead, they may elect to place emergency orders up to 2-3 times per year when stock levels get low or set a high minimum stock levels (50% of annual working stock) at which point they will begin requesting medicines transfers. At sites where there are no designated minimum or maximum stock levels, based on average monthly consumption, site staff rely on experience or personnel dedicated to monitoring stock levels to determine when an emergency order is necessary.

Stock outs may also be averted by redistribution of stock within the oblast, or among them. Intra-oblast transfers are relatively easily and quickly accomplished, while inter-oblast transfers require MOH involvement and an order to finalize the transfer. In theory, oblasts may refuse to provide medicines requested by the MOH for redistribution; in practice it is not known the extent to which this is truly “voluntary.”

During this visit, Kyiv City TB Hospital #1 and Kharkiv Oblast TB Hospital reported stock-outs or expired stocks in recent history (last 5 years). Kyiv City experienced a shortage of streptomycin and expiry of the first-line medicine ethambutol and second-line medicines—ethionomide, levofloxacin, capreomycin, clarithromycin and ciprofloxacin. Kharkiv Oblast Hospital had a stock out of pyrazinamide, which was resolved by using oblast funds to purchase medicines locally to avoid treatment interruption.

### Tendering

Local procurement is governed by national regulations on tenders. According to Ukrainian law, there is a tender committee within the hospital. Committee members include relevant parties (chief doctor, head of treatment, head of pharmacy, etc.) and may change slightly depending upon the type of procurement or facility. Members are required to receive training in procurement procedures from the MOE at the programmatic cost of 800-1000 Ukrainian Hryvnia (UAH) annually. However, if there aren't sufficient funds, then the staffs do not receive the training.

If the total value of a given procurement is less than 100,000 UAH, then the chief physician can make the decision about selection of distributor. If the total value is 100,000--200,000 UAH, then the tender committee provides its recommendation, although the chief physician may make the final decision. The tender committee advertises requests for proposal (RFP) publicly for orders of 200,000 UAH or more.

The Chief Doctor selects the supplier; most often it will be a firm that offers them flexibility terms of payment, so that they don't run out of stock. Tendering documents specify the conditions of the delivery schedule. Payments are made when budget funds are released. More expensive foreign drugs may be of better quality (Belgian Z&E) but are more expensive and difficult to procure.

Regulations govern how local budgets are to be used for non-drug expenditures (disinfectant, x-ray films and staff salaries), and non-program medicines, while MOH funds are designated for TB and other program medicines procurement. Attitudes about procuring anti-TB medicines locally vary; some sites categorically will not procure them, while others have done so to avert stock outs and treatment interruption. Several facilities reviewed indicated reluctance to procure medicines locally because of the bureaucratic tendering process, the need for approval to appropriate local funds for medicines use and, for some facilities, because they have donated medicines to fill any gaps in supply or can transfer medicines more readily than procuring them.

### Ordering

Sites place annual orders with the oblast electronically, although this must be followed up with a hard copy, which is signed and sealed. If order quantities appear unreasonable, then the oblast hospital chief doctor will call the site to verify or clarify the order requested. The oblast collates the orders and places a total oblast-level order with the MOH 15-18 months in advance of expected delivery.

Sites first place a preliminary quantification estimate and order in April or May of the current year, 2009 for example, for receipt the following year (2010). Final order amounts are determined in September (2009) with forecasted needs for up to 18 months in the future. The MOH usually conducts its tender sometime from December to February (2010). The order is typically received in July (2010). Order forms (zayavka) are the same for both MOH orders and local procurements. The order form includes the name of each drug, dosage form, unit, the number of units per package, and quantity of packages. Orders for 2009 are currently at least 6 months late, but sites expect long delays each year and account for them in their forecasts, inflating their needs by some indeterminate amount.

Once orders are filled, UkrVaccina holds the stocks briefly at central level before sending to the oblasts for distribution, according to a distribution order from the MOH. UkrVaccina does not draw on oblast budgets to store or deliver anti-TB medicines. In the case of Kharkiv Oblast, stocks are provided to the oblast from UkrVaccina in six-month installments, since there is insufficient space at the oblast TB facility for the full annual order. This provides an opportunity to review the quantification and stock balance. The rayons, however, receive the full annual order at one time. It is not known how many oblasts make use of multiple shipments. Nearly all facilities indicated that they often had little notice from UkrVaccina as to exactly when shipments would arrive, making it difficult to arrange for adequate staffing and storage.

### *Storekeeping*

#### Storeroom Management

Hospitals have ordering procedures in place between the departments and the pharmacy store and use an order form for regular (e.g. every 10 days to monthly) orders from hospital

departments. Multiple copies of forms ensure that the information is available to the pharmacist or nurse in charge of the pharmacy stores, bookkeeping, and to the ordering department. Other hospitals transfer medicines from the storeroom to the dispensing area. Pharmacy stores and dispensing areas use manual journals as stock registers to track the internal movement of medicines.

### Storeroom Conditions

At the time of the visit, most of the medicines stores (bulk storage areas) were generally organized (medicines grouped alphabetically or by disease) with adequate pallets or shelving, clean, secure (personnel controlled locks or electronic alarm system), protected from sun and rain exposure, with temperature and humidity records available. Medicines were stored and dispensed according to first-expired, first-out principles. Regular physical stock inventories are conducted at all facilities.

A number of the storerooms visited were in the basement of the building with small amounts brought up to the dispensary as needed, negating the need, in some cases, for mechanisms of temperature and humidity control. Staff at each site asserted that temperatures stayed within the required temperature ranges year round. Only Dniprodzerzhinsk City Hospital had new industrial refrigerators for cold storage in addition to temperature and humidity logs. Only one facility actually uses shelf labels, clearly marked with pertinent drug information (medicine name, quantity, batch number, order number and date and expiration date).

Notable deficiencies in storeroom conditions included:

- Frequent lack of shelf labels for medicines, describing medicine name, dose, and other pertinent information, in bulk storage or pharmacy areas.
- No emergency fire extinguishers were visible
- Power from back-up generators was reserved for the most critical functions in the hospital and not available for the TB store. Site staff indicated that power failure was rare despite one occurrence at the time of the visit.
- Lack of adequate space in a single or contiguous rooms to store all of the TB medicines
- Inconsistent use of pallets to keep medicines off the floor, away from the walls, and to control the number of boxes stacked. In the most extreme conditions, boxes or medicines and other commodities filled closets and office space, packed from floor to ceiling and wall-to-wall, without a means of getting to boxes behind those in front, and raising questions about how FEFO could be practiced.

### Conditions in the dispensing areas

Storage conditions in the dispensing area were variable, usually less well managed than in the general facility bulk storeroom. In some facilities, the medicines fit into a locked cabinet or safe, whereas in others, medicines were found in multiple unlocked cabinets, or stacked on the floor and along the walls of the room. Some facilities employ a two stage process, with medicines kept in the nurse's office, and per patient dispensing occurring in the treatment room, while in others, the operation is self-contained in one room.

There was no air conditioning in the dispensing areas, although at the time of our visit, when it was over 90 degrees F (32 degrees C), the staff tried to ensure ventilation with windows and assured us that temperatures were never sustained over 25 degrees C.

### *Distribution*

#### MOH Supplied Medicines

The distribution process is initiated by an MOH distribution order to all of the oblasts and municipalities following completion of the procurement process. This order accompanies the goods to the oblast dispensary. The oblast/municipal health administration also prepares a distribution order for all of the facilities in its network, specifying the name and amount of medicines that will be sent to each facility.

Some oblasts require that rayon and municipal facilities pick-up the medicines from an oblast-level central warehouse or oblast hospital medicines store. Others arrange for transportation to deliver the medicines to each of the local facilities in the oblast according to the budget-adjusted amount ordered. Occasionally, TB specialists from the rayon polyclinic may deliver medicines to village health workers (feldshers) to support continuous phase out-patient treatment for patients that lived too far from the polyclinic to travel daily. In such cases, the TB specialist or nurse at the polyclinic repackaged enough medicines for the dispensing period (30-40 tablets) into small plastic bags labeled with the drug name, dose, number of tablets and batch number before distributing.

Annual MOH orders received at the central store from the supplier (UkrVaccina) must be accompanied by:

- Invoice/ Delivery Form—form from UkrVaccina which shows MOH payment for goods. The pharmacist signs the form to acknowledge receipt of the medicines and keeps a copy. The invoice documents the product name, manufacturer name, registration number, date of registration, batch number, expiration form, number of tablets in the order, cost per tablet, and total cost. This is logged into the medicines storage area and into bookkeeping, since this involves the transfer of budgetary assets.
- Quality assurance certificate--name of drug, quantity, name of company, batch number, expiration date, drug registration
- Act Transfer/Drug Receipt Form--submitted monthly to UkrVaccina and includes the drug name, order invoice number, date of goods receipt, form of medicine, number of tablets, cost per tablet and total cost.

In order to be accepted into stock all paperwork must accompany the order. If boxes appear to be suspicious and if drugs have 6 months or less until expiry they are exchanged with the supplier for fresh stock. Once received, the pharmacist or other responsible party conducts a visual verification and quality check (on tampered or damaged containers only). Discrepancy reports are available to document damages or differences between goods ordered and goods received. In such cases, the manufacturer either brings replacement drugs or reimburses for the cost of the lost goods. In the last several years, no goods received were damaged, short or not filled in full. Stock is not generally all received at the same time. Often one or more drugs may

be delivered at one time, while other medicines are delivered at another time, after their receipt by UkrVaccina.

### Locally Supplied Medicines

Following a local procurement, local wholesalers send drugs directly to the TB store; usually within the same day of the order. The oblast store is not responsible for managing rayon level private wholesaler procurements. As with the MOH procurements, the receiving store manager conducts a visual verification and quality check, which consists of opening boxes that look like they may have been damaged and looking at jars. No locally procured medicines were reported as damaged or short in quantity upon receipt.

### Recording and Reporting

Records required from the oblast to the national level (MOH, UkrVaccina) include:

- Form #81: Documents that nurse picked-up medicines in preparation for dispensing to the patient
- Quarterly MOH Report: annual request, amount in stock, balance, plan for centralized procurement, amount received from previous quarter, how much of local budget is already spent, how much humanitarian aid received, how much of the drugs were consumed in a quarter and how many months will the drug last
- Annual MOH Information Form: drug name, dose, start balance, amount received, cost, total received, total used, total in stock
- Form #1: Monthly Financial Report—provided monthly to UkrVaccina and quarterly to the MOH/DOE with drug name, dose, start balance, amount received, cost, total received, total used, total in stock
- Monthly Medicines Consumption Report for UkrVaccina and MOH Department of Economics (DOE): starting balance, amount of medicines received and dispensed, ending balance. Separate reports are submitted for centrally procured, locally procured, and donated medicines.
- Act of Control between UkrVaccina and TB Treatment Center: amount of medicine site ordered and the amount delivered
- TB Store Forms
  - Local health administration report to oblast
  - Act to confirm authorization for pick-up; contains batch, drug name, number of tablets, price and total
  - Delivery documents: invoice, transportation declaration, registration certificate, quality testing certificate

Many of the forms and guidelines documented at the site level during the course of the review were developed at site level (homemade) according to the information required. In Kharkiv Oblast, these additional forms for managing the medicines were integrated into the oblast reporting system from the rayon level. In the other oblasts reviewed, however, forms were homemade at the facility level and not disseminated or standardized for oblast-wide use. Though

many of the forms are functional, use of ad hoc forms creates inconsistency within and across treatment centers, and introduces a greater potential for data collection and analysis gaps and errors. Annex 2 contains a list of the homemade and other non-standard forms for pharmaceutical management documented during the site visits.

Additional case management reports are required from the oblasts to the national level quarterly that are indirectly related to the management of medicines and commodities; these include:

- TB-01: *Patient Medical Record for TB Treatment (intensive treatment, lab results, hospital discharge, and continuation treatment)*
- TB-01MDR TB: *Patient Medical Record for MDR TB Treatment (category IV)*
- TB-07: *New Cases and Relapses of TB by Category*
- TB-08: *Results of Treatment for Lung TB for Cohort of Patients Registered 12-15 Months Ago by Category*
- TB-10: *Report of Conversion of Patients at the end of the Intensive Phase*
- TB-11: *Cohort Analysis of Resistance of Antibacterials in a Given Quarter*

### *Use*

#### Diagnosis and Treatment Policy and Protocol

Initial testing and diagnosis may initially be done at the rayon, however, the rayon TB specialist will prepare documentation for the oblast commission, since each TB case is confirmed by the Central Medical Consulting Commission (ЦБKK) from the Oblast. If patient is confirmed by the oblast commission, then the patient is officially registered and the case is reported within 24 hours to the epidemiological control department. There may be multiple commissions in a given oblast, each with its own defined geographic area. For example, in Dnipropetrovsk Oblast, there are three: Dnipropetrovsk Oblast TB Dispensary, Dnipropetrovsk City, and Krivij Rih, as determined by the oblast level order.

The diagnosis for each TB patient is signed by the deputy doctor for treatment of the facility where the patient was diagnosed. The department head should review all patient records and check patient histories; however as existing human resources time is limited, this was not always possible. If the chief doctor disagrees with the prescribed treatment, s/he will discuss the case with the Commission on the Treatment Effectiveness– JKK (head of outpatient clinic, head of department, x-ray and other specialty staffs) at weekly meeting to review problematic cases..

If the patient is doing worse post intensive-phase treatment, the case will have a specialized reviewed by a medical commission (according to the nakaz); which may result in the patient being put on second line therapy or an individualized treatment regimen. The criteria for sending cases for review to the oblast commission include:

- Changes in diagnosis (new diagnosis or patient cured)
- Patient insists that he or she does not agree with treatment
- Seek technical guidance on any really complex cases

Complex cases, including severe ADRs and patient refusal are referred to the Central Medical Consultant Commission consisting of the outpatient clinical doctor, TB Medical University chair, TB specialist and radiologist. The Committee discusses the case and may decide to

change regimen (Order 318). Although this process was explained at one facility, it is not known how active such reviews are at other TB facilities in the PATH oblasts or non-project areas.

Although over half of the facilities reviewed carried at least some second-line medicines in stock, only one was authorized to treat MDR-TB patients. At that facility, the diagnosis and treatment initiation for MDR-TB cases requires signature approval from the physician in charge of the patient, the deputy doctor, and the chief doctor.

#### Treatment Protocols for Sensitive TB

The outline of currently practiced treatment protocols for sensitive TB patients is listed below as documented during the site visits; though some sites mentioned unconventional practices:

- 1<sup>st</sup> line treatment course is 8 months (2-3 months intensive, 5-6 months continuous)
- If patient is ss- TB at diagnosis and ss- at 6 months, then treat with INH monotherapy for month 8-12
- If patient ss+ at diagnosis and ss- at month 6 then treat with INH monotherapy for months 8-12
- If patient ss+ at diagnosis and ss+ at month 6 then start presumptive second-line treatment while waiting for drug sensitivity testing (DST).
  - If DST shows sensitivity to first-line medicines then patients are designated as a Category II (retreatment) case.
  - If DST shows resistance then patients are designated as Category IV and second line treatment begins.

Patients are generally treated in the hospital for the intensive phase. After completion of the intensive phase of treatment, only ss- patients are sent back to rayon level facility for continuation therapy. The dispensary informs the rayon staff closest to the patient's home that the patient is being discharged. The patient is supposed to report to the rayon TB specialist the following day for registration.

If the patient reports to the polyclinic out-patient support services for TB, s/he is expected to return daily to the designated facility for doses of continuous phase medicines (to TB cabinet/office). If the patient elects not to come or lives too far from the rayon center to travel there daily, the TB specialist informs the nurse or feldsher responsible for the patient's area of residence. The feldsher picks up the medication for the patient at the polyclinic; starting with a 10- 30 day supply. It is also possible for a family doctor to administer continuation therapy, but this was not observed in any of the sites visited.

After two months of continuous phase treatment, the patient comes to the polyclinic for a sputum smear test. If able to travel, the patient is sent to the oblast level with a referral form and test results. The pattern of testing and follow-up visit to the oblast level is repeated at months 5, 8 and 12 as required by the order. Oblast medical staffs determine if the patient needs to continue treatment past 5 months of the continuous phase. The criteria for completion of treatment area ss- test result, lack of clinical symptoms, and no disease progression on x-ray. If the test results indicate the patient is still ss+ and the patient continues to be symptomatic; the patient continues treatment with first-line medicines. After completing full course of treatment (8 months), patients receive INH prophylaxis until month 12. Afterwards, patients are categorized as

Category V for a period of five years during which they receive annual x-ray and sputum smear exams.

#### Treatment Protocols for Drug Resistant TB

The MDR-TB treatment standard regimen is inconsistently provided as presumptive treatment while patient waits for 2-3 months to receive DST results. Individual regimens are prescribed based on DST at 3.5-4 months of treatment.

Patients are often asked by care providers to purchase some second-line drugs from private sellers because the drugs are too costly to procure at the state treatment site. Prohibitive costs of drugs from private sellers may cause treatment interruptions or incomplete regimens.

Inappropriate use of second-line medicines to treat sensitive TB or non-TB related infections is a high probability given that three of the sites reviewed carry a stock of second-line medicines. For example, one oblast dispensary received a shipment in June 2009 that included second-line medicines in tablet form. Staff thought that these tablets might be best used for outpatient care following patient discharge, rather than during the inpatient intensive phase.

#### Dispensing

Site staff indicated that they practice DOTS in the facilities visited, though dispensing to patients was only observed by the review team at the Nova Vodolaha Rayon Polyclinic. A dispensing log was also observed at the Dniprodzerzhinsk Municipal Dispensary Staff spoon medicines into a dispensing cup from the storage container. Patients receive medicines in the cup with their information handwritten on a label. Medicines are taken with water in the presence of the nurse. Before leaving, the patient signs the dispensing log to indicate that s/he has received treatment on the date given.

#### Drug Forms: Loose vs. FDC

Some doctors prefer loose drugs for the intensive phase of treatment, since they think it is easier to pinpoint which drug is causing an adverse reaction. FDCs are considered by site staff to be better for adherence to out-patient treatment. Village health centers get a supply of tablets from polyclinic TB Specialists for a week to 10 days. The designated dose of FDCs per regimen is available in orders (nakaz) 384 and 385.

#### Adverse Drug Reactions (ADR)

Most facilities visited do not provide medicines for ADRs to the patient directly through the TB program. Patients either receive medicines for ADRs on an emergency basis through the general hospital supply system or, for chronic conditions, are referred to open market suppliers and provided with a prescription as necessary.

There is not a consistent way of dealing with patients, who have experienced an adverse drug reaction. Uniquely, the protocol in Dnipropetrovsk oblast hospital is 1) to stop all medicines for three days if the patient experiences an allergic reaction; 2) restart the regimen, adding one drug at a time until reaction recurs and 3) replace the drug causing the reaction with a different drug. According to the site, Order #384 directs the doctor with procedures for once a single drug is pinpointed. Only one site indicated that, given their long history of use, the ADRs of commonly

used first line therapy medicines are well known, such that a standardized approach to dealing with them is possible.

### *Program Management*

#### Financial Resources

The four sources of programmatic and commodities procurement are--

- MOH: state budget
- Oblast level: state budget + oblast budget
- Rayon level: State budget + oblast budget + rayon budget
- Village level: State +oblast+ rayon+ village

State budgets cover procurement of TB drugs, lab media and expensive equipment. Budgets are allocated according to the number of patient beds and estimated daily polyclinic visits, which is at odds with medicines and lab commodities needs estimates which are based on morbidity. The formula encourages longer intensive phase hospitalization, rather than quicker progress to ambulatory continuation phase. An order determines staff to beds ratios..

Under local budgets, there are a couple of categories: those that are fully funded (protected), and those that are partially funded (non-protected). The first category covers salaries, taxes for salaries, utilities, drugs, and food, whereas the partially funded includes repairs, equipment, travel expenses, internet, telephone, clothes, blankets, etc. The level of funding depends on the economic situation in the oblast or other administrative unit, and may significantly affect how the health facilities are managed. Often chief doctors are expected to pursue additional funding to their facility to cover these costs, however, in the end, the patient may be expected to purchase medicines, syringes, IV sets, or other supplies.

Sites visited exhibited different adaptations to budgetary constraints. In one instance, the lack of funds was blamed for inability to purchase disinfecting supplies, lab reagents, syringes, or medicines. In another case, the site was able to obtain some supplies through another program, since it was for HIV/TB co-infected patients.

Second line anti-TB medicines represent a particularly challenging problem. Until very recently, there were no approved standard treatment guidelines for MDR-TB. Therefore, patients were, for the most part, expected to purchase their own medicines. Covering the cost of even one of the second-line medicines is prohibitive to treatment for many patients, and it has not been possible to track if patients actually take all of the prescribed drugs. This type of funding-based treatment obstacle increases the risk of MDR-TB.

#### Human Resources

Human resource capacity is strained at the local level. With few exceptions, recruitment of additional human resources is limited by lack of funding, and lack of trained, qualified and motivated professionals in the local area. The trend is likely to worsen in the future as newly graduating medical professionals are not motivated to work in the TB field and the current already middle-aged or older staff begin to retire from service.

All of the sites visited had fewer positions filled than required to staff the TB hospital, except for the polyclinics which may require only one TB Specialist. Sites address the issue by requiring existing physicians to work extra hours to cover all of the activities and TB specialists to each be responsible for two or more areas instead of one. While some sites can afford to motivate staff to take on the additional work by compensating them with salary increases or additional vacation days, others do not have such resources. When possible, city or oblast hospitals lend doctors and staff to uncovered areas and send some patients to oblast facilities.

Because of the volume of standards, orders, and associated reports to track and submit to the national level, oblast TB hospitals each select a different solution to manage the reporting requirement. Some sites elect to have a full or part-time bookkeeper or accountant on staff. Where local budgets are constrained, this may preclude hiring additional needed pharmacy, nursing or medical staffs to the treatment center. In other cases, facility administrators may supplement the salary of an existing nurse or pharmacist in exchange for doing the work of a bookkeeper.

On-the-job or professional training courses are key to maintaining staff skill sets and acquiring new knowledge, skills and abilities as accepted practices in the field change. Conditions at sites visited indicate that there is a need to strengthen basic pharmaceutical management skills to ensure consistent availability of quality anti-TB medicines.

Pharmacists are trained in pharmaceutical management as part of their professional training and continued education courses, but they are rarely found on staff at TB hospital dispensaries, partly due to the inability of the public sector to compete with private sector salaries. Pharmaceutical management training for pharmacy technicians or non-pharmacy staff is not feasible without an MOH order or outside funding. This problem is likely to become more acute as second line therapy is introduced or scaled up, since this will require more dynamic pharmaceutical management. The MOH occasionally substitutes such trainings for memorandum containing MOH instructions or letters of recommendation for site staff review and application.

Instead of regular professional trainings, TB Specialists engage each other in regular experience exchanges. All patient information goes to the oblast dispensary once per month with TB specialists for a “Day of TB Specialists” where specialists meet to discuss and analyze TB mortality rates, impacts on short and long term disability to patients, new protocols, etc. On a quarterly basis, other topics are discussed. This group provides information and analyzes how many patients were detected in each dispensary. It is not known to what extent pharmaceutical management topics are covered, other than potential stock shortages and redistribution.

### Monitoring and Supervision

Each site receives national and state level monitoring and supervision visits. On occasion, staff may also be invited to monitor another rayon level site. Since there is a dearth of TB specialists, monitoring is more difficult with the current system, which is three tiered:

- head of department review
- chief doctor reviews

- central oblast commission

KRU comes every other year to conduct physical stock checks and ensure inventory management and PMIS is conducted according to all orders, standards, protocols and guidelines. City health administration monitors the site to inspect activities in addition to the state inspection.

Oblast staff take turns monitoring each of the rayon-level facilities about once every three months. During the visit, supervisors—

- Use report forms to conduct physical stock checks
- Twice per year there is a quality control inspection but each controlling body informs staff of the visit 10 days in advance. Quality control includes visual inspections of storage conditions, temperature and humidity levels, and also includes random checks of packaging, expiration dates, and checking goods against documents
- In the past, supervisors have used a checklist to identify gaps in pharmaceutical management, however, according to one site, staffs are so experienced in their routine that they no longer use checklists, nor document their findings. In general, they check form TB-01 (Patient hospital discharge form) and dispensing procedures. The lack of documentation of findings makes it difficult to evaluate how useful these monitoring visits are to improved pharmaceutical management.

The oblast administrations conduct a quarterly meeting of all departments that might be involved in TB control, including health, education, family, culture, architecture, police, prosecution, State Security Service (SBU), mass information, finance, social protection; the deputies of each department participate. The participants are the heads of rayon administration, who report on TB control in their rayon.

## **Summary and Recommendations**

The review of previous assessment documents and discussions with national level MOH staff, PATH, and dispensary staff on the site visits were very useful in identifying a number of issues in effectively managing anti-TB medicines and other commodities in Ukraine. These may not be representative of all Ukrainian oblasts, but, in combination with previous assessment, they suggest a number of issues in pharmaceutical management for TB. These issues and challenges are detailed below, followed by recommendations for next steps. A number of these issues may be addressed through this project, however, other central-level issues are much broader, and may require collaboration with other organizations and donors in collaboration with the MOH; and require policy changes, or other longer term actions.

It is also worth noting that some of the issues are already being addressed through the PATH Project, as well as through the MSH Strengthening Pharmaceutical Systems (SPS) Program. These include the adaptation and introduction of the e-TB Manager, a web-based tool for recording TB patient diagnosis, case management, and surveillance. The implementation of the e-TB manager has been approved by the MOH and received its enthusiastic support. It is anticipated that implementation of the e-TB Manager will facilitate timely reporting, as required by the MOH, and generate information needed for improved case management, and more effective drug management.

In order to reach the goal of consistent availability of anti-TB medicines and other commodities of assured quality, however, there is still a need to strengthen basic pharmaceutical management skills at all levels. Some facilities have developed very effective systems, and it is hoped that counterparts will fully participate in sharing these lessons learned with their peers, and in further developing their own capacity, and that of their colleagues.

### ***Key Strengths***

Ukraine's TB pharmaceutical management systems were performing well in the following areas:

- At the time of the visit, DOTS medicines were available at the point of care, with no reported stock outs or treatment interruptions
- Standards, orders, and protocols are available and followed as directed for quantification; ordering; receiving and dispensing medicines; and reporting
- Communication and coordination between provincial, city, and rayon level sites is relatively good with staff working together to redistribute or locally procure medicines as needed when stocks are low
- The MOH has approved and is supportive of implementation of the eTB Manager to improve information systems, reporting, and the use of the resulting data for decision making and program management

### ***Key Challenges in TB and MDR-TB Control and Treatment***

Several challenges, however, impede progress to improving TB treatment and control:

- Uncertainty about the procurement schedule has been the source of consistent challenges in forecasting annual needs at the local level

- Infrequency of procurements further challenges local medicines and commodities budgeting and forecasting capacity. The short shelf-life of costly second line medicines will necessitate changes to the ordering and receiving schedule.
- Stock outs, failure to adhere, and other treatment interruptions can result in treatment failure and the rapid development of drug resistance. Although sites visited have not experienced stock outs recently, other reports have documented sustained stock outs annually, since 2002
- Poor quality of medicines and laboratory commodities can contribute to drug resistance
- FDCs are available in only a few oblasts, and second line drugs are not currently available through the GLC
- The supply system is not sufficiently responsive to needs of new patients, treatment status and location changes, regimen alterations related to disease status, and changes to guidelines
- Compliance with required reporting is generally accomplished in an inefficient manner, including the use of non-standardized forms, duplicate information submission (monthly, quarterly, manual, electronic)
- The collection and submission of data does not, generally, result in analysis and use of these data by local staff for improving their own program management

### ***Key Issues***

Programmatic areas of concern with respect to pharmaceutical management for TB are:

- *Quantification*
  - Lead times on procurements are 15-18 months making forecasting challenging
  - Site forecasts are often adjusted to meet budget constraints
  - Stockouts have been avoided because oblast staff monitor city and rayon stock levels to anticipate and troubleshoot shortages
  - Oblast level staff use may local funds to directly procure medicines from local manufacturers to close supply gap, but this is at the expense of other categories of goods and services
  - Rayon or city level sites may request redistribution from other sites within the oblast to meet medicines demand
  - The understanding of what constitutes buffer stock is inconsistent, and is confused with acceptable increases to accommodate growth in the number of patients. This may lead to errors in quantification calculations.
- *Record keeping and reporting*
  - Standard forms monitor the financial aspects of medicines as opposed to medicines or program management
  - A wide variety of locally developed (home-made) forms are used to monitor site inventory (expiration, stock balance, received, issued)
  - Staff often hand copy patient information into journals to consolidate essential information from several reports or patient forms.
  - Electronic tools in facilities are generally unavailable for pharmaceutical management, making the process time intensive and laborious; usually these are used for accounting, which is not responsible for pharmaceutical management

- *Inventory Management*
  - Deliveries of annual quantities of anti-TB medicines are problematic for sites, that have inadequate storage space to accommodate an annual supply of medicines at one time
  - Sites use re-distribution as a mechanism for avoiding stock outs, rather than periodic ordering and delivery of shipments to reflect actual needs
  - Some staff have insufficient knowledge of or training in comprehensive pharmaceutical management
  - Few job aids exist for reference, or to serve as checklists
- *Monitoring and Supervision*
  - Staff responsible for conducting supervision visits don't have or don't use a pharmaceutical management checklist; it is unclear exactly what or how they conduct monitoring activities
  - Staff do not use non-financial indicators to monitor the status of medicines and commodities management
- *Training*
  - Training for pharmaceutical management is not available to non-pharmacists, and rarely occurs for pharmacists as part of their continuing education

### ***Strengthening TB and MDR-TB Pharmaceutical Management in Ukraine***

#### **Recommendations:**

- Conduct an options analysis to review findings, prioritize issues, and develop a plan for addressing them
- Strengthen quantification of anti-TB medicines (first and second line) through technical assistance and training
- Review and revise existing instructions for annual quantification to reflect the most recent standard treatment guidelines
- Develop or refine practical record keeping tools to facilitate data collection, analysis, and reporting relative to medicines; make the tools consistent with and complementary to the eTB Manager
- Work with counterparts to adapt effective pharmaceutical management tools, and develop methodology and tools to address gaps in inventory management practices
- Further enhance counterpart capacity to assess and monitor pharmaceutical management practices by including them in site visits to other PATH project focus sites

#### ***Action Plan and Next Steps***

Given the findings and proposed long and short term recommendations in this report, PATH and MSH/CPM will work with stakeholders in an options analysis workshop to review and prioritize issues and needs, identify and analyze options for addressing them, and develop an action plan to strengthen existing TB and MDR-TB medicines management systems.

## **ANNEX 1 – PERSONS INTERVIEWED**

### **Ministry of Health**

- Svitlana Oleksandrivna Cherenko, Director, Committee on HIV/AIDS, TB, and Other Socially Dangerous Diseases

### **Kyiv Municipal TB Hospital**

- Leonid Vasyliovych Stadnyk, Chief Doctor
- Alla Georgivna Cherkaska, Pharmacy Director
- Svetlana Hryhorivna Pavlenko, Deputy Director for Treatment

### **Kharkiv Oblast TB Hospital**

- Tatiana Vasilivna Sencheva, Chief Doctor, Chief TB Specialist for Kharkiv Oblast
- Irina Mykolajivna Kalmykova, Deputy Director/Head of Treatment
- Taisia Fedorivna Kovalova, Head of Organization and Methodology Department
- Lyubov Mykolajivna Kosachenko, Bookeeper/accountant
- Natalia Ivanivna Kolontajivska, Pharmacist

### **Nova Vodolaha Rayon Polyclinic (Kharkiv Oblast)**

- Ivan Nikolayevich Konovalov, Hospital Director
- Olha Borisivna Zavada, Rayon TB Specialist
- Liudmila Mykolayivna Moroz, , Chief Doctor
- Valentina Mykhailivna Holovash. First Deputy for Medical Assistance to the Population
- Maria Fedorivna, Doctor (Lab Specialist)

### **Dnipropetrovsk Oblast Hospital for TB and Other Lung Diseases**

- Dmytrij Geogievich Kryzhanovskyj, Director
- Olena Vitalijna Vorontsova, Deputy Director for Treatment
- Alla Aleksandrivna Kotelnikova, Information and Analytical Department
- Natalia Lukianova, nurse in charge of drug stores

### **Dniprodzerzhynsk City TB Hospital**

- Oleh Fedorovych Yatsenko, Chief Doctor
- Tatiana Vasyliivna Podkovirova, Deputy Director and Head of Treatment
- Irina Mishyna, Chief Nurse
- Lyubov Mykytivna Buhayova, Head of Lab
- Alina Volodymyrivna Korniyenko, Statistics Department

### **USAID**

- Leslie Perry, Director, Office of Health and Social Transition
- Alina Yurova, Program Manager, PATH CTO

## **ANNEX 2. EXAMPLES OF LOCALLY DEVELOPED FORMS**

- Kharkiv Oblast TB Hospital
  - Expiration: tracking sheet with drug name, quantity, batch and expiration
  - Stock record/bin card: medicines received, date, amount dispensed to oblasts and running balance
- Nova Vodolaha Rayon Polyclinic
  - Medicines Ordering Documents: homemade order form for both regular and emergency orders with the name of the drug, dose, form and quantity with signatures
  - Dispensing/DOTS treatment record: name of patient, birthday, TB category, pill number, medicines, dose, starting drug balance, drug producer, dispensed drug and amount, nurse signature
  - Distribution record to health centers: date, patient name, birth year, number of drugs, name of drugs, village of residence, TB category, feldsher's name, signature
- Kyiv City TB Hospital #1
  - Monthly Financial Report: submitted to the accounting department with date received, drug name, source received from (dispensary or manufacturer), batch number, quantity of medicines, price and expiration date
  - Inventory Management and Pharmaceutical Management Information Systems (PMIS):
    - Stock record (journal) for each TB medicine: drug name, batch, packaging type, monthly starting balance, number received, number dispensed, price per unit, total price, monthly ending balance, total value of end balance
    - Treatment report forms: patient medical record with clinical history, and prescribing form
- Dnipropetrovsk Oblast Hospital for TB and Other Lung Diseases
  - Stock report: expiry dates and stock levels
  - Stock record (journal): Medicines received/dispensed record, running balance: date received, batch number, how many requested by/dispensed to internal departments, cost and total
  - Expiration: tracking and analysis record
  - Order form: request for medicines from departments to the pharmacy; one copy each is provided to the bookkeeper, pharmacy and requesting department

**Consultative services under the Ukraine TB Control Partnership  
Project**

**Report from mission 10 – 19 December, 2008**

**Consultants:**

*Giovanni Battista Migliori, M.D.*

*Alberto Matteelli, M.D.*

## **MISSION REPORT**

### **BACKGROUND: THE PATH PROJECT**

PATH is a contractor of USAID for a 4-year project (2008 – 2011) to help Ukraine achieve a case detection rate of TB of 70% and a TB cure rate of 85%.

PATH has considerable experience in the field of TB action in Ukraine: it participated in the WHO sponsored first phase of the Donetsk DOTS pilot project (2001 – 2003) and USAID sponsored DOTS expansion projects in 8 more oblasts (2003 – 2007).

The current PATH project has several objectives:

1. Support the human resource development programme on TB for health staff in the TB programme and the Primary Health Care System
2. Support the update of the TB component of undergraduate training curricula for several health professionals
3. To develop and implement advocacy strategies for TB at national and regional level
4. To enhance laboratory capacities to detect TB and DR-TB through procurement of essential equipment and supplies, supporting quality control procedures, training of lab staff
5. Strengthen the recording and reporting system and the analytical capacity
6. Provide technical assistance for the development of TB control policies in the penitentiary system
7. Strengthen the management of MDR-TB by reviewing national recommendations, establishing a national reference centre and support two additional DOTS-plus projects
8. Strengthen the management of TB/HIV co-infection by making a baseline analysis of current practices
9. at oblast level and support the development of collaboration mechanisms, developing action plans and monitoring and evaluating the plans. In addition, a human resource development plan will be prepared based on the training of trainers.
10. Determine the policy, legal, regulatory fiscal and attitudinal barriers hampering TB and TB/HIV control

The PATH project targets 10 of the 24 oblasts and 2 municipalities which constitute Ukraine.

### **TERMS OF REFERENCE FOR THE VISIT**

1. To assess TB/HIV basic regulations, procedures, and practices at the National and oblast level in Ukraine

2. To provide recommendations for revision of TB/HIV practices, if required, in accordance with international standards and best practices
3. Assess the TB case detection and referral routine practices at the HIV/AIDS centers, and the TB/HIV case management practices in the TB hospitals in project oblasts
4. To plan for baseline trainings and TOT on TB/HIV collaborative case management for the selected TB hospitals and HIV/AIDS Centers staff in project oblasts.

### **MAIN ACTIVITIES DURING THE VISIT**

1. Briefing with the PATH responsible persons and technical staff and discussion on the overall objectives and activities of the TB/HIV intervention as a component of the PATH project for TB support in Ukraine
2. Meeting with representatives and technical staff of partners at National Institutions and at municipality clinical sites
3. Visiting Zaporizhzhya Oblast and meeting with stakeholders of TB/HIV activities
4. Reviewing national epidemiological information and national policy documents
5. Managing strategic discussion with stakeholders to identify an agreed-upon strategy for TB/HIV training able to have an impact on TB/HIV collaborative activities in the country

### **MAIN FINDINGS OF THE VISIT**

#### **A. TB and TB/HIV epidemiology and response in Ukraine**

##### The country:

Ukraine is located in Eastern Europe. Total area of Ukraine is 603,7 thousand square metre. Population - 46 6million (2006), urban population - 67,9% , density of population – 83 persons on square metre. Kyiv, the capital city, is the largest city in Ukraine with a population of 2.6 million.

Administrative structure\_: 24 Oblasts , autonomous republic Crimea, Kyiv and Sevastopol Cities. Ukraine have 448 towns, 897 urban villages and more then 28 thousand villages.

Main ethnic group: Ukrainian; official language: Ukrainian; religion: different confession of Christian, GDP per capita: \$1520.

##### Health indicators:

Life expectancy at birth: 66 yrs; maternal mortality rate: 30.2; infant mortality rate: 61.7; under 5 mortality rate: 24.7; fertility rate: 1.9 children born/woman. Main causes of death tuberculosis, acute & chronic infections, cardiovascular and oncological diseases.

#### TB indicators:

The 2006 TB indicators for Ukraine are as follows: TB mortality reached 15/100,000, from 6 in 1990; TB incidence of all forms is up at 106 /100,000 from 41/100,000 in 1990; smear positive PTB cases are up at 47/100,000 from 19/100,000 in 1990. This rates translate into 49,000 TB cases (among whom 21,000 smear positive PTB cases) diagnosed and managed by the TB service in the country per year. The number of prevalent cases is 53,000, only marginally larger than incidence.

The case detection rate is 79% among all forms and 65% among smear positive PTB.

Figures on the treatment success rate are not officially available in the country. However, Ukrainian unofficial data quote a success rate of 56.2% and a default rate of 8.8% in 2006.

#### MDR-TB indicators:

MDR-TB cases are not routinely reported and their number is unknown. A DST survey (DRS) has not been performed in the country.

There is no NRL identified for DST in the country. Some laboratories do perform DST in Kyev, but there data cannot be quoted since the laboratories do not adopt any quality control programme.

The existence and importance of the MDR-TB epidemic in Ukraine is suggested by the survey conducted in the Donetsk Oblast from 2002 to 2007, showing a prevalence of MDR-TB of 15% among unselected new TB cases and above 40% among previously treated TB cases.

WHO has estimated that 22% of new TB cases (all forms) are MDR – one of the highest in the world and that the number of estimated MDR-TB cases in 2006 was 13,429.

#### TB control programme:

DOTS Programme started in 2004 and reached an official 100% coverage of civil population (but all components of the Stop TB Strategy are not implemented in at least 60% of the population), while the coverage in prisons is presently difficult to estimate. Political commitment to DOTS is good, but only 20% of the 64 points of National TB programme 2007-2011 are covered by the national budget and about 30% of all activities have no budget at all. GLC programmes were approved in Ukraine in 2006 and 2007.

Many of the current TB strategies are still not consistent with international recommendations and the use of resources is not cost-effective. Examples of interventions with questionable efficacy include case detection using mass photo-fluorography, mass annual tuberculin screening of children, multiple BCG re-vaccination, mandatory hospitalization of sputum smear positive patients in TB hospitals, TB diagnosis restricted to TB specialists (even in cases confirmed by the laboratory), non-standard treatment, long-term hospitalization and follow-up of patients after completion of treatment. Obsolete regulations are not in line with more recent international guidelines.

#### HIV indicators:

At the end of 2007 139,660 cumulative HIV cases were registered in Ukraine; of them, 26,351 had developed AIDS and 14,918 had died. Although the remainder cases are considered to be alive, there are doubts on the capacity of the current HIV reporting system to capture this information. Ukraine has the fastest grow in the HIV epidemic of all countries in the European region: the annual new HIV diagnoses have more than doubled since 2001 (UNAIDS global report, 2008). The UNAIDS estimates of the number of PLWHA in Ukraine exceeds 440,000. Women represent about 40% of the cases. Intravenous drug abuse is the main risk factor, with an increase of the sexual way of transmission: in 2002 specific weight of IDUs among HIV positive registered persons was 52.4% in 2007 – 40%.

HIV prevalence was 16.5% among IVDU in 2006, rising from 11% in 2001 (EuroHIV, 2007). However, studies conducted among IDU participating in harm reduction and outreach programmes since 2001 found prevalence levels of >50% in Poltava, Odessa, Simferopol and Nikolaiev. Among blood donors HIV prevalence increased from 2.1 per 100,000 donations in 1995 to 128.4 in 2004, and has since stabilised with a reported prevalence of 127.1 per 100,000 in 2006 (EuroHIV, 2007). Exceptionally high HIV prevalence, exceeding 1%, was reported among pregnant women in three large, densely populated regions: Odessa oblast, Kiev oblast and Mykolaiev oblast (Ministry of Health [Ukraine], 2008). Most of these women were probably infected during sex with a partner who had been infected through use of contaminated drug injecting equipment (Scherbinska, 2006; EuroHIV, 2007a).

MOH reports that 10,000 HIV infected persons are receiving antiretroviral therapy: therefore much less than 10% of the persons with an HIV diagnosis have current access to antiretroviral therapy.

#### HIV control programme:

A national strategy for information, education and prevention, including special activities for vulnerable groups has been developed.

HIV care is structured with a central Service, the Ukrainian National AIDS Centre, which is responsible for the implementation of the AIDS control programme. At each of the 24 Oblasts of Ukraine (and in the 2 municipalities as well) there is an Oblast AIDS centre; all oblast AIDS centres are supervised quarterly by the central service, and provide epidemiological data quarterly.

Counseling and testing capacities may still not be optimal. HIV testing consists of two consecutive IFAT for screening. Confirmation is required for all cases with positive IFAT, based on addition IFAT. IFAT test are available at every Regional Hospital, CD4 cell count are measured by cytofluorometry in Oblasts level labs. HIV testing is proposed by doctors to all pregnant women.

HIV drugs are available and purchased by Ukrainian HIV/AIDS Alliance Global Fund Project, but drug access is limited to an oblast level AIDS Centers. Plans for decentralization of ARV access have not been implemented yet, according to agreement among Global Fund and MOU ART will be supplied with Ukrainian National budget.

#### TB/HIV indicators:

The number of persons with TB/HIV co-infection reported to MOH increased from 1,526 in 2005 to 1,967 in 2006, which makes Ukraine the country with the largest number of reported cases in Europe, having taken over the Russian Federation.

There is no national surveillance of the prevalence of HIV infection among TB patients. The Donetsk Oblast carried out a special survey on a representative sample of newly diagnosed TB patients in the first half of 2006 finding a prevalence of 15.5% and 23.7% in the civilian and penitentiary system respectively. The WHO estimate of HIV infection among TB patients was 8% in 2007, a likely underestimation according to the Donetsk data.

There are no data on the incidence of TB among HIV infected persons.

The analysis of the reports to MOH shows that of the 14,918 death among HIV infected persons, 60% had been attributed to TB.

#### TB/HIV collaborative activities:

Ukraine has a national coordinating body and Coordinating Body on Oblasts level but have no national and oblasts plan for collaborative TB/HIV activities.

Since 2006 till 2008 a pilot project was implemented in 3 small Cities of Donetska and Dnipropetrovska oblast. Main goal of the project was to develop a model of TB/HIV collaboration. Since October 2007 the “TB Control Partnership” Project supported by USAID was launched in 10 oblasts. The goal of this project is to provide access to TB/HIV co-infection services to 30% of the population by 2011. To achieve this goal PATH planned to expand developed model of TB/HIV case management teams, implement TB symptom screening, referral process, and treatment support using HIV service organizations and PLWHIV NGOs as key service points,

#### Global Fund:

Ukraine received a grant in the frame of the 6<sup>th</sup> round of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) in 2004. The 60 US\$ million grant to control HIV aimed at strengthening HIV control including implementing TB/HIV collaborative interventions and providing prevention programs focused on the needs of vulnerable populations, and improving access to care, support and treatment for HIV/AIDS patients (including ARV and supplies procurement).

#### **B. Human resource development (HDR) in the field of TB/HIV in Ukraine**

No HRD plan is available at the national level. Information on existing training activities is reported below:

1) The All Ukrainian network of PLWHA, that is a co-recipient of the GFATM proposal (round 6) has planned, among other activities to train 600 staff by 22 one-week training courses. The curriculum for the course, which focuses on TB/HIV treatment and case-management of IVDU cases, is derived from the Regional Knowledge Hub for the Care and Treatment of HIV/AIDS in Eurasia, located in Kiev, Ukraine. The trainings have been recognised and certified by the Kiev Academia of Post-Graduate Education. No information on the geographical location of the training is available. Participants were selected from Infectious Disease specialists engaged in HIV case management at Oblast level. Five course were implemented in Ukraine in the period 2006-2008. Two courses were held in 2006, the remainder three were carried out in the second half of 2008. A sixth course is planned for the coming future. The courses have provided training to about 165 physicians (but no official data are available) on a total of 600 planned.

A summary of this training course agenda with comments is reported as Appendix 3.

The 2009 plans of their activities include a) a TB/HIV new course targeting specifically TB specialists at Oblast level; b) a ToT course on TB/HIV; c) a refresh course for staff who received training in 2006 and 2007.

2) Clinical training was organised by Clinton Foundation in 1 Oblast (Dnipopetrovska). According with the information available 2 training courses were organised but information on output is not available.

### **C. TB/HIV case management policies and practices**

#### *Political support*

The head of health care administration of the Zaporizhzhya Oblast declared awareness on the significance of TB/HIV co-infection as a public health problem and promised support for the planning and implementation of TB/HIV collaborative activities in the Oblast.

A coordinator of TB/HIV activities at national level was not available for discussion.

#### *Plans on TB/HIV collaborative activities*

A national plan for TB/HIV control activities has not been developed so far.

An array of activities are implemented countrywide which, however, do not follow a national strategy.

The process to develop a plan of TB/HIV activities in the Zaporizhzhya Oblast was recently started.

An agenda of the works and a timetable are not available.

A national policy document on TB/HIV collaborative activities has been published by the MOH in 2008.

#### *Surveillance of HIV incidence among TB patients*

Information on the proportion of HIV positive subjects among newly diagnosed TB patients in Ukraine is not available.

The current TB notification forms identifies the concomitant presence of HIV infection in the reported TB case. The data collection department of the National TB Institute collects information on the number of newly diagnosed TB patients. However, the denominator is unknown because the number of persons being tested for HIV is not registered. Hence, even the prevalence of HIV infection among TB patients remains unknown.

Diagnosis of HIV infection in a TB patient. According to the approved TB/HIV national protocols every new TB patient should receive an offer for HIV testing.

Information on this recommendation is widely available at TB services. However, the proportion of patients being tested is not currently monitored.

Pre test counselling for HIV testing among TB patients is performed by doctors at TB facilities. The quality of counselling procedures has not been evaluated.

The result of the HIV test may not always be returned to the facility prescribing the test. It was mentioned that sometimes TB clinicians need to be informed by the TB patients themselves on the patient's HIV status.

In general, staff at the TB clinical services does not seem to be adequately empowered on the comprehensive case management of TB/HIV co-infected persons

TB case detection among PLWHA. All HIV centres in Ukraine are supposed to have access to regular consultation from TB specialists, which are carried out at the HIV centre itself.

Approved TB/HIV protocols for PLWHA include initial and follow-up assessment in asymptomatic HIV persons, management of contacts of TB contagious cases, and management of symptomatic HIV persons. Assessment of the cases is based on history of exposure and symptoms, chest X-ray and smear sputum microscopy.

The diagnosis of smear negative pulmonary and extrapulmonary TB remains challenging. HIV clinicians complaint that some HIV infected TB suspect are denied TB treatment by the TB services. The proportion of smear positive TB cases is, at national level, 44.4%, not far from the expected one. At the same time, the proportion of smear positive among HIV infected TB cases is only 35%, which may be justified by either early treatment of TB suspect among HIV infected persons, or by particularly poor TB diagnostic capacities in HIV infected persons.

Patients flow between HIV and TB services is currently in place (though requiring patients to consult separately the two services): this seems to work in urban areas. The performance of the referral system in rural areas was not observed.

There are no indicators to monitor the performance of the screening system of HIV infected persons.

There are no indicators to monitor the performance of the referral system between TB and HIV services.

Infection control in TB hospitals: HIV infected persons with TB are hospitalised in TB hospitals if they have smear positive pulmonary TB, and in HIV hospitals in affected by non contagious forms of TB.

Infectiousness of TB/HIV co-infected persons is excluded by smear microscopy: patients with smear negative pulmonary TB are admitted to HIV ward with other HIV infected persons.

Infection control measures are not implemented in TB hospitals. Patients with MDR-TB are confined in rooms with other patients with MDR-TB. However, there is wide recirculation of the air between MDR rooms and common spaces. Respirators are not used for protection of health staff entering the rooms (including MDR rooms).

As a result HIV infected persons are at considerable risk of MDR infection and disease.

Isoniazid (INH) preventive treatment (IPT). The national policy document does not include a section on this issue, although the draft version included a paragraph on this.

The most logical interpretation is that IPT is not strongly recommended as a component of TB/HIV interventions. However, there is little awareness of this recommendation even with clinical persons at centrally located services.

As observed during the field visit, in the clinical practice some HIV doctors mentioned that isoniazid plus ethambutol for three months was prescribed as preventive therapy for TB patients. The reported criterium to prescribe preventive therapy was a CD4 cell count  $< 200 \text{ mm}^3$ . The Zaphorizhzya AIDS centre has prescribed isoniazid and ethambutol preventive therapy to 41 HIV infected persons in 2008, which accounts for 2% of the total number of HIV infected persons followed at the centre.

No role was apparently recognised for tuberculin skin testing, however, this test is reportedly applied in a substantial proportion of HIV infected patients for undocumented purposes.

A careful search of existing documents allowed to trace a Prikaz covering this issue (N° 344, issued on December 15<sup>th</sup>, 2000 and reproduced in a 2004 version: Methodological recommendation on improving medical management of patients with HIV/AIDS). The Prikaz allows specialists to prescribe IPT when PPD conversion is observed (defined as increase by  $> 6 \text{ mm}$  from previous results available), when fibrotic lesions are available in the CXR and in contacts of SS+ cases. The Prikaz does not specify that active TB disease needs to be excluded before prescribing IPT. The regimens recommended 3 month with isoniazid + ethambutol or isoniazid + pyrazinamide. Finally, HIV specialists, after consulting with TB specialists, can prescribe IPT in HIV positive individuals with  $< 1,500$  lymphocytes or  $< 200 \text{ CD4 cells/ mm}^3$ .

The regimen is the one recommended before, prescribed once a year for 3 months.

Cotrimoxazole (CTX) prophylaxis for TB/HIV co-infected patients: The national policy document endorse the use of CTX for all co-infected patients (although with some confounder of CD4 cell count).

Antiretroviral (ARV) treatment and clinical management of TB/HIV patients. The national policy document endorses the use of combined HIV and TB therapy, but does not specifically encourage timely initiation of HIV therapy on immunocompromised persons.

In clinical practice ARV therapy is considerably delayed, also and most importantly in immunocompromised patients, on the basis of the fear of the immunoreconstitution syndrome, the risk of drug toxicity, and concerns on adherence.

In general, clinicians are reluctant to prescribe ARV for HIV infected patients who are drug addicts on the basis of anticipated poor adherence and limited availability of HIV drugs.

There is no current monitoring system to measure the proportion of TB/HIV patients starting ARV. Initial management of TB/HIV infected patients is currently preponderantly carried out as inpatients service. There are advantages in this practice, as TB hospital beds are widely available, admission duration can be extended as much as necessary, high quality TB specialist care is available, and regular HIV consultancies are organised. However, supervised administration of TB drugs is reportedly not ensured even for hospitalised patients.

Treatment continuation and adherence. The current strategy for follow-up procedures of TB/HIV patients is based on separate and parallel follow-up by TB and HIV services. Follow-up of out-patient TB treatment is carried out at TB dispensaries. Out-patient follow-up for HIV is carried out at AIDS centres. Patients, hence, need to independently consult two services during the continuation phase of TB therapy.

Monitoring and reporting systems. A M&E plan for TB/HIV activities does not exist.

## **D. Training for TB/HIV clinical management**

### **PATH mission on the topic**

According to the project, PATH should train at least 300 people in selected Oblasts (3 to start to reach 10 by the end) from 2009 to 2011. The training should be organised in a way to ensure sustainability as well as quality conduction of M&E.

## **Analysis of facts**

Discussion with PATH staff, stakeholders and partners suggested the following:

1. The existing TB/HIV training is not coordinated among partners and stakeholders
2. There is no plan for HRD in the country (neither for TB/HIV nor for TB)
3. Agreed-upon standard training materials have not been developed
4. Training materials and learning objectives were not based on task analysis and needs assessment
5. Geographical distribution (where to perform the training) and outputs (how many participants need to be trained) have not been discussed among partners
6. The existing training content is exclusively clinical
7. M&E of the training effort has not been planned, the only (weak) indicator being the number of participants trained
8. The existing training is unlikely to impact TB/HIV coordinated activities in Ukraine

## **Opportunities**

Discussion with PATH staff, stakeholders and partners suggested the following:

1. PATH has the opportunity to be a catalyst of TB/HIV training in Ukraine
2. Opportunity exists for PATH to coordinate TB/HIV training in Ukraine, stimulating implementation of a working group able to decide how to cover the country with quality training addressing the issue of both quality and quantity
3. Agreement was found to base the training on the WHO TB/HIV module performed in Sondalo, of whom a Russian translation is already available
4. Agreement was found in sharing the Sondalo module with partners to allow comments and relevant input
5. Agreement was found in implementing a 2-steps procedure consisting on: a) 5-day TB/HIV training for staff in selected Oblasts; b) 5 days ToT designed to allow selected facilitators to run a 4-day TB/HIV training at Oblast level
6. Opportunity exists for PATH to implement a quality M&E of the training performed and to use it to stimulate a similar process in Ukraine. In particular, on the top of the output indicator (number of persons trained), the evaluation process can benefit from using other tools, designed to approach quality of training on the top of the quantity (see recommendations).

### **Timeline of activities**

- 1) PATH Kiev Office to initiate steps to convene a TB/HIV training working group (by 20 Jan 09)
- 2) PATH Kiev Office to initiate strategic discussion within the working group (objectives, targets, etc) (by 20 Feb 09)
- 3) PATH consultants to provide revised and updated version of the Sondalo TB/HIV Package with available Russian translated modules by 15 March 2009. In addition, Facilitator Manual for ToT to be made available for translation into Russian.
- 4) PATH consultant/s available to attend 1 day meeting in Kiev with the working group if necessary (15-30 March 09)
- 5) PATH Kiev Office and working group to comment, include slides relevant to the Ukrainian context and part of the modules specific for the country (e.g. R&R forms) (by 30 March 09)
- 6) PATH Kiev Office and working group to made final materials available for translation by 15 April
- 7) Translator to made the whole kit of materials translated by April 15
- 8) Training to be done in Kiev from 18 to 23 May 09 (International facilitators: Prof. GB Migliori and Giovanni Sotgiu)
- 9) Selection of facilitators to train to be done by the end of the training
- 10) ToT to be done in Kiev from 8 to 14 June (International facilitators: Prof. GB Migliori and Alberto Matteelli)
- 11) Training in Oblast to be performed according to a timeline to be defined within the working group
- 12) Need to develop an HRD plan to be proposed to MOH by the working group

The above mentioned plan of activities allows PATH to cover the points 1,5,8,9 of its project.

### **CONCLUSIONS AND RECOMMENDATIONS:**

#### **1) TB/HIV recording and recording**

A monitoring and evaluation plan should be drafted and adopted by the MOH. It should identify indicators, monitoring tools and responsible persons.

The newly developed TB reporting forms should be introduced, in order to allow for monitoring HIV infection rates among newly diagnosed TB patients.

The use of the new pre-ART and ART registers should strongly be supported, as they represent the backbone of the system to conduct cohort analysis.

On the MDR-side, the implementation of a specific MDR-TB register is recommended. This will generate the positive process of looking at the DST results in the laboratory and to couple them with the data available in the laboratory. Unfortunately, at present, even the data available in the laboratory are often not request by clinicians to be used in the clinical practice.

## **2) TB/HIV collaborative activities**

A TB/HIV management group should officially be established in the intervention Oblasts. Reports on meetings should be utilized to monitor the output of the group.

A plan of action for TB/HIV collaborative activities should be prepared in intervention Oblasts. The plans should consider the national TB/HIV guideline and translate it into an activity plan. The plan should include the identification of programme and epidemiological indicators.

HIV infected subjects who are suspect TB cases should be screened with microbiological methods (microscopy and culture). TB therapy should be strongly considered even in absence of microbiological confirmation. Treatment should not be delayed, especially in severely immunocompromised persons.

HIV infected persons should not be hospitalized in TB hospitals, unless adequate infection control measures are ensured.

HIV therapy should be started as soon as possible after 2 weeks of TB therapy in TB/HIV co-infected patients and CD4 cell count < 200.

Operation research should be planned in the field of treatment of latent tuberculosis infection in HIV infected persons (including criteria for treatment and adequate treatment regimens).

## **3) TB/HIV training**

It is recommended to implement the timeline mentioned above.

Although it is necessary to involve stakeholders and accept their suggestions, it is recommended to guide firmly the process to keep the basic structure as approved by all stakeholders. This structure is based on internationally recognised guidelines, and allows to train participants on how TB and HIV/AIDS programmes work. Public health vision is necessary in Ukraine to allow clinical activities to be run in a cost-effective and evidence-based manner.

All contributions related to Ukrainian-specific issues are welcome (e.g. addition of slides on epidemiology, activities, experiences, etc, on the top of the mandatory Unit on recording and reporting forms used in Ukraine), but the overall balance of arguments should be maintained. The June course is done over 5 days considering the extra time needed for consecutive translation. The final format to be managed at Oblast level will be on 4 days.

M&E can be based on a reaction evaluation questionnaire (distributed to participants at the beginning of the training and filled-in on a daily basis) and on outcomes represented by, e.g., the exercises performed by participants, the plan on TB/HIV collaborative activities implementation drafted by participants and the recommendations made by participants on how to improve the TB/HIV R&R system. Finally, the participant and facilitator manual translated into Russian will remain as a relevant outcome of this initiative.

## **SPECIFIC RECOMMENDATIONS FOR PATH**

1. A comprehensive human resource development programme on TB/HIV should be developed, implemented and monitored according to the steps described above.
2. A M&E plan for TB/HIV activities should be developed at national level and in intervention Oblasts.
3. Support should be given to the establishment of TB/HIV collaborative committees and plans in intervention Oblast, whose main purpose is build capacity of collaboration between TB and HIV/AIDS services.
4. Microbiological diagnostic capacities for TB should be strengthened for TB/HIV co-infected persons, primarily by establishing a quality control system for microscopy, culture, and DST.
5. TB services should be encouraged to become a significant entry point for ARV care by making ARV accessible to severely immunocompromised TB/HIV patients in the early phase of TB treatment

6. HIV/AIDS services should be encouraged to rapidly explore the need and possibilities for decentralisation of access to ARV in semi-urban and rural areas for HIV infected persons in general and TB patients in particular
7. Operational research in the field of treatment of latent TB infection among HIV infected persons should be supported

### **Acknowledgements**

We wish to thank all PATH Kyiv Office staff for their competent and pro-active attitude, making out visit fruitful and pleasant.

*Appendix 1. Agenda of the mission*

**Wednesday, December 10 2008**

- Arrival in Kyiv

**Thursday, December 11 2008**

- Briefing with PATH staff
- Meeting with the chief, HIV services, and visit to the National AIDS Hospital
- Meeting with the responsible of the NGO “All Ukrainian network of PLWHA”
- Departure to Zaporizhzhya. The travel was later aborted due to adverse climatic conditions

**Friday, December 12 2008**

- Working session with Natalia and Olena
- Working on documents

**Saturday, December 13 2008**

- Working on documents

**Sunday, December 14 2008**

- Working on documents
- Departure to Zaporizhzhya

**Monday, December 15 2008**

- Arrival in Zaporizhzhya
- Meeting with Ms. N. Motovitzya, head Oblast Health Care administration
- Working session at the Oblast TB Dispensary and Hospital with Dr. A I Akhtirskyi, Dr. Y V Prosvetou, Dr. N N Shvets, Dr. M A Aleksyeyevna, Dr. A I Pirog. Visit of the Oblast TB Hospital
- Visit to the City TB Dispensary and meeting with the Dispensary Director
- Visit to the Oblast AIDS Centre and meeting with the Director Genral
- Visit to the Oblast AIDS Hospital
- Departure to Kyiv

**Tuesday, December 16 2008**

- Arrival in Kyiv
- Meeting at the Ukrainian Centre for AIDS prevention and meeting with Lyudmyla Storozhuk
- Meeting at the National Institute of TB and Lung Diseases with the Deputy Director and the Chief of Information System
- Meeting with the Coordinator of training programmes in TB/HIV of the NGO “All Ukrainian Network of PLWHA”

**Wednesday, December 17 2008**

- Internal meeting and working of documents
- Departure to Milano (Prof. Matteelli)

**Thursday, December 18 2008**

- Internal meeting and working of documents
- Departure to Milano (Prof. Migliori)

*Appendix 2. Persons met and institutions visited*

**PATH**

Dr. Katya Gamazina, Head of Country Office

Dr. Olena Radziyevska, Deputy Director, TB control Project

Dr. Nataliya Zalka, Sr. Programme Officer in charge for TB/HIV programme

Ms. Oxana Yudina, assistant of VCT and TB/HIV component

**WHO EURO Region, TB Department**

Dr. Pierpaolo De Colombani, Medical Officer, TB control

**Institute of Epidemiology and Infectious Diseases, Kyiv City**

Dr. Svitlana Antonyak, Head of HIV Department

**NGO Time to live positive**

Ms Ileana Simeonova, Representative

**Zaporizhzhya Health Care Administration**

Ms. Nataliya Yakivnia Motovitzya

**TB Dispensary, Zaporizhzhya Oblast**

Dr. Alexandre Ivanovic Akhtirskyi, Director General

Dr. Nataliya Nikolayevna Shvets, Deputy Director

Dr Mikhaylova Adelina Aleksyeyevna, Deputy Director on dispensary work

Dr. Alla Ivanovna Pirog, Deputy Director on treatment work

Dr. Nina Ievgenievna Roman, Chief of Information system department

**Zaporizhzhya Medical Academy**

Dr. Yuriy Valilyevich Prosvetou

**Zaporizhzhya City TB Dispensary**

Dr. Nataliya Nikolaievna Nekrasova, Dispensary Director

**Zaporizhzhya Oblast AIDS Centre**

Dr. Alexander Alexandrov, Director General

**Zaporizhzhya Oblast AIDS Hospital**

Laushtan Antonina Nikolaievna, Chief of Oblast AIDS Dispensary

Kaltunnik Elena Leonidovna, Chief of Zaporizzia City TB dispensary

Tatiana Vladimirovna Bulana, TB doctor of AIDS center

**Ukrainian Centre for AIDS prevention**

Dr. Lyudmila Storozhuk,

**National Institute of TB and Lung Diseases**

Dr. Svitlana Alexandrovna Cherenko, Deputy Director

Dr. Oxana Smetanina, Chief of Information System

**All Ukrainian Network of PLWHA**

Ms. Anna Koshikova, Coordinator of training programmes in TB/HIV

Appendix 3 Comments on Knowledge Hub agenda

	CURRENT AGENDA	COMMENTS
<b>DAY 1</b>		
09:00-09:30	Welcome, introduction of the participants, objectives of the course. Review of the training curriculum.	<b>OK</b>
09:30-10:00	Pre-Workshop Questionnaires	<b>OK</b>
10:00-11:00	TB/HIV co-infection: an overview of HIV and TB epidemiologic situation in the world and in Ukraine. Coordination of HIV/TB activities at the regional level.	<b>OK</b>
11:00-11:45	Basic principles of counseling. Role of pre- and post-test counseling in detection of TB/HIV co-infection.	<b>Put later when discussing the elements of TB/HIV activities</b>
11:45-12:00	COFFEE BREAK	
12:00-17:45	After the coffee break participants will be divided into two groups to study separately to the rest of the day with a break for lunch and a coffee break: one group for TB-specialists and another one for infectious disease (ID) specialists.	<b>Make the choice whether to separate them. The alternative is to allocate this time to presentation of the basic elements of TB and HIV and elements of control from the Sondalo course</b>
13:15-14:15	LUNCH	
15:45-16:15	COFFEE BREAK	
	<p><b>TB specialists</b> will learn about</p> <ol style="list-style-type: none"> <li>1. Etiology and pathogenesis of HIV infection. ARV drugs. Before the lunch (45 min).</li> <li>2. HIV Staging System (according to the WHO Classification System and Ukrainian National Protocols). Diagnostic criteria. AIDS case definition. Before the lunch (30 min).</li> <li>3. Small group practical skills training on counseling. After the lunch (45 min).</li> <li>4. Current approaches to the management of HIV/AIDS patients. Antiretroviral therapy. After the lunch (45 min).</li> <li>5. Practical exercise: Trainer will present a case study of HIV-positive patient. Task: the participants will be able to determine the stage of HIV infection, develop an algorithm for follow-up, and suggest an ART regimen. After the lunch (75 min).</li> <li>6. Knowledge assessment test. Summary of the day. After the lunch (15 min).</li> </ol> <p><b>ID specialists</b> will learn about</p> <ol style="list-style-type: none"> <li>1. Etiology and pathogenesis of TB disease. Before the lunch (30 min).</li> <li>2. TB Classification System (according to the WHO Classification System and Ukrainian National Protocols). Diagnosis of pulmonary tuberculosis. Case definition of tuberculosis. Before the lunch (45 min)</li> <li>3. Small group practical skills training on counseling. After the lunch (45 min)</li> <li>4. Current approaches to the treatment of pulmonary TB; main anti-TB drugs (according to the WHO Guidelines and Ukrainian National protocols). After the lunch (45 min).</li> <li>5. Practical exercise: Trainer will present a TB patient.</li> </ol>	

	Task: determine the stage of TB disease, develop an algorithm for follow-up, and suggest a treatment regimen. After the lunch (75 min) 6. Knowledge assessment test. Summary of the day. After the lunch (15 min).	
<b>DAY 2</b>		
09:00-09:30	TB and HIV infection. Tuberculosis as HIV-related disease. Clinical symptoms of TB at each stage of HIV disease.	<b>Not useful, could be deleted</b>
09:30-10:15	TB detection. The role of the tuberculin skin test in the diagnosis of TB. Latent TB infection. Chemoprophylaxis for TB in HIV-positive patients. Differentiating latent TB infection from active TB.	<b>Divide this into two: 1. Early diagnosis of TB among HIV infected; 2) IPT</b>
10:15-10:45	<b>COFFEE BREAK</b>	
10:45-11:45	Practical exercises on providing TB chemoprophylaxis in HIV-positive patients based on two case studies (positive skin test without clinical symptoms and positive skin test with clinical symptoms)	<b>Incorporate into the two above</b>
11:45-12:30	Pulmonary TB: clinical manifestations, diagnosis and treatment of pulmonary TB in HIV-positive patients.	<b>Useless, already covered under the TB clinical presentation and control strategy</b>
12:30-13:30	<b>LUNCH</b>	
13:30-14:15	Differential diagnosis between pulmonary TB and other HIV-related pulmonary diseases. Mixed infection. Antibiotic therapy for pulmonary diseases in HIV-positive patients.	<b>Merge with the one below</b>
14:15-15:15	Practical exercises on diagnosis and treatment of pulmonary TB in HIV-positive patients based on case studies. Participants will be divided into groups that include TB specialists and ID specialists. Facilitators: all trainers.	<b>OK</b>
15:15-15:30	<b>COFFEE BREAK</b>	
15:30-16:30	Extrapulmonary TB in HIV-positive patients. Diagnosis, clinical features, treatment approaches.	<b>Useless, already covered under the TB clinical presentation and control strategy</b>
16:30-17:30	Breakout session: case studies on differential diagnosis and treatment of TB meningitis in HIV-positive patients. Review two patient reports/case studies.	<b>OK</b>
17:30-17:45	Knowledge assessment test. Summary of the day.	
<b>DAY 3</b>		
09:00-09:45	Atypical mycobacteriosis (including one case presentation for 15 min)	<b>Is it relevant for Ukraine?</b>
09:45-10:45	Prevention of stigma and discrimination. Exercise "Yarlyki/Labels".	<b>OK</b>
10:45-11:15	<b>COFFEE BREAK</b>	
11:15-12:00	Case study on differential diagnosis and treatment of TB of lymph nodes in HIV-positive patients. Review one patient report/case study.	<b>OK</b>
12:00-12:45	Case study on differential diagnosis and treatment of skin TB in HIV-positive patients. Review one patient report/case study and assess treatment approaches.	<b>Is it relevant ?</b>
12:45-13:45	<b>LUNCH</b>	
13:45-14:30	Anti-TB and ARV drug interactions	<b>Merge with the one below</b>
14:30-15:30	ART in patients with HIV/TB co-infection. Immune reconstitution syndrome and its implications for ART and anti-TB therapy timing. Anti-TB therapy in HIV-positive patients.	<b>OK</b>
15:30-15:45	<b>COFFEE BREAK</b>	

15:45-16:45	Practical exercise. Task: to develop a treatment plan for a patient with HIV/TB co-infection. Review two case studies.	<b>OK</b>
16:45-17:30	Case study on differential diagnosis and treatment of bone TB in HIV-positive patients. Review one patient report/case study.	<b>May not be essential</b>
17:30-17:45	Knowledge assessment test. Summary of the day.	
<b>DAY 4</b>		
09:00-09:45	Adherence promotion and monitoring.	<b>OK</b>
09:45-10:45	Role-play exercise: Counseling of patients with HIV/TB co-infection before initiating therapy.	<b>OK</b>
10:45-11:15	COFFEE BREAK	
11:15-12:15	Treatment monitoring (side effects of ARV and anti-TB drugs, treatment efficacy) in patients treated for both TB and HIV infection.	<b>OK</b>
12:15-13:00	Case study on differential diagnosis and treatment of GI TB in HIV-positive patients. Review one patient report/case study.	<b>May not be essential</b>
13:00-14:00	LUNCH	
14:00-14:45	Special considerations for treatment of IDUs with HIV/TB co-infection.	<b>OK</b>
14:45-15:15	Special considerations for treatment of pregnant women with HIV/TB co-infection.	<b>Not essential</b>
15:15-16:00	Role play exercise: Counseling on treatment adherence in patients with TB/HIV co-infection.	<b>May be covered already by the morning presentation</b>
16:00-16:30	COFFEE BREAK	
16:30-17:30	Infection control. Participants will be divided into two groups:  1. TB specialists will learn about general precautions for preventing HIV transmission and procedures for PEP. 2. ID specialists will learn about infection control regulations in TB facilities.	<b>Need to be expanded</b>
17:30-17:45	Knowledge assessment test. Summary of the day.	
<b>DAY 5</b>		
09:00-09:45	Team approach in providing care and treatment to patients with TB/HIV co-infection. Roles and responsibilities of care team members.	<b>OK</b>
09:45-10:30	Breakout group discussion: Roles and responsibilities of care team members. Implementation of the team approach in the regions.	<b>OK</b>
10:30-11:00	COFFEE BREAK	
11:00-11:30	WHO and Ukrainian National guidelines on registration, reporting and referral system for patients with TB/HIV. Monitoring.	<b>Need to be greatly expanded and include work group</b>
11:30-12:15	Breakout group discussion: Coordination of HIV/TB activities at the regional level.	<b>Unclear to me</b>
12:15-13:00	Case study presentations and discussions (2–3 teams present their case studies).	<b>Unclear to me</b>
13:00-14:00	LUNCH	
14:00-15:30	Continuation. Practical exercise. How to work effectively as a team. Coordination of HIV/TB activities at the regional level.	<b>Is similar to the unit done in the morning</b>
15:30-16:00	Post-workshop Questionnaire. Closing remarks.	<b>OK</b>

**What is lacking in the training:**

- Unit on international and Ukrainian policies for TB/HIV collaborative activities
- Unit on surveillance of HIV among TB patients. Ideally to be included in the unit of HIV testing of TB patients. Require country information on adopted strategy and results
- Intensified case finding need to have a separate unit and adequate time, including group work
- Infection control need to be expanded
- A small section on cotrimoxazole preventive therapy
- A unit on the overlapping of MDR and HIV epidemics with discussion on the implications for clinical management

**What is different from the Sondalo course:**

- planning is not included
- costing and budgeting is not included
- human resource development is not included (this would be the core of a TOT course)
- monitoring and evaluation is not included (only recording and reporting)
- other elements of the STOP-TB strategy are not included
- necessary to add on clinical case management and differential diagnosis of pulmonary, meningeal, lymphatic TB, etc.