

Ukraine Tuberculosis Control Partnership Project

IQC TASC 2 –
Contract Number GHS-I-00-03-00034-00

Year 1 Annual Report
(October 1, 2007–September 30, 2008)

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Regional Mission to Ukraine,
Moldova, and Belarus
(USAID/Ukraine)**

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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 3, started in October 2007. PATH is supporting Ukraine in expanding international standards for TB control and improving the quality of TB services. To ensure sustainability of effective TB-related interventions at national and regional levels, the project seeks 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 is also helping Ukraine’s civil society groups active in the TB and TB/HIV domain to bolster the 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

Although the TB incidence rate (case-notification rate) at the national level and in each project area serves a monitoring function only (not as an indicator for project progress), it was used to analyze the status of the TB epidemic in Ukraine at the beginning of the project (Year 1). Table 1 contains the final national- and oblast-level data for 2007 compared to 2006. TB epidemiological data for 2008 will become available in March 2009. Over the last two years, stabilization of TB incidence has been reported, with the average TB incidence rate in Ukraine decreasing by 4.6 percent in 2007 compared to 2006 data (from 83.2 to 79.8 TB cases per 100,000 population). This stabilization, however, may not last long if the spread of HIV infection—which has the potential to fuel the TB epidemic—continues at the current rate (the HIV growth rate is one of the highest in the world), and if the treatment success rate remains at the same low level with a high proportion of defaults (Table 2).

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

Year	Administrative regions and areas (project sites)										
	UKRAINE	Luga-nska	Odeska	Dniprop-etrovsk	Khar-kivsk	Khers-onska	Done-tska	Zapori-zhsk	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

Baseline data have been collected according to the project monitoring and evaluation plan. Data on treatment success rates in patients who started treatment in 2006 (based on cohort analysis results) are reliable only in the oblasts that have been previously covered by project activities. Oblasts that started analysis of TB-treatment effectiveness based on cohort analysis as part of the new monitoring and evaluation (M&E) system introduced in 2007 have not yet provided these data; thus, a reliable overall rate in Ukraine cannot yet be calculated. Data from the project sites suggest that they fall far short of the global target of 85 percent in all project areas (see Table 2).

Table 2. Treatment success rates among newly detected cases in the project sites (%)

UKRAINE	Donet-ska	Dnipro-petrovska	Khar-kivska	Kherson-ska	Crimea	Zapori-zhska	Luganska	Odeska	Kyiv	Sevas-topol
n/a	59.2	50.4	57.7	43.2	69	56.9	n/a	n/a	59	59.3

Progress in the fourth quarter towards achieving targets established in the Project Monitoring and Evaluation Plan (PMEP) is reflected in Table 3 and covers indicators that require quarterly reporting (Detailed Implementation Plan Year 1 Activity 05).

Table 3. Indicators according to the M&E plan which require quarterly reporting (progress in the fourth quarter)

PMEP's Indicator # 8	PMEP's Indicator # 9	PMEP's Indicator # 10	PMEP's Indicator # 14	PMEP's Indicator # 22	PMEP's Indicator # 25	PMEP's Indicator # 30
Number of people trained in any Stop TB Strategy elements:	Number of laboratory review meetings held in the project regions:	Number of project regions providing accurate and timely TB surveillance and NTP performance data:	Number of laboratories performing quality-assured TB culture and first-line drug susceptibility testing according to international standards:	Number of individuals trained to provide clinical prophylaxis and/or treatment of TB in HIV-infected individuals:	Number of individuals trained in HIV-related institutional capacity-building:	Number of individuals trained to provide social-support services and in HIV- and TB-related stigma and discrimination reduction:
309	10	8	1	47	28	31

As reflected in the PMEP, attached as Annex 1, PATH planned to train at least 600 individuals in Year 1 of the project. PATH exceeded this target, as training on the Stop TB Strategy essential components covered 1,124 persons in Year 1. Specifically, PATH's training focused on directly observed treatment, short course (DOTS)-based diagnosis, 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 toward achieving project targets is reflected in the PMEP (Annex 1) and in the report narrative, which covers monitoring indicators of project performance—as well as of Ukraine's TB control program performance—to better understand the TB situation in the country.

II. Key achievements

PATH and project oblast health administrations signed Memoranda of Understanding (MOUs), with the exception of Luganska oblast. The MOU with Luganska Oblast is currently being developed. The USAID TB Control Partnership project has been registered at the Ministry of Economy, as required by Ukrainian regulation. Subcontracts were agreed upon and joint plans of actions were developed with key national civil-society partners (e.g., Ukrainians Against Tuberculosis [UATB], the Ukrainian Coalition of HIV-Service Organizations, and the National Committee of the Ukrainian Red Cross Society) to bolster advocacy, communication, and community involvement, and to improve TB/HIV service collaboration.

Countrywide DOTS coverage has increased by 5.6 percent to 34.6 percent, indicating the proportion of the Ukraine's population that has access to high-quality DOTS-based services. In Year 1, PATH staff and Ukrainian TB consultants and trainers provided training courses in DOTS principles and TB program management and evaluation to a total of 1,124 health care practitioners, representing a two-fold increase over the year 1 target. 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.

PATH organized an assessment of TB facilities, including laboratories, by specialists from the Latvia State Agency for Tuberculosis and Lung Diseases, with the goal of selecting an Oblast TB Dispensary to become a multidrug resistant (MDR) TB Center of Excellence in Ukraine. Also, a baseline assessment was undertaken to define the needs of clients, NGOs, communities, and health facilities in strengthening TB/HIV collaborative activities in the project sites.

UATB has focused its activities at the national and regional levels to reach key policy institutions and providers. During the reporting period, UATB successfully organized and facilitated parliamentary hearings on TB, conducted a press conference with representatives from the central media, and supported the timely scheduling and provided leadership in development of the agenda for meetings of the National Council (NC).

Through discussions with the HIV/AIDS Service Capacity Project in Ukraine (being implemented by Constella Futures Group), a coordinated approach to building the capacity of the Regional Coordination Councils on TB and HIV/AIDS was developed. Within the framework of these joint efforts, PATH is providing technical support to strengthen the Regional Coordination Councils' functions in guiding and monitoring TB/HIV collaborative activities at local and regional levels in the project oblasts. In addition, PATH staff helped develop a tool to guide operational research regarding ex-prisoners' social support and health protection needs related to TB and TB/HIV issues. The main objective of this research is to collect and analyze data that will support strategic planning and decision-making processes within the Regional Coordination Councils.

PATH continued to support the Committee on HIV and TB within the Ministry of Health (MOH) by raising the awareness among key policy makers on the global TB strategy and the European regional response to the TB epidemic. PATH also suggested priority actions in accordance with international approaches. With PATH technical support, the MOH Advisory Group on monitoring and effective implementation of the national TB program analyzed comments and suggestions for improvement, as well as revisions of the temporary TB statistical forms provided by specialists from project regions. These forms have been revised in accordance with the requirements of the Ministry of Justice for their further endorsement for permanent use, not only in the health care system but also by health services in the penitentiary and military systems. In addition, a comprehensive analysis of the TB monitoring and surveillance practices at primary health facility, district, regional, and central levels was conducted. A list of priority actions to improve the TB surveillance system was developed. Ukraine's first protocol on drug resistant TB case management was drafted with PATH technical assistance.

III. Results and project elements

Start-up and general management activities

A Life-of-Task Order Plan (Project Plan), a Detailed Implementation Plan for Year 1 (DIP 1), and a PMEP were developed in consultation with USAID, project partners, and stakeholders. They were submitted to the USAID Cognizant Technical Officer (CTO) by the due date in the first quarter and approved by USAID/Kyiv in the second quarter of Project Year 1 (DIP 1 activities 1 and 4). Key personnel were selected, approved by USAID, and hired by PATH in the second quarter (DIP 1 Activity 2). A plan of action for monitoring activities, based on the PMEP, was developed to guide regular monitoring of project and National TB Control Program (NTP) progress towards stated targets (DIP 1 Activity 5). Data on monitoring of TB control activities in each project area were summarized in the fourth quarter to provide for quarterly and annual analyses of project and NTP accomplishments (see Section 1 of this report). Quarterly reports and a DIP for Year 2 were submitted to USAID/Kyiv for approval in due time (DIP 1 Activity 7).

With USAID's guidance, an initial meeting primarily for international and national-level Ukrainian stakeholders was conducted on November 19, 2007. The project was presented, and an implementation plan was discussed with the stakeholders (DIP 1 Activity 6). Also, after receiving USAID/Kyiv's approval of the project plans, PATH conducted a partner meeting from February 21–22, 2008. Participants comprised key representatives from each project administrative area; institutions including the MOH, Penitentiary Department of the Ministry of Justice, National TB and Lung Diseases Institute, and the Ukrainian AIDS Center; as well as national and international NGO and civil-society representatives—including the All-Ukrainian People Living with HIV/AIDS Network, Coalition of HIV Service NGOs, Constella Futures Group, the World Health Organization (WHO), and the CTO from USAID/Kyiv.

Each component of the project was presented at this partner meeting by both a national expert in TB control, who analyzed the situation in Ukraine regarding a specific TB control area, and a PATH staff member, who proposed activities in response to identified issues. The areas covered included TB laboratory capacity; DOTS training; MDR-TB; TB/HIV collaborative measures; TB services in prisons; TB control monitoring; and advocacy, communication, and social mobilization activities. The project implementation plan was also discussed with partners. Additionally, plans of action were presented at breakout sessions by representatives of each administrative area in order to address their particular needs and to discuss MOUs to be signed with partner regions. To ensure rapid scale-up of project activities in all project sites, PATH identified a key group of local project consultants to collaborate with at the central and oblast levels. These consultants and their scopes of work have been approved by USAID.

Following the approval of the above plans, PATH and project oblast health administrations signed MOUs—during the second quarter with Zaporizska and Kharkivska Oblasts and during the third quarter with all other project administrative areas (DIP 1 Activity 3), except Luganska Oblast. Also, an MOU was signed with the National Institute of TB and Lung Diseases. In addition, the MOH issued a letter recognizing itself as a beneficiary of the USAID TB Control Partnership project given that it is mandatory to designate a collaborative central governmental body for project registration at the Ministry of Economy (MOE). PATH submitted the required

documents to USAID/Kyiv for further registration of the TB Control Partnership project at the MOE by the USAID Mission (DIP 1 Activity 3), and the registration process was completed successfully. The MOU with the new project region, Luganska Oblast, is currently being developed to be signed in first quarter of Project Year 2 with the launch of intensive interventions in this region. Even in the absence of an MOU, PATH has already involved health administrators and TB specialists from this oblast in training and monitoring activities being conducted in other project regions, which also provides opportunities to discuss potential interventions in Luganska Oblast.

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.

DOTS Expansion Areas

Previous PATH and WHO TB activities supported by USAID resulted in the coverage of approximately 29 percent of the Ukrainian population with DOTS services in eight administrative areas of the country, comprising five regions/oblasts (Donetska, Dnipropetrovska, Kharkivska, Khersonska, Zaporizhska), one autonomous region (Crimea), and two municipalities (Kyiv City and Sevastopol City). The previous TB activities did not make DOTS services available to the entire population in the initial administrative areas. To ensure availability of high-quality DOTS services for the entire population in the initial project areas, PATH has identified uncovered districts (rayons) and areas covered already by initial DOTS training where the quality of DOTS services still needs further improvement. Mapping the results of this analysis helps visualize and guide gradual introduction and/or improvement of DOTS-based anti-TB practices in the initial regions (see Annex 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 approximately an additional 10 percent of the Ukraine’s population. Coverage by DOTS-based TB control services of the entire population (approximately 19 million) in the initial administrative areas and Odeska and Luganska Oblasts will result in approximately 24 million people—50 percent of the population of Ukraine—having access to DOTS services (50 percent DOTS coverage).

As virtually all TB specialists have been trained in the initial project areas, this year’s primary focus was on training doctors, nurses, and laboratory staff in the general health care system in the uncovered rayons within the initial project areas. Based on an analysis of TB treatment outcomes and other indicators, PATH has confirmed the need to continue working on improving the quality of TB control practices at the specialized TB and general health care levels in existing DOTS areas. 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, countrywide DOTS coverage has increased to approximately 35 percent (precisely 34.6 percent). Thus, Year 1’s target of making high-quality DOTS services available to 35 percent of the population has been achieved. This figure is a sum of the baseline coverage of 29 percent and additional coverage of 5.6 percent achieved this year by: 1) expanding DOTS-based services to uncovered rayons, and 2) improving the quality of TB-control activities in existing DOTS sites in the initial eight administrative areas. PATH will continue expanding high-quality DOTS services to cover the entire population of those administrative areas.

The selection of the new oblasts to expand DOTS coverage to an additional five million people was not completed in the first quarter, pending advice and approval of the final oblast choices from USAID/Kyiv. PATH had initially proposed to expand DOTS TB services to Odeska Oblast (2.4 million people) and L'vivska Oblast (2.6 million people). USAID/Kyiv expressed reservations about extending to L'vivska Oblast, and discussions on oblast selection concluded in the second quarter. As a result, USAID approved the final choice of Odeska Oblast and Luganska Oblast (2.5 million people). As noted earlier, activities in Odeska Oblast began during the project's first year. Project activities in Luganska Oblast will be initiated in Year 2.

PATH launched expansion of the TB Control Partnership project's activities in the new project region, Odeska Oblast, by an initial assessment visit. The assessment revealed low bacteriological confirmation of TB cases, intensive population-based active screening for TB by fluorography, obsolete TB practices such as preventive "anti-relapse" treatments, and diagnostic treatment using TB drugs that are not supported by internationally accepted standards. Deficient understanding of international TB control approaches and standards in Odeska Oblast is being addressed through the provision of technical assistance and trainings.

DOTS training

PATH has worked to improve the skills of existing health care staff in TB control and general health services to implement DOTS-based anti-TB practices. In Year 1, PATH staff and Ukrainian TB consultants provided training courses in DOTS principles and TB program management and evaluation to a total of 1,124 health care practitioners (DIP 1, activities 1.1, 1.8 and 1.10; PMEP indicator 8), including 130 TB specialists, 372 primary health care providers, 195 laboratory specialists, 155 M&E specialists, 8 infectious-disease specialists, 259 nurses, and 4 psychologists representing all project administrative areas. A breakdown by quarters and type of training of the above numbers of health care providers trained demonstrates that 50 people were trained through five TB laboratory trainings in the first quarter; one training-of-trainers (TOT) course, eight basic DOTS trainings, and one laboratory training course were provided to 230 people in the second quarter; four TB laboratory trainings, nine basic DOTS trainings, and eight training courses in M&E procedures were provided to 535 people in the third quarter; and one TOT course, three TB laboratory trainings, five basic DOTS trainings, and two M&E trainings were delivered to 280 people in the fourth quarter. Also, two training courses in interpersonal communication and counseling was provided to 29 TB and HIV specialists in the fourth quarter to improve screening, testing, adherence to treatment, and collaboration of TB and HIV services in addressing TB/HIV co-infection. A breakdown of training activities in DOTS elements per the number of specialists trained, project administrative area, and type of training is presented in Annex 12.

Per DIP 1 Activity 1.4, TB control orientation presentations were delivered to chief doctors of general health facilities and rayon chief TB specialists during DOTS and laboratory review meetings in Dnipropetrovska and Kharkivska Oblasts on May 6 and June 20, 2008, respectively. A training program in the new project region, Odeska Oblast, started with a one-day course during which PATH presented its multifaceted health activities undertaken in Ukraine in previous years, introduced the new TB project, and delivered a TB control orientation presentation. The course was attended by the oblast's senior health administrators, regional and

district TB authorities and providers, and district primary health care administrations and providers focusing on the Stop TB Strategy components, international standards of TB care, and other internationally accepted approaches in TB control. The expansion of training activities in Odeska Oblast continued with TB laboratory trainings in the fourth quarter.

These training activities included three TOT courses which were provided to TB specialists in Kyiv and Zaporizhzhya. At a TOT course in Kyiv City, PATH increased knowledge and awareness among ten district TB coordinators from all Kyiv districts and three leading TB specialists of the central Kyiv TB dispensary. Specifically, the training focused on up-to-date international approaches to TB control, including the Stop TB Strategy and Plan, international standards of TB care, and best practices. A TOT course in interpersonal communication and counseling was provided to 15 TB and HIV specialists and psychologists. In addition, a TOT course on DOTS practices and basic principles of MDR-TB and TB/HIV case management was provided in Zaporizhzhya to 15 TB specialists from the Zaporizhzhya, Kherson, and Donetsk regions (DIP 1 Activity 1.1). Also, PATH worked specifically with the Zaporizhska Oblast TB system to develop a two-year training plan for primary health care providers in order to ensure 100 percent coverage of the entire oblast population by DOTS services by the end of the project's second year.

In discussions with NGOs and while assessing social-support practices utilized to improve TB treatment completion, it was confirmed that a significant number of TB patients who receive social support provided by the Red Cross or are in need of such support are also co-infected by HIV. PATH deems it appropriate to bolster involvement of the Red Cross in the provision of TB/HIV services in addition to strengthening services provided by the Coalition of HIV service NGOs and the All-Ukrainian Network of People Living with HIV/AIDS. As part of improving DOTS services—especially in supporting TB treatment adherence, as well as part of improving TB/HIV co-infection services (DIP 1 activities 1.1, 1.12, and 3.4)—a TOT course was provided to twelve Red Cross coordinators. They were trained in TB/HIV detection, treatment adherence, and social support practices under the subcontract with the National Committee of the Ukrainian Red Cross Society (PMEP indicator 30). Also, a monitoring tool and plan for assessing the Red Cross program was developed during this training. Three follow-on trainings on appropriate TB/HIV case management were then delivered to 46 nurses by Red Cross project coordinators in Khersonska and Luganska Oblasts and Sevastopol City (DIP Activity 3.4; PMEP indicator 22).

In fulfilling DIP 1 Activity 1.2, PATH has worked with leading TB specialists of the National Research Institute of TB and Lung Diseases; the TB departments of the Donetsk and Dnipropetrovsk Medical Universities; the Kyiv and Kharkiv Medical Academies for Postgraduate Continuous Education; the MOH Committee on TB and HIV/AIDS Control; the WHO/Ukraine TB Unit; and the Ukraine-based charitable foundation, Development of Ukraine to evaluate the availability of training materials and to analyze the quality of information on essential TB control components in accordance with international approaches. As a result of these consultations, a working group on standardizing training curricula development was officially established by MOH order as a collaborative effort between PATH and Development of Ukraine and has started its work. The goal of the group is to develop standardized curricula based on the components of the Stop TB Strategy and international guidelines. In addition, the group will recommend that these curricula be institutionalized by the MOH and used in medical

and nursing schools, as well as for continuous medical education for TB and primary health care physicians and nurses. This work also serves as a platform for prioritizing and synchronizing PATH's training activities with the training plans of other TB control partners.

TB-control training materials will include a set of training plans, aids, and handouts that will eventually include curricula on TB case management and TB laboratory practices and quality control, as well as a set of training plans and training materials on monitoring and supervision components, interpersonal communication and counseling, and others. Dnipropetrovsk medical and nursing schools have already incorporated training in DOTS elements into their regular training (DIP 1 Activity 1.2).

PATH continued to work with consultants from the Division of Clinical Laboratory Diagnostics at the Kyiv Medical Academy of Postgraduate Education on preparing an academic curriculum for training of laboratory specialists at institutions of higher medical education and departments of postgraduate education. This task is critical for improving the quality of TB diagnosis, increasing the TB detection rate, and ensuring sustainability of interventions, as currently only two to four hours of training is dedicated to TB during the two-month training at postgraduate departments. As part of this effort, PATH has developed a first draft, 36-hour TB microscopy and quality-control training plan (see Annex 13) and training materials. This course has been designed for heads of clinical diagnostic laboratories, laboratory physicians, and laboratory specialists with backgrounds in specialized laboratory education at institutions of postgraduate continuous education. Also, draft training materials were developed on interpersonal communication and counseling. These will be further reviewed and revised, if necessary.

PATH staff collected and reviewed internationally available assessment instruments and questionnaires for conducting a TB human-resource assessment (DIP Activity 1.5). Preliminary information on the staffing situation and needs for TB-related laboratory, clinical, and management personnel was collected in discussions with the Kyiv City Chief TB Specialist and during monitoring visits by the PATH team to Dnipropetrovska and Zaporizhzhya Oblasts, as well as while assessing TB services in Odeska Oblast. PATH will move forward with this process according to the initial agreement with Health Strategies International (HSI), a potential subcontractor indicated in the PATH proposal, to formally execute this assessment during Year 2 in three project areas. Although this assessment had been planned for Year 1, PATH was unable to firmly commit to a timeframe until after the workplan was approved. At that point, HSI was fully booked for the remaining months of Year 1. PATH is currently finalizing dates with HSI, with the goal of scheduling the assessment early in Year 2.

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. The Ukrainian Red Cross Society, the Ukrainian Coalition of HIV Service Organizations, and UATB were subcontracted to bolster advocacy, communication, social mobilization, and community involvement in TB control.

Under its subcontract, UATB focused its activities at the national and regional levels to reach key policy institutions and providers. UATB’s accomplishments during the reporting period are as follows:

- Organized and facilitated parliamentary hearings on TB.
- Conducted a press conference with representatives from the central media.
- Encouraged the timely scheduling and provided leadership in developing the agenda for the NC.
- Developed a MOU with the Ministry of Family, Youth and Sport.
- Worked with the health committee within the Ukrainian President’s office, a very important and strategic body focused on TB and TB/HIV issues.

An important limitation in garnering political support is the lack of awareness about the TB situation, the global TB strategy, and the European regional response among decision makers at all levels. PATH has drafted an advocacy presentation on TB to orient key policy- and decision-making audiences (DIP Activity 1.3). An informational manual on the TB situation—both globally and in Ukraine—and internationally recommended TB control approaches was issued by UATB and PATH 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 Head of the Committee, Dr. Petrenko, and the Deputy Head, Dr. Stelmakh, to discuss strategies for implementing the National TB Program and priorities for development of the Committee’s action plan. PATH also provided technical assistance to the Committee in providing an analysis of TB program implementation during 2007.

Increasing laboratory capacity and quality

Data on the number of TB-microscopy-testing and quality-control trainings, and on the number of individuals trained in laboratory practices, have been already detailed above as a part of training activities in essential DOTS components (as well as in Annex 12, attached). More detailed information on laboratory trainings in smear microscopy and quality control is also provided in Table 4 below (DIP 1 Activity 1.8).

Table 4. Laboratory training activities in TB Control Partnership Project Year 1 (October 1, 2007–September 30, 2008)

Administrative Area	Title of Training	# Trained	Type of Service	Date of Training	Trainers
Kyiv	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	50	PHC-45 TB-5	Nov 19–21, 2007 Nov 26–28, 2007 Dec 3–5, 2007 Dec 10–12, 2007 Dec 17–19, 2007	Nataliya Goncharenko, Kateryna Polovko, Maria Karnaukhova

Zaporizhzhya	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	29	PHC-10 TB-19	Mar 24-28, 2008 Apr 22-25, 2008	Tamara Ivanenko, Maria Novokhatska, Olena Yann, Nataliya Rokhmanova
Dnipropetrovsk	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	26	PHC-15 TB-11 (including one TB specialist from Odeska)	May 26-30, 2008 June 2-6, 2008	Maria Novokhatska, Mariya Fonariova, Anna Barbova
Kharkiv	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	24	PHC-11 TB-13 (including two TB specialists from Odeska)	June 17-21, 2008	Maria Novokhatska, Anna Drashpul
Odeska	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	36	PHC-30 TB-5 1- Head of Lab, Pre-trial Prison	Aug 26-28, 2008	Tamara Ivanenko, Maria Novokhatska, Olena Kononova
Kherson	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	18	PHC-16 TB-2 (including 1 TB specialist from Donetsk)	Aug 26-29, 2008	Olena Yann, Luydmyla Talashenko, Iryna Morozova

Crimea	Laboratory diagnostics of TB by smear microscopy. Quality assurance of smear microscopy in the laboratories.	13	PHC-3 TB-10 (including 1 TB specialist from Donetsk Oblast)	July 14-18, 2008	Anna Barbova, Lidia Prokhorenko
Total		196	Laboratory specialists at PHC facilities-130 Laboratory specialists at TB-specialized facilities-66	13 trainings	

The unstable situation in Donetsk Oblast (changes in administration, renovation of the oblast TB dispensary, disassembling of the training center at this facility—which was previously established with PATH support) precluded PATH from providing laboratory training in this region. However, almost all laboratory specialists dealing with TB detection and diagnosis in the new project area, Odeska Oblast, have been trained in TB microscopy and quality control (36 out of 40 laboratory specialists).

There is an urgent need to train laboratory specialists in TB culture and TB drug-susceptibility testing (DST) to significantly improve the current practices of performing these tests and enabling improved management of MDR-TB. PATH is currently in communication with the National Bacteriology Laboratory of the Latvia State Agency for Tuberculosis and Lung Diseases and additional laboratories in Estonia and Poland, with the goal of organizing hands-on training courses in TB culture and DST for Ukrainian laboratory specialists.

PATH has equipped a training center in the Zaporizhzhya Oblast TB Hospital. In cooperation with the World Bank, the WHO, and other international organizations, PATH provided technical input to the MOH/World Bank's Working Group responsible for procurement of harm-reduction supplies within the penitentiary system and laboratory equipment under the World Bank's loan to Ukraine to implement the TB and HIV programs. In addition, the need to procure equipment and supplies to ensure safe and efficient functioning of TB hospitals in Odeska Oblast was verified through an inventory assessment that the MOH completed in June 2008 (DIP Activity 1.7). In the framework of the World Bank's loan, catch-up procurement efforts ensured that all laboratories in Odeska Oblast that perform sputum microscopy testing have binocular microscopes and laboratory supplies. In order to improve the process of data collection, feedback delivery, and information exchange among laboratories, PATH supported internet access for four oblast TB laboratories.

To fulfill DIP 1 Activities 1.9 and 1.11, monitoring visits to laboratory review meetings were conducted in Kherson (two review meetings), Zaporizhzhya (three review meetings), Dnipropetrovsk, and Kharkiv Oblasts, as well as in Sevastopol, Kyiv City, and Crimea, to oversee TB control practices and laboratory performance in TB diagnosis (PMEP indicator 9). Project oblast data on the results of external quality control of smear microscopy in 2007 were collected, analyzed, and used as a foundation for further improvement during the laboratory review meetings. PATH led the development of the monitoring tools, in particular revising and unifying checklists and indicators for supervision of TB and general clinical laboratories to be utilized during monitoring visits in the project regions.

PATH had planned to provide support and technical input to a total of 24 general and laboratory review meetings this year, providing that each initial project area followed its TB control monitoring plan and had monitoring review meetings quarterly. It was also envisioned that senior oblast and city laboratory administrators would participate in these review meetings to become aware of laboratory performance in TB control and support effective corrective actions. Unfortunately, it proved to be impossible for the oblasts to conduct regular monitoring and to convene review meetings as planned due to insufficient funding for these activities and heavy workloads of senior laboratory specialists. PATH will continue promoting the organization of general and laboratory review meetings at least on a semiannual basis in each project area to analyze results of monitoring visits and oblast TB-control program performance as a tool for sustainable improvement.

At the review meetings that were convened, PATH suggested that laboratory specialists be joined by TB and primary health care administrators and clinical providers. It was confirmed that TB microscopy was performed following appropriate standards (in 75 to 85 percent of laboratories); however, despite marked improvements in TB laboratory diagnosis in recent years, much remains to be done to increase laboratory verification of TB cases. For example, in the Kherson Oblast TB hospital, only 17 percent of TB cases were confirmed by microscopy, while this indicator should be at least 50 percent to verify proper functioning of a TB institution's laboratory. At the same time, 2 percent of TB cases suspected at the primary health care facilities in Kherson Oblast were detected to be sputum smear-positive cases, which indicates good performance of the first-level laboratories and appropriate selection of TB suspects among patients with respiratory symptoms. Also, only 37 percent of TB cases were confirmed by TB culture investigations in the Kherson Oblast TB hospital, while the standard level is at least 85 percent.

In the Zaporizhzhya TB hospital, 38 percent of TB cases were confirmed by microscopy, and 46 percent of reported TB cases were confirmed by culture investigations, a percentage that is still far below standard levels. The reasons for the low effectiveness of TB bacteriological diagnosis in visited oblasts included lack of up-to-date equipment, deficiency in human resources, incorrect selection of TB suspects among patients with respiratory symptoms, and a large number of incorrectly collected and investigated specimens.

The following problems were also addressed at review meetings:

- 1) Up to 30 percent of materials collected for TB microscopy and other laboratory testing were of poor quality (saliva instead of sputum).
- 2) Proper procedures for collecting materials were not in place at many primary health care facilities.
- 3) Not all laboratories participated in external quality control of TB microscopy testing, and as a result, laboratory specialists were not confident in laboratory results they produced.
- 4) Selection and referral of TB suspects for laboratory testing still suffered—in some primary health care facilities all patients with respiratory symptoms were referred for microscopy testing, which burdened laboratories, while in others only 10 to 13 suspects a year were referred for laboratory testing.
- 5) Collaboration of primary health care clinical providers and laboratory specialists needed improvement in many districts.

In summary, the laboratory service is ready and eager to practice in accordance with internationally recommended standards but external quality control (EQC) and regular monitoring must be strengthened. Additional specific training and technical assistance are required to significantly improve implementation of laboratory EQC. Currently, it is not possible to compare results of EQC received from different oblasts because of varying EQC practices, nonrepresentative sampling, and other deficiencies.

To date, only one oblast TB laboratory in the Donetsk Oblast TB hospital executed EQC in collaboration with a supranational reference laboratory, which was temporarily assigned by the WHO to support a TB drug-resistance prevalence survey from 2005 to 2007.

In March 2008, following a request from the National Research Institute of TB and Lung Diseases of the Academy of Medical Sciences of Ukraine, the MOH asked WHO to assign a supranational reference laboratory for Ukraine. The National TB Institute is interested in engaging a supranational laboratory to evaluate the quality of its TB laboratory investigations, primarily for research in TB diagnosis and treatment. Currently, the laboratory of the TB Institute does not fully function as the National Reference Laboratory for the TB laboratory network in Ukraine. In June 2008, WHO assigned the Latvia State Agency for Tuberculosis and Lung Diseases Bacteriology Reference Laboratory to provide support to Ukraine in EQC of laboratory testing for TB.

In addition, WHO requested that Ukraine assign the National Reference Laboratory as the responsible entity to assure quality performance of the TB laboratory network in Ukraine. The MOH and the National Research Institute of TB and Lung Diseases have had several meetings to discuss the gradual transformation of the Institute's laboratory to the National Reference Laboratory, as well as associated functions, resources, timeframe, and the potential of establishing sub- and/or inter-regional reference laboratories to carry out routine quality control activities. However, the official decision for the Institute's laboratory to become the National Reference Laboratory is yet to be made, and as a result, the laboratory network assessment by the supranational laboratory has been postponed. As the Latvia State Agency was initially planned in

PATH's proposal as an international partner for the TB control project, PATH decided not to wait for the above mentioned assessment to take place, thus proceeding to arrange a visit by the Latvia team.

An assessment of laboratories was conducted by Dr. Girts Skenders, Head of the Bacteriology Reference Laboratory of the Latvia State Agency for Tuberculosis and Lung Diseases from September 22–26, 2008. This review focused on assessing basic procedures for drug-sensitivity testing in laboratories in three project oblasts—Dnipropetrovska, Kyivska and Kharkivska—to provide laboratory support to the potential MDR-TB Center of Excellence in Ukraine. The findings and recommendations of the MDR-TB-related assessment are described under Result 2.

Additionally, PATH followed up on the possibility of conducting an infection-control assessment in laboratories within project regions in conjunction with assessing TB laboratories by the Latvia National TB Agency/supranational laboratory for Ukraine (DIP Activity 1.6). PATH also has contacted other international experts in infection control to provide technical input in developing regulatory documents on infection control and improving practices in project Year 2.

As indicated in the assessment report attached as Annex 14, the overall low understanding of biosafety and infection control (IC) principles and insufficient utilization of biosafety measures and IC practices were confirmed during assessment visits to three project sites. To increase general understanding of IC principles for tuberculosis, general IC training is needed for health care professionals at all levels, starting with health administrators in facilities (head doctors, head nurses) and representatives of the MOH. Technical assistance will be provided to specify requirements for the most important equipment for IC—ultraviolet lamps and respirators. This kind of training is critical in light of the upcoming MDR-TB-related renovations of TB facilities. Implementation of IC practices in laboratories needs official recognition and instructions on minimal technical requirements (biosafety cabinets, centrifuges, and autoclaves). This is an area of concern in all visited laboratories. Class II biosafety cabinets have been installed, although issues related to proper installation and maintenance need ongoing attention. Recommendations on biosafety principles based on international guidelines should be issued in the country and accepted by the Sanitary Epidemiological Service and, in general, throughout the MOH.

Strengthening the surveillance system

An advisory working group on monitoring and effective implementation of Ukraine's NTB was established by the MOH's March 3, 2008 order #71-adm. In addition to bringing the recording and reporting system in line with international standards (it is essential that all definitions and indicators be consistent with DOTS, as currently discrepancies exist), this group will focus on the following activities:

- Develop a surveillance system for the TB/HIV co-infection program and work toward approval.
- Improve the drug-management system.
- Strengthen the supervisory system for routine on-the-job monitoring (i.e., checklists).
- Ensure that data generated from the surveillance system ("cohort analyses") are used to take action to address weaknesses in the system as they emerge.

With PATH's leadership and technical assistance, this advisory group reviewed the statistical forms for collecting TB-related information in accordance with international recommendations. These forms had been endorsed by the MOH for pilot utilization in Ukraine in 2006. Members of this advisory group on monitoring analyzed comments and suggestions provided by specialists from the project regions for improving the temporary forms. The forms have now been revised following useful suggestions for changes. The associated instructions for using them have been drafted in accordance with the requirements of the Ministry of Justice. PATH expects further endorsement for permanent use, not only in the health care system, but also by health services in the penitentiary and military systems. In addition, following a comprehensive analysis of the TB monitoring and surveillance practices at the primary/health facility, district, regional, and central level, a list of priority actions to improve the TB surveillance system was developed.

Training activities to improve M&E practices (DIP 1 Activity 1.10) are reflected under the DOTS training component of this report. PATH provided technical assistance to strengthen the regional recording and reporting system during a monitoring visit to Zaporizhska Oblast. In particular, PATH reviewed and discussed completed statistical forms and provided technical recommendations on the process of collecting and analyzing TB-related data. As part of this visit, PATH staff facilitated discussions and provided technical input on the benefits of conducting a quarterly review meeting at the oblast level. Checklists of supervisory visits and quarterly statistical reports from two rayons of Zaporizhska Oblast were reviewed (DIP 1 Activity 1.11). Also, PATH provided similar technical assistance in Kharkov Oblast, Sevastopol, Kyiv City, and Crimea. In general, new pilot TB-recording and reporting forms based on international recommendations are in use in the initial oblasts, in addition to the traditional "Soviet-style" statistical forms. Cohort analysis of TB treatment effectiveness in all rayons is being reported through the new forms and system. Refresher training on data definitions, the process for correctly completing forms, how to analyze the statistical forms, and what actions to take based on the results, however, is necessary to improve M&E practices. As a result, follow-on M&E trainings were provided in Zaporizhzhya Oblast in the third and fourth quarters.

Increasing case detection and case-holding

PATH has provided a 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 for provision of DOTS 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 and encourage timely consultations with medical providers and to 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 educational 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 1.12).

Working with prisons and prisoners

PATH continues to provide technical assistance to the civilian penitentiary TB Working Group in Dnipropetrovska Oblast, the establishment of which was triggered by PATH under previous TB-related activities to support continuum of care and treatment adherence among released prisoners. This civilian-penitentiary "bridge" working group continues its regular meetings, although it requires ongoing support for analysis of those released prisoners who have not been registered in any governmental institution (DIP Activity 1.13).

In addition, according to its subcontract, URCS continues to provide social support, counseling, and referrals for released prisoners. PATH is seeking NGOs able to work with prisoners at the prerelease stage (2 to 3 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.

Assessment of the drug management system

During the Global Drug Facility (GDF) monitoring mission in January 2008, a leading specialist from Management Sciences in Health (MSH) conducted a drug-management assessment in project regions that were scheduled to use TB drugs from the GDF. As this assessment covered many of the key issues that the project had intended to review, its findings and recommendations were adopted by the PATH team to fulfill DIP Activity 1.14 and conserve resources. (See the report of the GDF monitoring mission in Annex 15.) Also, in collaboration with PATH, an assessment of drug management in Ukraine was conducted by two MSH consultants during the assessment of management information systems in March 2008. Key findings and challenges were discussed with PATH and the MOH and were also presented to USAID (Annex 16). PATH staff organized and facilitated meetings and provided technical input during the implementation of this assessment. Although the USAID/PATH TB Control Partnership project did not provide funding for this mission, the trip was conducted in coordination with PATH and provided information in support of DIP Activity 1.14. In addition, the management information systems-related mission complemented PATH's M&E activities.

Result 2: High-quality DOTS-plus (including MDR-TB, extensively drug-resistant 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

PATH analyzed international guidelines and reports and assessed available national data, guidelines, practices, and supplies in MDR/XDR-TB control in the project regions and at the national level. With PATH technical input and support, Ukraine's first protocol on drug-resistant TB case management was drafted and submitted to the MOH for further review. Notably, the protocol was placed on the website for open public review, discussion, and revision (DIP Activity 2.1).

PATH staff accompanied the USAID/Washington TB Advisor to assess the MDR-TB situation in the Donetsk region. With support from WHO and the Development of Ukraine Foundation, a pilot project to address MDR-TB has been initiated in Donetsk Oblast following the first regional drug-resistance survey. However, for reasons that are unclear, enrollment of patients into this program has been delayed. Nevertheless, the oblast's level 3 TB laboratory—the only laboratory in the country that has been certified by the supranational laboratory for drug-susceptibility testing (DST)—demonstrated the effective use of the software for surveillance of MDR-TB developed with PATH support.

The project team also provided technical input and participated in an assessment of the draft MDR/XDR-TB country assessment tool, which was being evaluated in a number of countries around the world with USAID core funding to PATH. This tool is designed to gather data and develop a situation-analysis report on MDR-TB and XDR-TB at the country 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 the MDR-TB cases and to diagnose and treat existing cases.

DIP 1 Activity 2.2—a feasibility assessment for the creation of a Ukrainian Center of Excellence for MDR-TB—was first 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 from August 30 through September 5, 2008. An assessment team worked with three project sites—Kyiv City Central TB Dispensary, Dnipropetrovsk Oblast TB Dispensary, and Kharkiv Oblast TB Dispensary—to investigate the general MDR-TB situation in Ukraine, routine MDR-TB case management, and the availability of knowledgeable clinicians and other staff to implement high-quality drug-resistant TB control. Specific attention was paid to clinical and treatment aspects of MDR-TB control, including availability of second-line drugs, treatment approaches, management of side effects, and other issues. Although the initial regimen choice and changes in pharmaceuticals and treatment schemes used for regular and drug-resistant TB in Ukrainian TB facilities were similar to those recommended internationally, the very weak organization of regular TB and MDR-TB treatment processes unpleasantly surprised the assessment team.

This assessment was continued by Dr. Girts Skenders, Head of the Bacteriology Reference Laboratory of the Latvia State Agency for TB and Lung Diseases, from September 22–26, 2008. This effort focused on laboratory aspects of MDR-TB control, including the assessment of basic procedures executed for drug-sensitivity testing in laboratories in three project oblasts—Dnipropetrovska, Kyivska and Kharkivska—in order to identify needed laboratory support to a potential MDR-TB Center of Excellence in Ukraine. It is yet to be decided whether it is feasible to establish an MDR-TB Center of Excellence and which project site could be the foundation for this activity.

As stated in the assessment report (Annex 14), it was recommended that a detailed quality control (QC) and quality assurance (QA) manual be developed, officially recognized by the MOH and introduced to laboratories through training. Current fragmented QC and QA actions suggest that maintaining quality of laboratory testing is poorly understood as an overarching

principle of laboratory services. Elimination of outdated laboratory techniques, biosafety, and IC measures would help improve the detection rate of TB by culture testing and ensure a safer work environment. Good TB culture is the basis for MDR-TB case detection. Standardizing DST methods, identifying a single source of the active ingredients of drugs, and improving internal QC would greatly increase Ukraine's ability to provide sustainable high-quality laboratory testing. It should be recognized that good laboratory services with quality-assured DST are not enough for excellent MDR-TB treatment and management; changes in TB treatment policies and implementation of infection control principles in clinics is of the highest priority. In addition, appropriate procedures to import and export biological materials for executing laboratory EQC should be arranged with responsible systems (customs, MOH, and others). Data collection on drug-resistance surveillance and linkages between laboratory and case-registration units should be established so that DST obtained on a specimen at the beginning of treatment can be subsequently identified.

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

In discussions with the HIV/AIDS Service Capacity Project in Ukraine (being implemented by Constella Futures Group), a coordinated approach was developed to build the capacity of the Regional Coordination Councils on TB and HIV/AIDS. Within the framework of these joint efforts, PATH is providing technical support to strengthen the Regional Coordination Councils' functions in guiding and monitoring TB/HIV collaborative activities at local and regional levels in the project oblasts. PATH staff helped develop a tool to guide operational research regarding ex-prisoners' social support and health protection needs related to TB and TB/HIV issues. The main objective of this research is to collect and analyze data that will support strategic planning and decision-making processes within the Regional Coordination Councils. In addition, joint training for NGO delegates who are members of local Coordination Committees was conducted for 30 participants from project regions.

Subcontracts were agreed upon and joint plans of actions were developed with the key national partners (the All-Ukrainian Network of People Living with HIV/AIDS, the Ukrainian Coalition of HIV-Service Organizations, and the National Committee of the URCS) to improve TB/HIV service collaboration. These organizations conducted a baseline assessment from July through August 2008 (DIP Activity 3.1; 4.4) to define the needs of clients, NGOs, communities, and health facilities in strengthening TB/HIV collaborative activities in the project sites (a full report is available upon request). A joint plan to execute the baseline assessment was developed with partners.

A baseline survey tool was reviewed and revised to focus more on local NGO collaboration and to improve referral of clients at risk of TB/HIV. Also, the attitudes and knowledge of medical experts and NGO staff on TB/HIV, the existing policy and practice of TB/HIV co-infection case detection and treatment, and social support and care to people with TB/HIV co-infection were assessed. The main goal was to identify barriers to the provision of timely and comprehensive care and support to people with TB/HIV co-infection and to determine directions for project activities in the TB/HIV domain. Interestingly, it was revealed during the provision of technical assistance to partners in developing this baseline assessment tool that local NGOs are perceived to be more competitive than collaborative with each other and that they typically do not share

information or pursue coordinated activities. Based on the assessment results, a strategic plan will be developed for local NGOs in each pilot oblast, in particular to support appropriate communication and promote collaborative approaches.

An analysis of data received suggests that neither existing legislation nor regulations contain any barriers to implementing a comprehensive approach to the provision of medical and social support to people with TB/HIV co-infection. As seen by medical experts, the main barriers to the provision of effective support to TB/HIV patients include the absence of an appropriate TB/HIV case-registration, reporting, and monitoring system and clearly defined algorithms guiding provision of services and support. Experts' answers demonstrate the segregation of TB and HIV services, the absence of information exchange and planning of joint activities, and lack of information on the provision of care and support to people dually affected.

In addition, the assessment findings from nine regions of Ukraine provide important information about the needs of TB/HIV co-infected individuals and the role of NGOs in addressing those needs. With regard to people living with HIV's knowledge on TB/HIV co-infection, it was revealed that clients of HIV-service NGOs have some basic knowledge on HIV/AIDS, although a significant number of them have incorrect knowledge regarding some of the modes of HIV transmission (for example, believing that all contraceptives are effective in preventing HIV infection and that transmission can occur through saliva, kissing, or insect bites). Also, many of these individuals believe HIV infection is equivalent to AIDS.

In terms of TB, participants usually knew two or three symptoms of TB, such as productive cough and fever; however, nobody knew the TB treatment process, or, in particular, the typical duration of in-patient TB care. In addition, a vast majority of participants do not realize that, as people living with HIV, they are at particularly high risk for developing TB. No significant differences in HIV and TB knowledge were noted among different age or gender groups. Slightly better knowledge was observed among respondents from Kyiv and Donetsk Oblast. The findings therefore suggest that the project should encourage medical providers at HIV/AIDS centers and NGO staff to systematically discuss TB with HIV-positive individuals, clarifying that TB is a respiratory infection to which everyone is susceptible and that HIV-positive individuals are especially vulnerable to developing TB. Other essential messages are that TB patients are required to stay in the hospital for two months and that it is critically important to complete a full course of treatment.

The clients of HIV-service NGOs noted a number of reasons for delays in seeking medical assistance, particularly HIV testing. Among them are the fear of a positive result, concern about disclosure of their status and consequences of such disclosure for them and their family, and a generally low perception of risk. The reasons for not seeking TB testing are essentially the same. Lack of available information on TB—especially on the dangerous consequences of TB treatment not being completed—and about TB-related health services being free of charge add to these reasons. A mistaken view among HIV-positive individuals that TB patients are required to stay in a TB facility for a very long time (6 months or longer), as well as the poor conditions of TB hospitals, are the main barriers for seeking TB treatment. Based on these findings, the assessment strongly suggests that there is a need to improve the communication and counseling skills of medical providers. Training should especially address issues such as confidentiality and stigma. NGO managers believe that it is important to develop a strategy for the provision of

highly active antiretroviral therapy and substitution therapy for intravenous drug users who have TB.

Nearly all participants emphasized the need for more detailed information on HIV/AIDS and TB. During educational campaigns, it will be essential to emphasize the importance of seeking timely diagnosis and treatment. About half of respondents cited NGOs as the most important source of information for them, with television as a second choice. In-depth interview participants offered ideas about key messages that educational materials should contain. Most suggestions include the need for early diagnosis and treatment.

In terms of the current status and effectiveness of TB/HIV medical services for HIV-positive individuals, nearly all participants indicated that they were tested for HIV; however, only two-thirds of them received counseling on HIV/AIDS. In addition, almost half of the people who came for HIV testing in Odessa, Donetsk, Dnipropetrovsk, and Zaporizhzhia were not referred to HIV-service NGOs, although there are many active HIV-service NGOs in their cities. All participants stated that TB testing in their cities is accessible and free of charge, but they did not have clear information about the cost of treatment. About two-thirds of them felt that treatment was accessible and free, while one-third felt that patients must pay. The level of coordination among government health organizations and NGOs is still very low. A vast majority of NGOs are members of TB/HIV coordination councils in their regions; however, some NGO managers stated that those meetings are irregular and not effective. Other barriers for establishing effective collaboration with the government organizations are lack of support and understanding from the local bureaucracy, lack of funding, TB/HIV stigma, reluctance in sharing information, and lack of trust towards NGOs.

In NGO managers' opinions, legislation should be changed to improve funding possibilities for NGOs, roles and responsibilities of all involved organizations should be defined, and a clear and legitimate referral system for TB/HIV co-infected individuals should be established. The majority of NGOs refer their clients to HIV/AIDS centers, TB dispensaries, narcology and STI clinics, and other medical institutions; however, a similar referral system (from medical institutions to NGOs) does not exist. The findings therefore suggest that NGOs should actively inform the population and medical providers about services that they provide to people living with HIV/AIDS.

The assessment findings suggest that it is necessary to develop a joint program of trainings for TB specialists, HIV/AIDS-center specialists, and HIV-service NGOs staff in order to improve cooperation, coordination of efforts, and understanding among the different service personnel. It is advisable to include them into the same group, especially for training on interpersonal communication and counseling. Also, it is necessary to develop a clear and legitimate referral system for TB/HIV co-infected individuals, as well as specific strategies for reducing stigma and discrimination within health services through training, roundtables, educational campaigns, and similar efforts. The majority of the HIV-positive individuals who participated in the assessment named NGOs providing services to HIV-positive individuals and people with TB in their cities. In their opinions, many NGOs provide very useful services free of charge, including psychosocial support, informational services, peer education, and support groups. In contrast,

however, the majority of participants from Kharkivs'ka Oblast and many from Crimea could not name a single NGO involved in this work.

The assessment data were discussed at three round tables (in Kyiv, Dnipropetrovsk, and Zaporizhzhya) with the participation of medical workers, NGOs, and Coordination Council members. The goal of these roundtables was to inform regional stakeholders about the assessment results and discuss the specifics of their regions in order to develop strategies for improving access to medical and social services among vulnerable populations in each project region. As a result of discussions, oblast action plans were developed. Key activities are summarized in Annex 17.

TB screening and monitoring tools as well as training and educational materials used by PATH for previous TB/HIV activities were reviewed, adapted, and pretested for use in this project (DIP Activity 3.4). PATH, in collaboration with the All-Ukrainian Network of People Living with HIV, continues development of a video training course on TB for providers and HIV-positive individuals.

Following the presentation of project interventions to improve collaborative TB/HIV activities to the Regional Coordination Council in Zaporizhzhya Oblast during the second quarter, a seminar was conducted for 28 members of the Council on June 19, 2008 (PMEP indicator 25). The focus was on strategic planning and implementation of a coordination algorithm for TB/HIV care and social support. With approval from the Council, a working group was established to develop a strategy and action plan to address TB/HIV issues (DIP Activity 4.2). The first meeting of this working group was planned for July 31, 2008.

PATH continued to provide technical 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. Also, this "office of trust" will serve as a center for training in interpersonal communication and counseling for health care providers and NGO activists from this city and other rayons of Zaporizhska Oblast. Equipment and furniture were purchased for the office to launch its activities in August 2008.

Information on TB/HIV activities was collected during an initial assessment visit to Odeska Oblast. A plan to improve these activities was developed, discussed, and agreed upon by all stakeholders.

Discussions with key local partners and visits to project regions confirmed the need for providing training on TB/HIV detection, treatment, and care, and for developing related training materials. As a result, existing training materials have been reviewed and revised accordingly (DIP Activity 3.3).

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 the awareness among key policy makers on global TB strategic approaches and the European regional response to the TB epidemic.

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 heads of health administrations and key TB specialists during visits to Odeska and Dnipropetrovska Oblasts, as well as with delegations from all project oblasts during the course of the Annual National TB Conference, which was held on May 28–31, 2008 in Ivano-Frankivsk. Participants discussed and evaluated the results of the national TB control program implementation in 2007. Participation in this conference allowed proactive discussion of necessary revisions to the TB regulatory documents, such as Ukraine's protocol on TB case management (MOH's order #384) and others.

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 4.1). As a result of the analysis, which revealed numerous discrepancies and an absence of clear systematization of documents in force, a request was sent out to appropriate decision-making bodies to initiate the process of codifying the Ukrainian legislative framework within the health care system, which could start with TB-related regulations. UATB continued its TB-related awareness and promotion activities among Ukrainian Parliament people's deputies, representatives of the government executive bodies, national NGOs, and beneficiaries in order to publicly discuss Ukrainian legislation on and practices regarding TB control. A presentation on the Stop TB Strategy, recommended TB control standards, and MDR-TB was delivered to the Ukrainian Parliament's Health Care Committee (DIP Activity 1.3). Informational materials were drafted for further meetings of the Parliament's Health Care Committee. An agreement concerning the development and publishing of informational materials for Parliament members and staff people on international approaches to and best practices of TB control was signed with the international journalist association, Health without Borders.

PATH reviewed and provided technical input to the following documents: MOH's recommendations on restructuring the TB service; organizational structure and functions of the National TB Reference Laboratory; guidelines on implementation of TB screening; national law regarding TB control; technical requirements for development of the TB Control Manual under the MOH/World Bank's TB and HIV project; and the national protocol on TB/HIV co-infection services. (DIP Activity 4.1).

UATB convened sixteen informational meetings with members of parliamentary committees on health care, budget matters, international affairs, education and science, national security, and

people's rights to overcome delays with allocation of national budget funds through the Ministry of Finance to the MOH to procure TB drugs and mitigate a dangerous situation caused by TB drug shortages at the oblast level. A press conference was held on April 23, 2008 to advocate for changes in financial practices as they relate to procurement of TB drugs. This is essential to ensuring their uninterrupted availability in TB hospitals. Twenty letters concerning TB drug-related financial policy were sent to the President of Ukraine, the Prime Minister of Ukraine, Parliament people's deputies, and ministry heads. As a result, despite difficulties with the national budgeting process and continued delay with appropriating national funds, the Ministry of Finance allocated funding, and TB drugs were procured by the MOH.

UATB also prepared and submitted 33 appeals to the President of Ukraine, the Prime Minister of Ukraine, Parliament people's deputies, and ministers regarding implementation of international TB control approaches, their relevance to Ukraine, and the need to make appropriate changes in Ukraine's legislative framework. An MOU between the Ministry of Family, Youth and Sport; UATB; Health without Borders was signed to identify joint anti-TB activities, including training of officials and employees of the centers for youth and social support under the auspices of this ministry.

With regard to work being conducted at the oblast level, the PATH team met with the heads of health administrations and key policy makers of Donetsk, Dnipropetrovska, Kharkivska, Zaporizka, and Odeska Oblasts, and Crimea to discuss a collaborative strategy for addressing the main barriers to strengthening TB and TB/HIV services. The PATH Deputy Project Director gave a presentation at the oblast multidisciplinary conference in Zaporizhzhya on the main approaches to TB control and the role that other services (e.g., social, media, police, oblast parliament, educational, and others) can play in strengthening routine TB and TB/HIV control (DIP Activity 4.2).

IV. Performance problems during the reporting period and variance from the annual implementation plan and PMP

The ongoing conflict between the MOH HIV/TB Committee and the National Institute of TB and Lung Diseases under Ukraine's Academy of Medical Sciences seriously limits the ability of already weak human resources to develop appropriate policies and technical documents. This continues to lead to requests from the MOH to PATH for providing technical assistance in multiple TB-related areas at the national level. This situation somewhat constrains the PATH's capacity to work more intensively at the oblast level.

V. Budget and expenditures

In the fourth quarter of Year 1, PATH has spent \$330,882.24 for Result 1, \$75,194.40 for Result 2, and \$103,790.61 for Result 3, totaling \$509,867.25 as of September 30, 2008.

VI. Key activities planned in Year 2 and estimated expenditures for each result

PATH plans to intensify training activities in Odeska Oblast and launch expansion of DOTS services in the next new project area, Luganska Oblast. Monitoring review meetings will enable analysis of project oblast TB-program performance and the development of site-specific plans for improvement. TOT courses will help to refresh both knowledge of international standards of TB control and methods to provide information for adult learning. Training focused on MDR-TB and TB/HIV case management will be underway. Key activities will be implemented in accordance with the Year 2 Detailed Implementation Plan (October 1, 2008–September 30, 2009).

Within the current cumulative obligated funding of \$4,188,000 for Year 1 and 2, PATH is planning to spend \$1,300,000 for Result 1, \$1,100,000 for Result 2, and \$400,000 for Result 3 in Year 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. Year I (2007-2008) - TB incidence (TB case notification) rates in 2007 Year II (2008-2009)—TB notification rate in 2008	Year I 79.8 TB cases per 100,000 population - TB incidence (TB case notification) rate at the national level in 2007	An increase in reported TB incidence may indicate improved TB diagnosis and case registration rather than worsening of the TB situation. Year I TB incidence rates in each project area is provided below in table 1 TB incidence (case notification) rate for 2008 will become available in March 2009.	Annually

Annex 1

<p>2 AI</p>	<p>DOTS-based TB case detection rate at the National level and in project regions</p>	<p>WHO estimates NTP data Oblast TB program data</p>	<p>DOTS-based TB detection rate for cases registered in 2006 is a baseline indicator for the project Not available for sub national regions.</p>	<p>At or approaching 70% case detection by 2011 in project regions (project goal). Year I (2007-2008) – DOTS-based TB detection rate for cases registered in 2006 Year II (2008-2009)– DOTS-based TB detection rate for cases registered in 2007</p>	<p>Year I - 65%</p>	<p>WHO made an estimated DOTS-based TB detection rate for 2006 TB cases available in March 2008. It is a usual practice that WHO estimates of detection rates are available for TB cases notified in countries two years earlier.</p>	<p>annually</p>
<p>3 AI</p>	<p>TB treatment outcomes by a cohort analysis: Treatment success · Treatment failure · Default · Died · Transferred</p>	<p>NTP data Oblast TB program data</p>	<p>Available for project regions. Data on treatment success rates in patients who started treatment in 2006 (based on cohort analysis results) are reliable only in the oblasts that have been covered previously by project activities. Oblasts that started analysis of TB treatment effectiveness based on cohort analysis as part of the new M&E system introduced in 2007 have not yet provided these data and thus a reliable overall rate in Ukraine cannot yet be calculated.</p>	<p>At or approaching 85% treatment success by 2011 in project regions (project goal). Year I (2007-2008) – treatment results for patients who started treatment in 2006 Year II (2008-2009)–TB treatment results for patients who started treatment in 2007</p>	<p>Year I – 54.4% (average for project regions) TB treatment outcomes of patients who started treatment in 2006 in each project areas, stratified by a cohort analysis into: Treatment success · Treatment failure · Default · Died · Transferred are provided below in table 2</p>	<p>Treatment success will be stratified into cure and completion.(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) 2007 cohort data are in progress and will be available in March 2009.</p>	<p>annually</p>

Annex 1

<p>4. AI</p>	<p>DOTS coverage</p>	<p>NTP data Project data</p>	<p>29%</p>	<p>50%</p> <p>Year I (2007-2008) – 35%</p> <p>Year II (2008-2009) – 40%</p> <p>Year III (2009-2010) – 45%</p>	<p>Year I - 35%</p>	<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%) in year III and IV.</p>	<p>annually</p>
<p>5 AI</p>	<p>Case notification rate in new sputum smear positive pulmonary TB cases</p>	<p>NTP data Oblast TB program data</p>	<p>Not available nationally, but can be calculated for the current project regions using the available data.</p>	<p>No target for this indicator—it will serve a monitoring function and for further calculation of TB surveillance and NTP performance indicators.</p> <p>Year I (2007-2008) – TB notification rate in new sputum smear positive pulmonary TB cases reported in 2007</p> <p>Year II (2008-2009) – TB</p>	<p>Year I - 35.3 SS+ TB cases per 100,000 population (average for project regions) Case notification rate in new SS+ TB cases in each project area is provided below in table 3</p> <p>National average in 2007 - 31.5 TB SS+ cases per 100 000 population.</p>	<p>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 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..</p>	<p>annually</p>

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				notification rate in new sputum smear positive pulmonary TB cases reported in 2008			
6 AI	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 maintained with one quality lab per 70 -100,000 population approximately, taking into account the need to ensure coverage of remote areas.	Year I – There is one Level I Lab per 55,000 population TB microscopy laboratory coverage in each project area is provided below in table 4 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.	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
7 AI	Proportion of TB laboratories with less than 5% error on sputum smear microscopy	Laboratory External Quality Assurance (EQA) records	Two laboratories in the current project regions functioning at this level of proficiency.	More than 70% of laboratories in the project regions with <5% error on smear results. Year II – 20% of laboratories in the project regions with <5% error on smear results.	Year I - Performed EQA procedures, non-representative sampling did not allow calculating accurately the proportion of error. . At this stage, EQA of TB microscopy was introduced through initial training		annually
Project Data							
8. AI	Number of people trained in any Stop TB Strategy elements	Project records	7,000 from all DOTS efforts (PATH and WHO).	10,000 Year I (2007-2008) – 600	Year I - 1,124 Previously established infrastructure for training, especially for primary health care providers, was the main reason that the	Cumulative total as a result of additional training through this project only	

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				<p>Year II (2008-2009) – 1000</p> <p>Year III (2009-2010) – 800</p>	project was able to exceed its Stop TB Strategy training targets.		
9.	Number of laboratory review meetings held in project regions	Project records	Not done currently	<p>Year I (2007-2008) - At least 24 lab review meetings held in the initial eight project regions</p> <p>Year II (2008-2009) – at least 18 lab review meetings held in 9 project areas (semi-annually)</p>	Year I - 10 laboratory review meetings.	Financial and time constraints may most probably allow conducting lab review meetings by oblast TB specialists semi-annually	Quarterly semi-annually
10.	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>Year I (2007-2008) - Eight current project regions provide accurate and timely TB data for annual data collection and analysis</p> <p>Year II (2008-2009) – nine project areas provide accurate and timely TB data for annual data collection and analysis</p>	Year I - 8 regions provide data in a timely manner, but accuracy needs to be addressed in further trainings (findings of supervision visits)		quarterly
11	Proportion of new TB cases diagnosed with MDR-TB	NTP data Oblast TB program data	No accurate data available.	<p>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.</p> <p>Year II (2008-2009) – data reported in 2008</p>	Year I - There is no reliable data on MDR-TB. 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.	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	Year I - There is no reliable data on XDR-TB.	No in-country capacity for second-line drug susceptibility testing	annually

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				effect on XDR-TB prevalence can be achieved during the project period Year II – preparation in progress		exists. PATH will work with the two labs capable of accurate first line DST to increase their capacity.	
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 from WHO.	2 additional pilot sites supported by the project. Year II (2008-2009) – preparation in progress	Year I – 1 MDR TB case management program operates in Donetsk oblast with WHO support		annually
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 Year II (2008-2009) – preparation in progress to assure appropriate TB culture and DST	Year I – Laboratory of the Donetsk Oblast TB Hospital only	It is anticipated that additional laboratory work will be funded through the Global Fund against AIDS, TB and Malaria	Quarterly
15	TB/HIV co-infection service coverage	AIDS Center records Oblast TB program data Project data	No data available	30% of the population country wide have access to both TB and HIV services through improved referral, diagnosis and treatment	Year I – TB/HIV services including HIV service NGOs and multidisciplinary teams were established & 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.		annually
16 AI	Number of HIV-infected clients attending HIV care/treatment services that are receiving	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	Year I - 300 TB/HIV cases were cross-checked in TB and AIDS centers	Reflecting the number of recorded TB/HIV patients, the indicator will serve primarily a monitoring function.	annually

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	treatment for TB disease			<p>Year I (2007-2008) - to cross-check 300 TB/HIV cases at TB and HIV AIDS centers</p> <p>Year II (2008-2009) recording of 300 TB/HIV cases will be cross-checked in TB and AIDS centers</p>			
17 PI	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.	<p>30,000 through this project (this indicator may require revision in discussion with USAID/Kyiv Mission).</p> <p>Year II (2008-2009) –350 cases receiving palliative care in health facilities in project areas which employ health professionals who were trained under the project</p> <p>Year III (2009-2010) - 400</p>	Year I - 350 TB/HIV cases	<p>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.</p> <p>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 collection.</p>	annually
18 PI	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.	<p>85 % of all registered TB patients by 2011.</p> <p>Year II (2008-2009) – at least 60% (9000 people) of registered TB patients in 9 oblasts receive quality counseling</p>	Year I – 9000 (60%)	<p>A preliminary data suggest that 1522 patients in Dnepropetrovsk Oblast which corresponds to 64% and 2210 patients in</p>	annually

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					Kherson oblast (65%) received HIV counseling, testing and received test results.		
19	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. Year II (2008-2009) – at least 50% of HIV-positive individuals in Donetska, Zaporizka, Khersonska, Kharkivska, Dnipropetrovska oblasts, Kyiv and Sevastopol cities	Year I – 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 collection.	Project will also introduce TB screening tool for use at each client visit, but this is too difficult to measure project wide and will be tracked as part of supervision.	annually
20.	Number of HIV service organizations participating in TB symptom screening of clients	Project records	No data	At least 16 organizations in pilot regions Year 1- at least 3 organizations Year II (2008-2009) – additional 5 organizations	Year I – 6		annually
21 PI	Number of service outlets providing voluntary HIV counseling and testing	AIDS Center data TB program data Health facility records	Data not available.	 Year II (2008-2009) – 24 (cumulative)	Year I - 16 (Initial Oblast TB and HIV Centers, 2 Kiev City dispensaries)	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.	annually
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 Year I (2007-2008) – 30 Year II (2008-2009) – 100 Year III (2009-20109) - 50	Year I - 47	This indicator was added as training in TB/HIV clinical management will be an objective of this project.	Quarterly
23	Cumulative number of	Project records	Data not available.	28			annually

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	service outlets providing clinical prophylaxis or treatment services for Tuberculosis for HIV-infected individuals			Year I (2007-2008) – 16 Year II (2008-2009) - 24	Year I - 16 (Initial Oblast TB and HIV Centers, 2 Kiev City dispensaries)		
24 PI	Number of local organizations provided with TA for HIV-related institutional capacity building	Project records	Data not available.	20 organizations Year II (2008-2009) - 5	Year I - 7	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 PI	Number of individuals trained in HIV-related institutional capacity building	Project records	Data not available	80 individuals Year II (2008-2009) – at least 30 persons	Year I - 28	As above.	Quarterly
26 PI	Number of civil society organizations provided with TA for participating in TB control, TB/HIV and HIV advocacy and /or policy development activities	Project records	<5	16 At least 2 organizations per project region will be active in TB control, TB/HIV and HIV advocacy and policy development on a consistent basis Year II (2008-2009) – 5 organizations	Year I - 6 (Odessa 1 + Dnipropetrovsk 1 + Zaporizhia 3 + Kiev 1)	This combines two suggested indicators, since organizations will receive both TB and HIV-related support.	annually
27 PI	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 Year II (2008-2009) – the number will be discussed with partner organizations	Year I - 8	This effort will be done in coordination with stakeholder organizations involved in HIV-related TA: HIV Alliance, Constella Futures and others	annually

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28.	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 Year II (2008-2009) – an additional medical school (Zaporizhzhya medical school is planned)	Year I - One medical school in Dnepropetrovsk region		annually
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 I - 2	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 I - 31	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 I - 12	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 I - 3	This replaces a suggested indicator.	annually

* - AI – Agency Indicator; PI – PEPFAR Indicator

TB incidence rates by region (per 100,000 population)

Year	Administrative regions and areas (project sites)										
	UKRAINE	Lugan-ska	Ode-ska	Dnipro-petrovska	Kharkiv-ska	Kherson-ska	Donet-ska	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

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
Average	54.4				

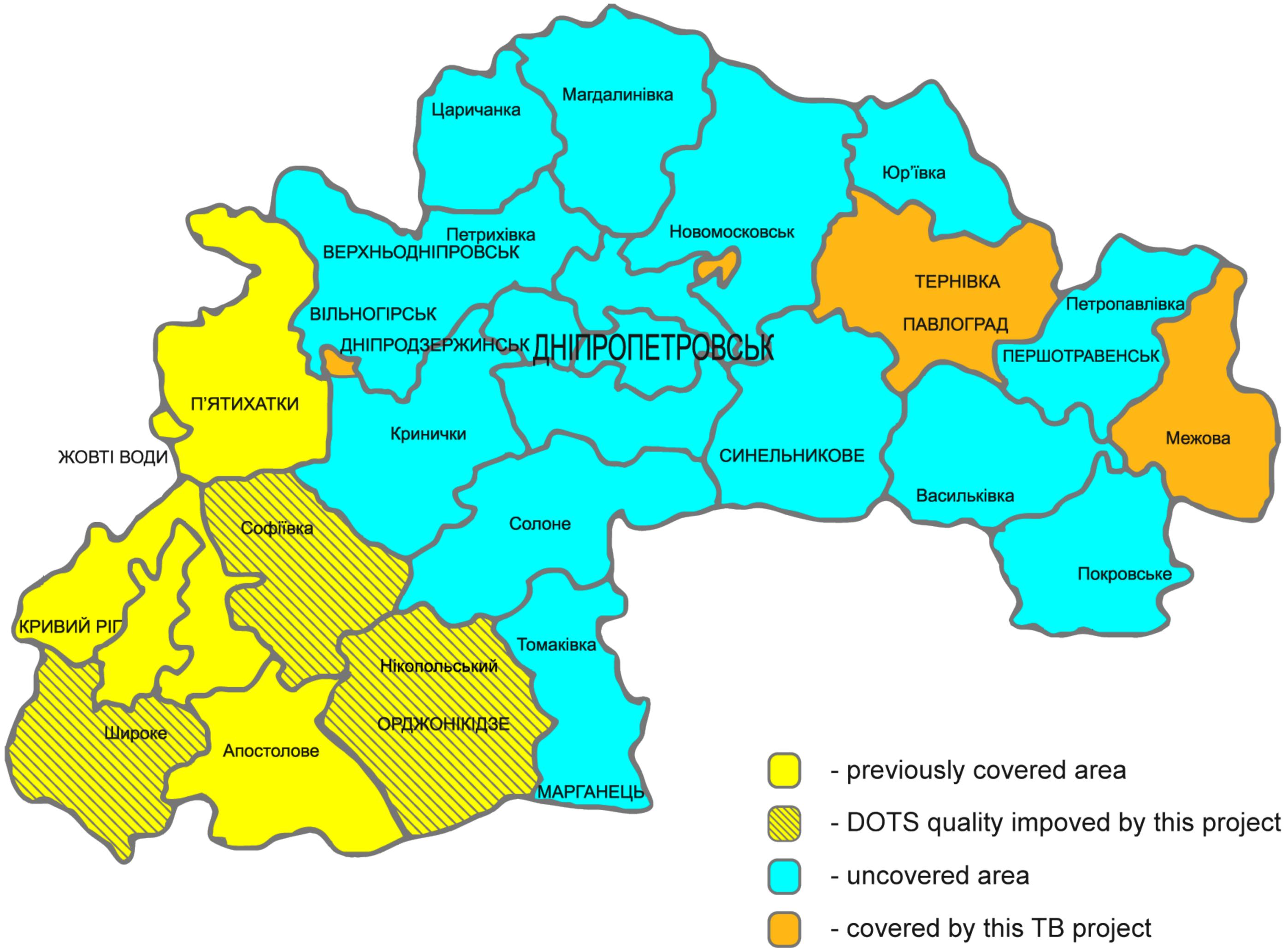
Case notification rate in new TB SS+ cases in 2007 (cases per 100 000 population)

AR Crimea	39.5
Dnipropetrovska	33.0
Donetska	33.9
Zaporizhska	38.5
Kharkivska	32.8
Khersonska	50.6
Kyiv	26.8
Sevastopol	28.1
Odeska	34.1
Average	35.3

Average population per TB microscopy unit, 2008

Oblasts	Population per Level I LAB	Population per Level II LAB	Population per Level III LAB
AR Crimea	75964	658357	1975070
Dnipropetrovska	66228	573978	3443866
Donetska	64930	329289	4610039
Zaporizhska	41339	620081	930121
Kharkivska	58612	468897	1406690
Khersonska	34092	281257	1125026
Kyiv	88397	883972	2651917
Sevastopol	41901		377109
Odessa	18924	596102	1192204
Average	54487		

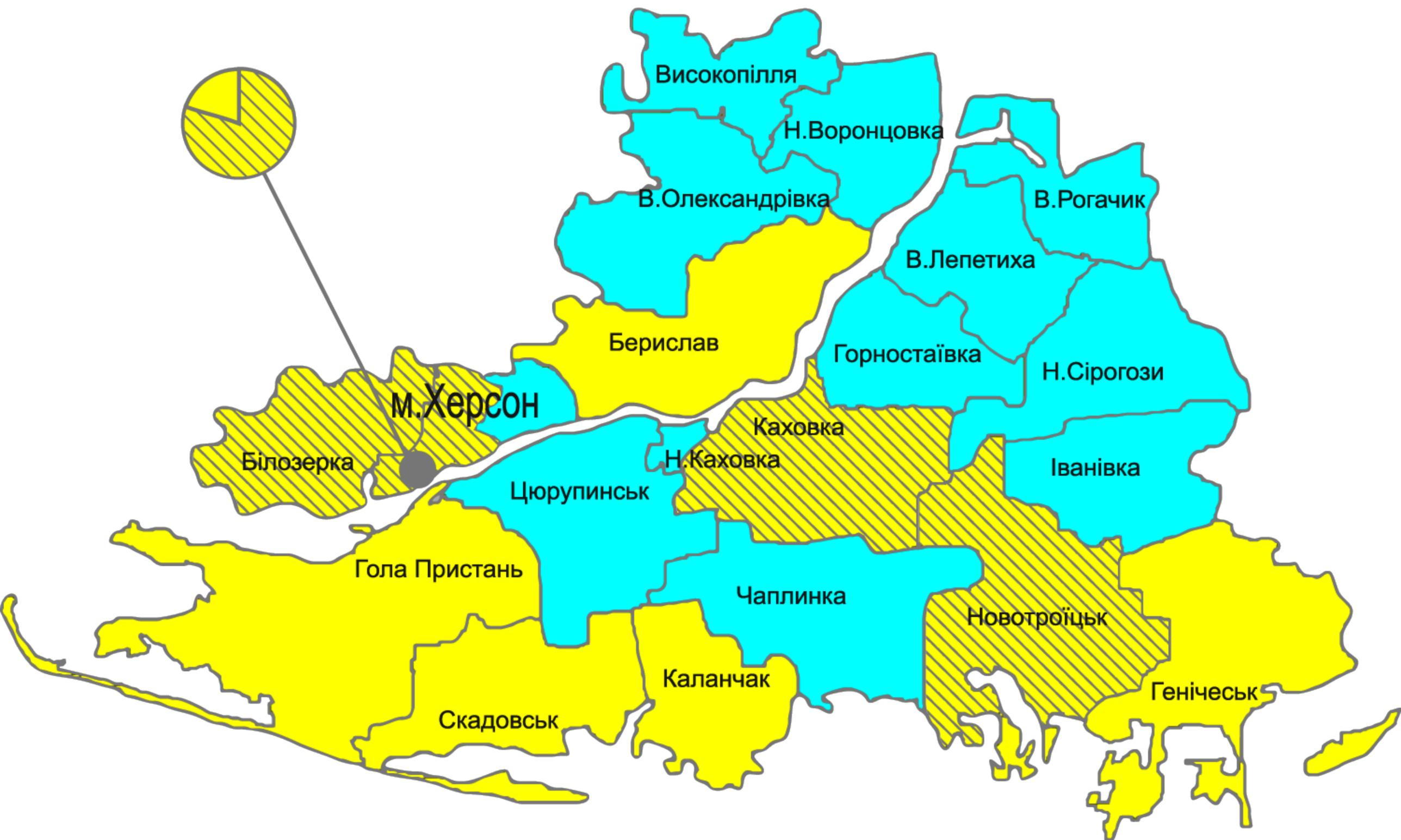
DOTS coverage 2007-2008



DOTS coverage 2007-2008



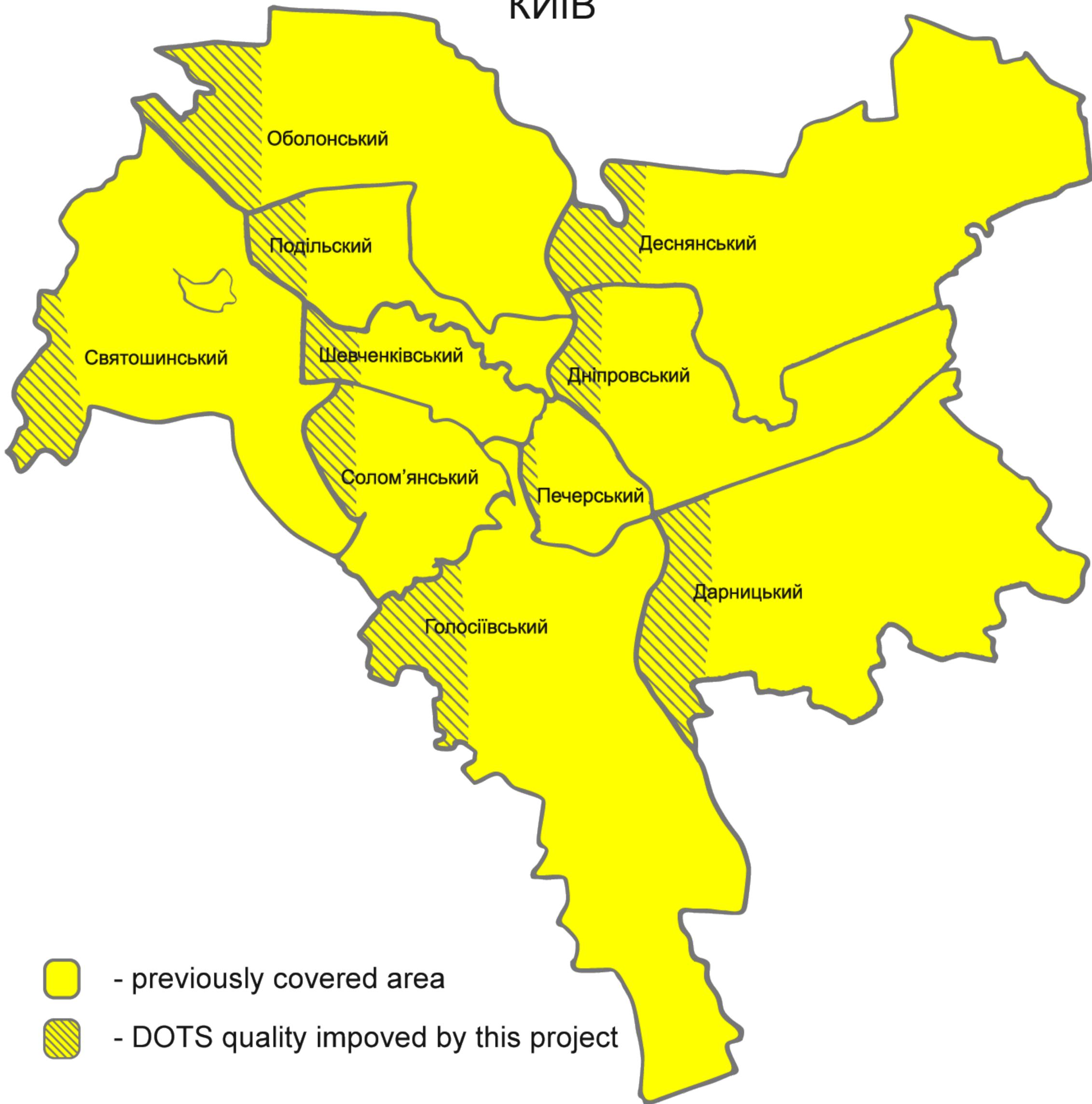
DOTS coverage 2007-2008



-  - previously covered area
-  - DOTS quality improved by this project
-  - uncovered area

DOTS coverage 2007-2008

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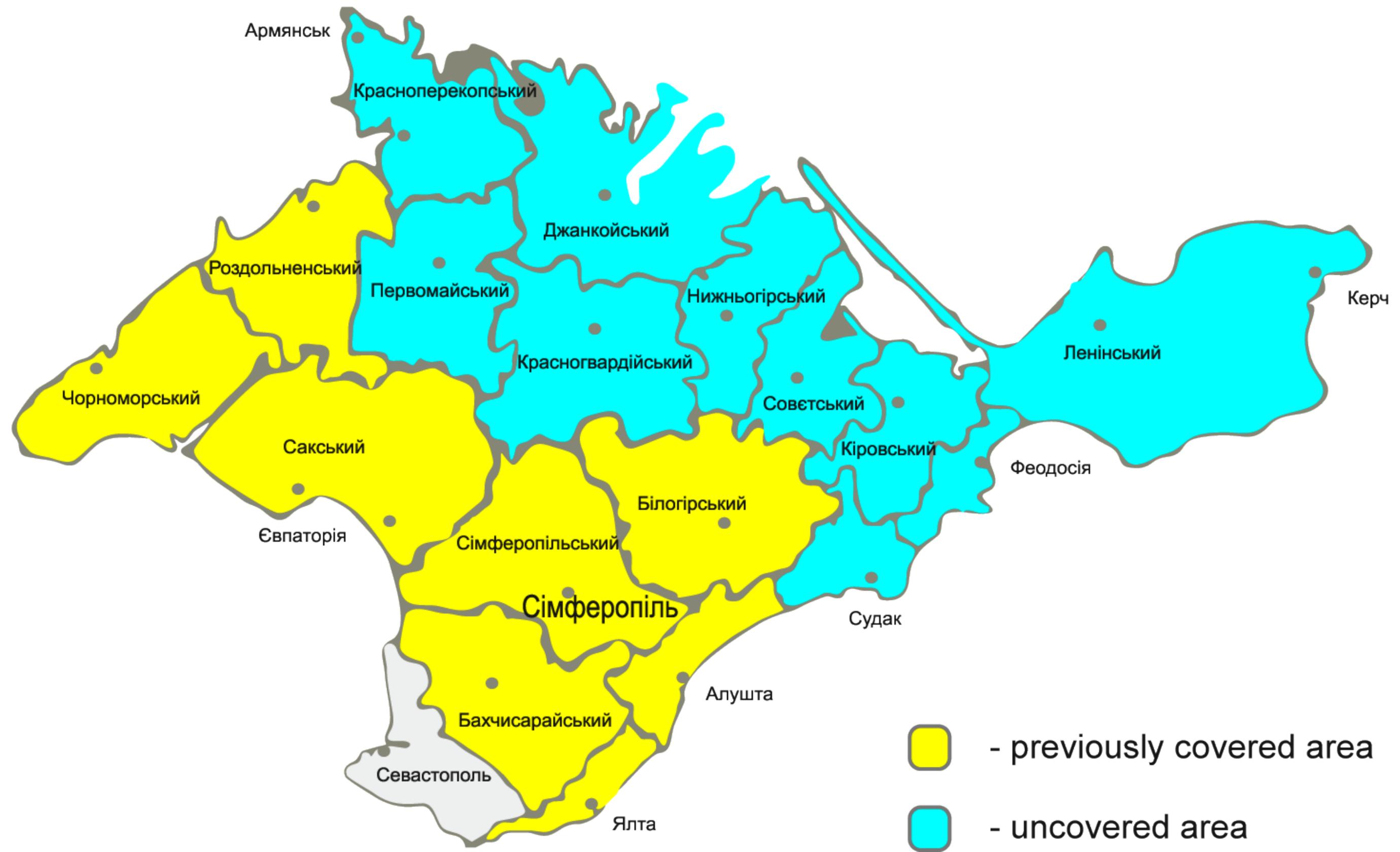
- previously covered area



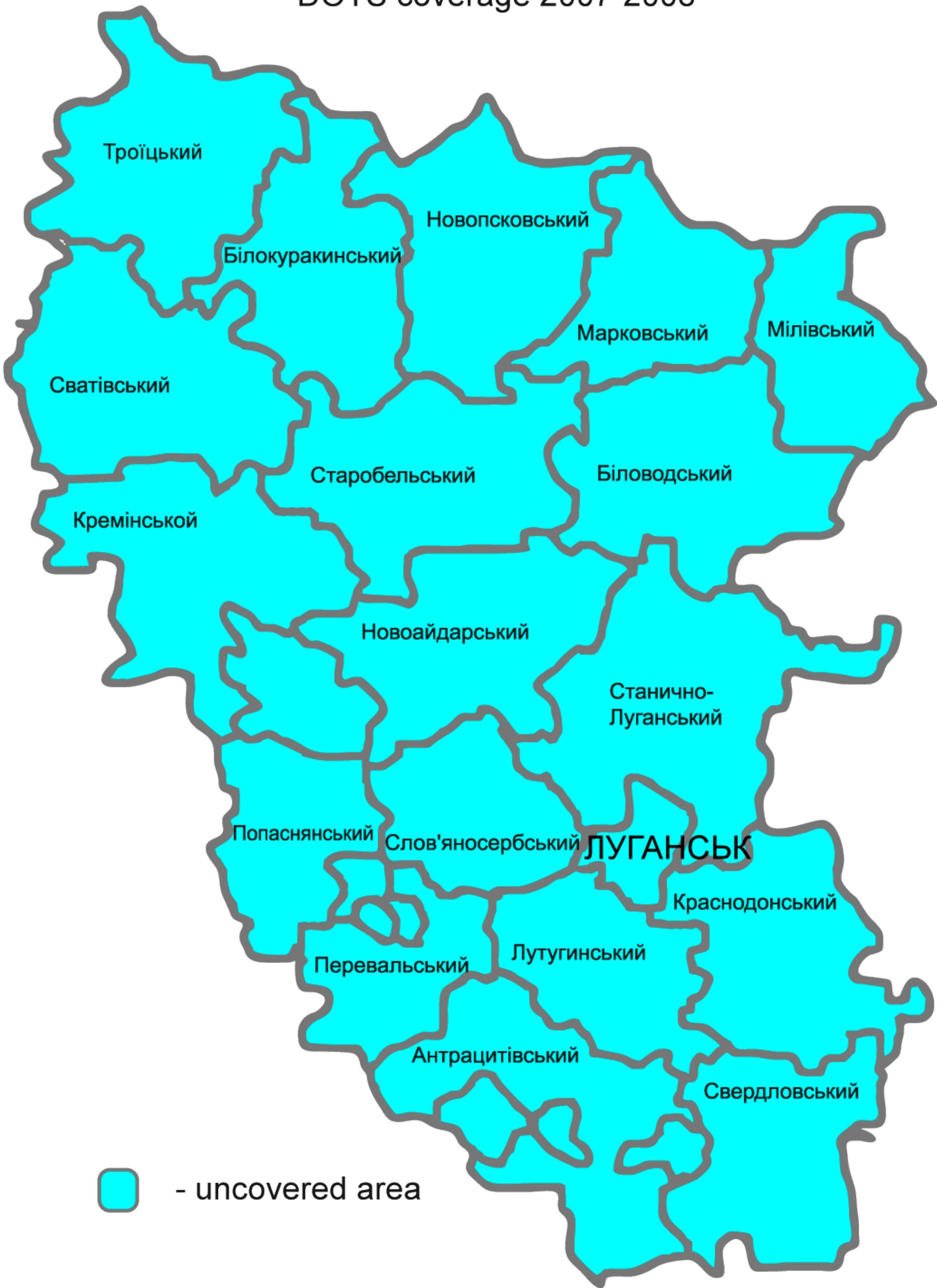
- DOTS quality improved by this project

DOTS coverage 2007-2008

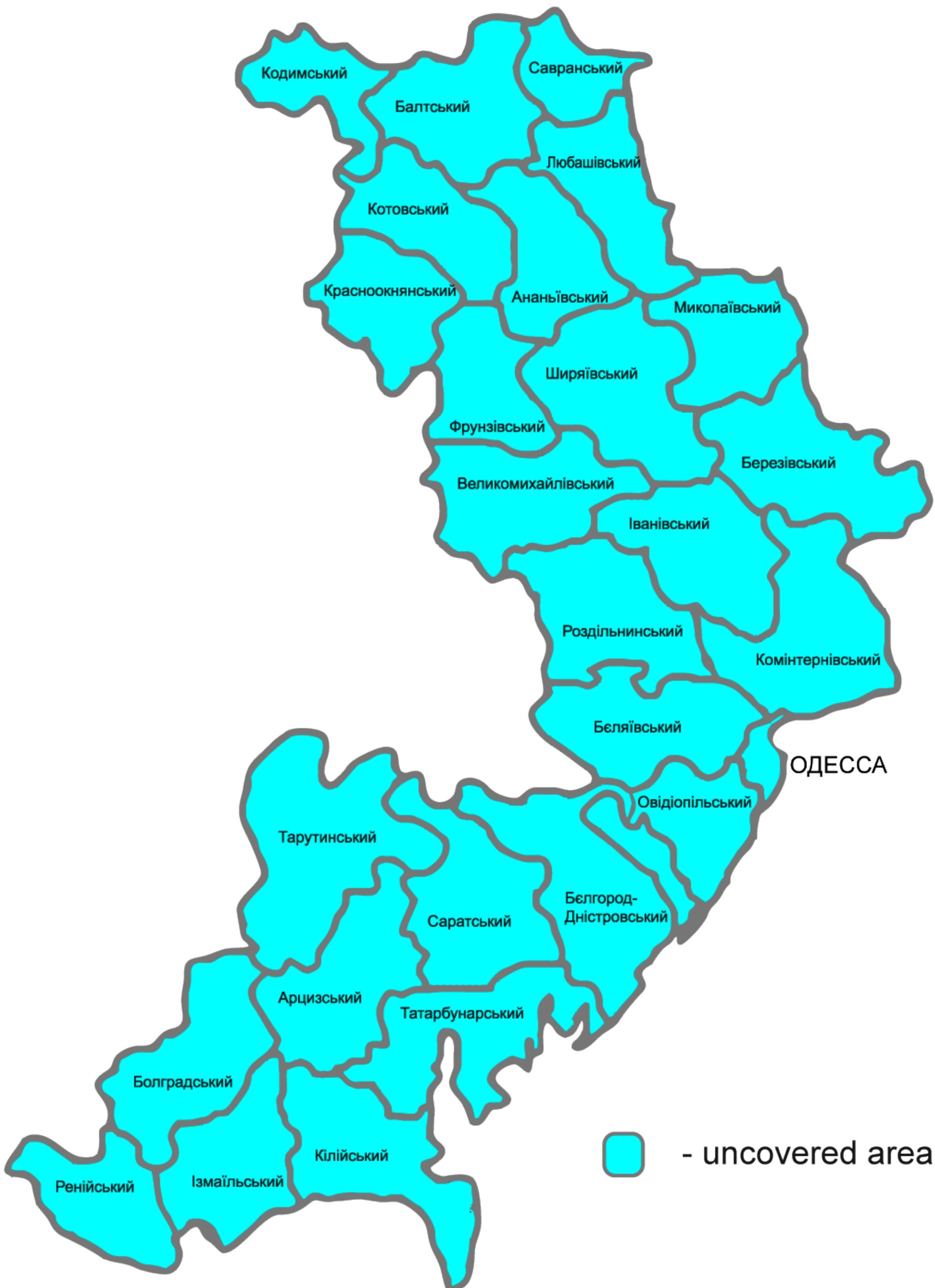
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DOTS coverage 2007-2008



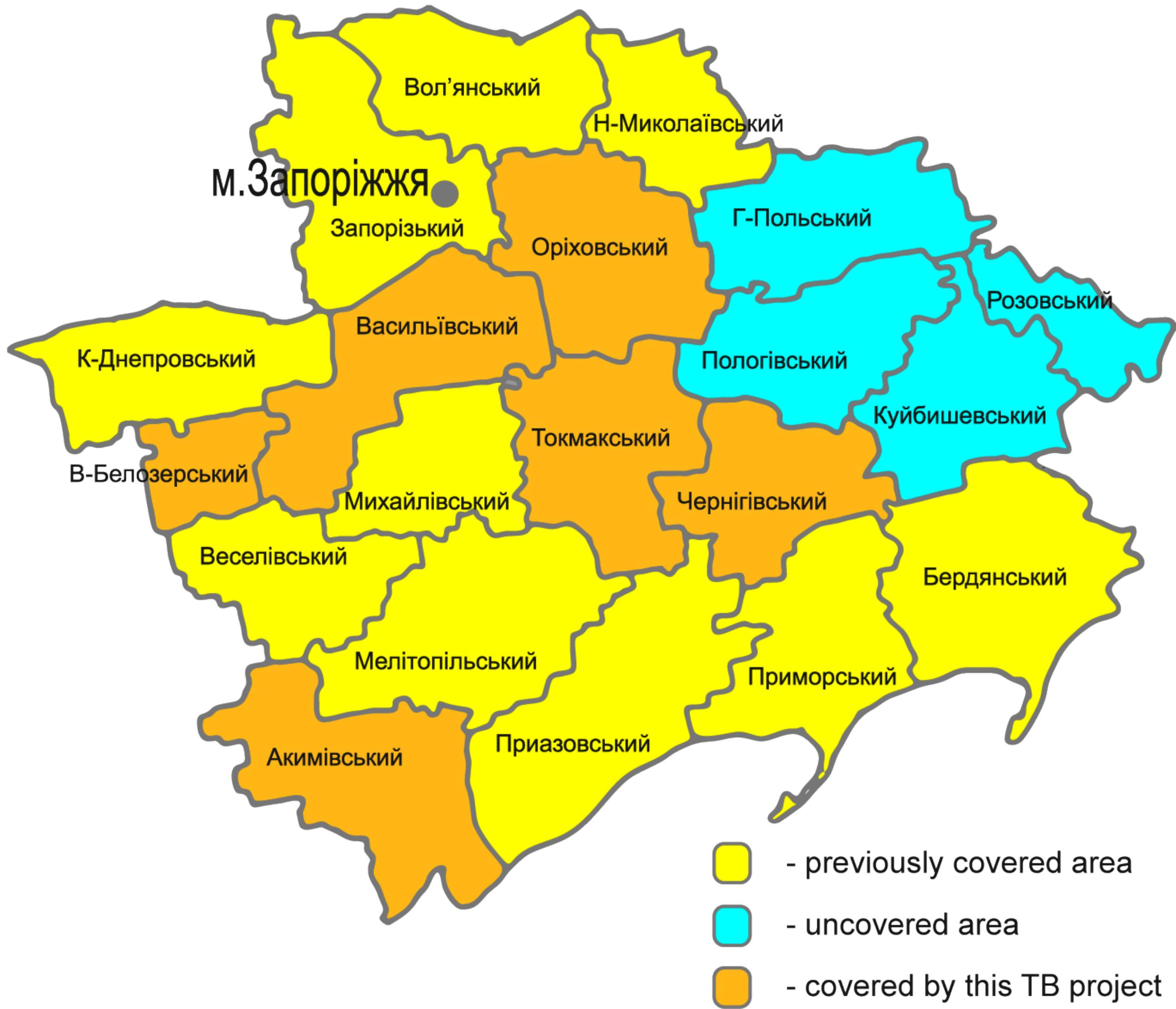
DOTS coverage 2007-2008



DOTS coverage 2007-2008



DOTS coverage 2007-2008



Training activities in TB Control Partnership Project, Year I (October 1, 2007–September 30, 2008)				
Sites	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
	Number and type of trained specialists:	Number and type of trained specialists:	Number and type of trained specialists:	Number and type of trained specialists:
Dnipro petrovsk Oblast			<ul style="list-style-type: none"> • 42 TB specialists (4 trainings on M&E system). • 5 statisticians (4 trainings on M&E system). • 15 PHC providers (2 lab trainings). • 10 TB specialists (2 lab trainings). 	
Donetsk Oblast				<ul style="list-style-type: none"> • 5 TB specialists (1 TOT in Zaporizhzhya, July 7–11). • 9 TB specialists (1 TB/HIV training). • 5 infectionists (1 TB/HIV training). • 1 TB specialist (lab training in Kherson).
Kharkiv Oblast			<ul style="list-style-type: none"> • 11 PHC providers (1 lab training). • 11 TB specialists (1 lab training). 	
Kherson Oblast		<ul style="list-style-type: none"> • 79 PHC providers (2 DOTS trainings). 		<ul style="list-style-type: none"> • 4 TB specialists (1 TOT in Zaporizhzhya, July 7–11). • 16 PHC providers (1 lab training). • 1 TB specialist (1 lab training). • 16 nurses (1 M&E training).
Kyiv	<ul style="list-style-type: none"> • 50 lab specialists (5 lab trainings). 	<ul style="list-style-type: none"> • 59 PHC providers (4 DOTS trainings). • 10 TB specialists (1 TOT). • 50 nurses (5 DOTS trainings). 	<ul style="list-style-type: none"> • 109 PHC providers (5 DOTS trainings). • 63 nurses (5 DOTS trainings). 	<ul style="list-style-type: none"> • 6 TB specialists (1 TB/HIV training). • 3 infectionists (1 TB/HIV training). • 4 psychologists (1 TB/HIV training).

Lugansk Oblast				
Odessa Oblast				<ul style="list-style-type: none"> • 3 TB specialists (2 lab trainings in Dnepropetrovsk and Kharkov). • 5 TB specialists (1 lab training). • 30 PHC providers (1 lab training).
Sevastopol				<ul style="list-style-type: none"> • 11 PHC providers (1 DOTS training).
Crimea				<ul style="list-style-type: none"> • 3 PHC providers (1 lab training). • 9 TB specialists (1 lab training).
Zaporizhzhya Oblast		<ul style="list-style-type: none"> • 8 PHC providers (1 DOTS training). • 14 nurses (1 DOTS training). • 10 lab specialists (1 lab training). 	<ul style="list-style-type: none"> • 37 TB specialists (3 trainings on M&E system). • 48 PHC providers (4 DOTS trainings). • 75 nurses (4 DOTS trainings). • 90 TB specialists (1 DOTS training at quarterly general review meeting). • 19 lab specialists (1 lab training). 	<ul style="list-style-type: none"> • 6 TB specialists (1 TOT in Zaporizhzhya, July 7–11). • 43 TB specialists (2 trainings on M&E system). • 13 nurses (2 trainings on M&E system). • 58 PHC providers (4 DOTS trainings). • 56 nurses (4 DOTS trainings).
Total personnel	50	230	535	309
Total trainings	5 Lab trainings	1 TOT	4 lab trainings	1 TOT
		7 DOTS trainings	9 DOTS trainings	3 lab trainings
		1 lab training	8 M&E trainings	5 DOTS trainings
				2 M&E trainings
				2 TB/HIV trainings
Total number of trained specialists:	372 PHC providers			
	130 TB specialists			

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	259 Nurses			
	196 Lab specialists			
	155 M\$E Specialists			
	8 Infectionists			
	4 Psychologists			
Total number of persons trained in 2007–2008	1,124			

Training plan

Laboratory diagnostics of tuberculosis (TB) by smear microscopy. Quality assurance of smear microscopy in the laboratories

Topic	Lecture	Workshop	Seminar	All
1. TB as a social and medical problem. TB epidemiological situation in the world and in Ukraine. Etiology and pathogenesis of TB.	2			2
2. Description of Koch's bacillus. Organization of activities of clinical diagnostic laboratories according to international standards. Biosafety.	2		1	3
3. Methods of laboratory diagnostics of TB. Description of smear microscopy method and its importance for TB detection.	2	16	6	24
3.1 Preparation of reagents, stains, and laboratory glass (standards, criteria)			2	2
3.2. Smear preparation for AFB microscopy-specification and standards.		4		4
3.3. Staining according to Ziehl-Neelsen method		2		2
3.4. AFB Smear microscopy according to Ziehl-Neelsen method		8		8
3.5. Qualitative and quantitative assessment of laboratory test results according to international standards. Reporting and recording forms, documents preparation and delivery to medical facilities.		2	4	6
4. Internal and external laboratory quality control of smear microscopy. Classification of errors, measures for error prevention. Regulations for technical documentation.	2		2	4
5. Pre-testing.			1	1
6. Post-testing and discussion.			2	2
Total:	8	16	12	36

TB laboratory network evaluation visit to Ukraine, 22-26 September 2008

Ģirts Šķenders

Head of Bacteriology Laboratory, State Agency for Tuberculosis and Lung Diseases of Latvia

Duties

1. Asses the basic procedures for drug sensitivity tests in the laboratories of 3 pilot site – Kyiv city, Dnepropetrovska, and Kharkovska oblasts.
2. Prepare technical report with the results of the assessment trip and provide recommendations regarding the best option for the laboratories in Ukraine in the selection of the method for drug sensitivity tests for MDR-TB diagnostics (taking into consideration the present conditions of the labs and the existing equipment).
3. Provide technical support and consultation services for the organization of the laboratory in the MDR TB Center of Excellence in Ukraine
4. Provide technical support for conducting training for laboratory specialists at the established MDR TB Centres of Excellence in Ukraine.
5. Ensure supervision and back up support to the activities of the laboratory of MDR TB center in Ukraine.

Main findings during mission

1. Introduction of detailed Quality control (QC) and quality assurance (QA) manual into laboratories are very important as current fragmented actions observed do not seem to be understood. To organize this activity finding the ways to obtain good reference strains are very important.
2. Overall low understanding of infectious nature of tuberculosis – tuberculosis are mainly transmissible via airborne particles – main task of tuberculosis programme is to reduce the incidence of TB infection (by finding active pulmonary tuberculosis cases, isolating them and treating with anti-TB drugs)

3. Biosafety measures used in laboratories visited performing culture and drug susceptibility testing (DST) are initiated and biosafety cabinets (BSC) have been found in all laboratories visited. Still proper maintenance and scheduled checking of BSC should be established. Also proper bio-safe centrifuges were available only in Kiev. This needs official recognition and instruction of minimal technical requirements (BSC).
4. External Quality Assessment for acid fast bacilli (AFB) microscopy, culture and DST still is very weak and needs strengthening and official recognition (for culture and DST).

Kiev City TB Hospital.

Laboratory serves 5 districts of Kiev. Workload – 8000-9000 smear microscopy/ year with positivity 6, 7%; 9500 cultures/year with positivity 26% ; DST – 1197/ year.

Laboratory performs also clinical and biochemistry tests. Overall laboratory staff consists of 12 people (for 17 staff units): 4 doctors (including head of lab), 5 technicians.

Well equipped laboratory with all necessary bio safety equipment including proper centrifuges with anti aerosol covers and cooling. It was suggested to decrease temperature during centrifugation to 8-10 0C. Laboratory use BSCs for all potential biohazard processes.

Laboratory has Leica fluorescent microscope which is not used and several Olympus CX21 light microscopes. It was recommended to use more Fluor chrome staining – that would allow more effectively use personnel.

For specimen decontamination Petroff method is used with NaOH initial concentration 4%.

Decontamination is stopped with phosphate buffer. 2 tubes of solid media – one LJ and one Finn 2 are inoculated. Overgrowth rate 2, 8-3%. Laboratory has Bactec MGIT 960 and BacT/ALERT 3D system which are not currently in use because of lack of reagents.

Laboratory has reagents for niacin detection. Also use nitrat reduction and catalase tests but identification is used only when primary culture has good growth. It is suggested to apply ID tests on control tube on the end of DST.

DST is performed using pure substances from Sigma. Laboratory also has received substances made in India without any documentation on potency, expiry dates etc. Laboratory performs EQ for smear microscopy in 26 PHC system laboratories. EQ – blinded rechecking 4 times a year.

However Internal Quality system elements exists in this laboratory but they are fragmented and does not seem that use of these elements are understood. This needs strengthening in form of correct documentation and training of staff.

Overall laboratory work is well organised and personnel do not seem overloaded. In talk with head of laboratory she agrees that technically workload could be increased to ~100 specimens per day if additional staff units are obtained.

I would suggest increasing amount of specimens this laboratory receives as for culture as DST however it should be organised in connection with optimised patient care.

Kharkiv Oblast TB Hospital

Kharkiv oblast with ~ 3 mil. Population. Incidence in oblast 79 cases/100 000 population with 2008 new cases in 2007. Mortality 20-22. There are 9 TB dispensaries in oblast – 7 receive finances from oblast, 1 from city and 1 from region budget. Laboratory network consists of 472 sputum collection points, 45 - 1st level laboratories, 9 - 2nd level laboratories, 2- 3rd level laboratories. Bacteriology finds 30-40% of all new cases in oblast. DSTs are performed in 4 laboratories 2 of them 2nd level. Laboratory serves Kharkiv Oblast. Workload – ~12000 smear microscopy/ year; cultures/year with positivity 26%; DST – 1197/ year.

Laboratory performs only bacteriology work. Overall laboratory staff consists of 7 people (for 10, 25 staff units): 2 doctors (including head of lab), 3 technicians, 2 cleaning staff.

For diagnostic laboratory makes 3 smears and 3 cultures. There is possibility reduce laboratory workload by changing diagnostic algorithm.

Laboratory is equipped with biosafety equipment – Biosafety Cabinets class II and use BSCs for all potential biohazard processes. For specimen treatment PC-6 (Russia) centrifuges are used with NO anti aerosol covers and cooling. It would be very necessary to obtain centrifuges with proper biosafety covers, cooling and suitable for 50 ml tubes.

There is no any fast automated liquid culture system in place. This issue should be addressed in the light of faster MDR TB case detection. However fast MDR TB detection can also be done using molecular methods like using Line Probe Assay (GenoType MTBDRplus, Hain Lifescience) and in Kharkiv Oblast TB Hospital Laboratory personnel is capable to learn it if premises and equipment is made available.

For specimen decontamination Petroff method is used with NaOH initial concentration 4%.

Decontamination is stopped with phosphate buffer. 2 tubes of solid media – one LJ and one Finn 2are inoculated. Overgrowth rate ~4%.

Laboratory uses niacin detection, nitrat reduction and catalase tests and adding Na salicilate tube when performing DST.

DST is performed using pure substances from India without any documentation on potency, expiry dates etc.

Laboratory control its proficiency in smear microscopy and DST comparing results with Donetsk. Laboratory performs EQ for smear microscopy – blinded rechecking 1, 5 times a year, panel testing 1 time per year BUT beside of EQ laboratory performs rechecking of all positive. It was suggested to stop rechecking of all positives as blinded rechecking proves quality of microscopy.

Laboratory has Internal Quality system elements and documentation. Also laboratory undergoes regular certification from state Center for Certification, Metrology and Standardization. This needs strengthening in form of training of staff and update of documents.

Overall laboratory work is very well organised and personnel seems dedicated to work they do and interested to improve.

Laboratory has database for DST result collection showing average MDR TB level in 2007 was ~20%.

Dnipropetrovsk Oblast TB Hospital

Dnipropetrovsk oblast with ~ 3, 5 mil. Population. There are ~2000-2500 new cases each year.

Laboratory serves Dnipropetrovsk Oblast. Workload --~16 000 smear microscopy/ year; 10 000 – 12 000 cultures/year with positivity.

Laboratory performs also clinical and biochemistry tests.

Laboratory is equipped with biosafety equipment – Biosafety Cabinets class II and use BSCs for all potential biohazard processes. For specimen treatment 2 PC-6 (Russia) centrifuges are used with NO anti aerosol covers and cooling. One centrifuge is fitted with rotor for 15ml tubes, other for 50 ml tubes. As above it would be very necessary to obtain centrifuges with proper biosafety covers, cooling and suitable for 50 ml tubes. Also yearly checking of BSCs for air flow speed and presence of particules inside is necessary.

Laboratory uses fluorescent microscopy (auramine staining) for specimens decontaminated for MGIT and Ziehl-Neelsen for other specimens.

There is BACTEC MGIT 960 liquid culture system in place. For this system specimens are decontaminated with MycoPrep (Becton Dickinson) reagents. At time of visit overgrowth rate in MGIT was 10%. It was suggested to change decontamination procedure by increasing initial percentage of NaOH to 6%. Also BACTEC machine is emitting humming sound and should be checked by Becton Dickinson representative.

For solid media inoculation specimen decontamination with 10% Na₂HPO₄ is used. This should be changed to Petroff or more suitably all specimens should undergo NALC-NaOH decontamination and centrifugation with at least 3000g.

2 tubes of solid media – one LJ and one Finn-II are inoculated. Overgrowth rate ~3.5%.

DST is performed using ready to use sets from India made by Tulip Diagnostics Ltd. And procured centrally. Kit includes tubes for Streptomycin, Isoniazide, Rifampicin, Ethambutol, However Internal Quality system elements exists in this laboratory but they are fragmented and does not seem that use of these elements are understood. This needs strengthening in form of correct documentation and training of staff.

Overall Laboratory work is very well organised and this laboratory is most optimal for becoming Laboratory for MDR TB Excellence Center because of administrative and financial support. This laboratory also could implement fast MDR TB using molecular methods like Line Probe Assay (GenoType MTBDRplus, Hain Lifescience) and in Dnipropetrovsk Oblast TB Hospital Laboratory personnel is capable to learn it if premises and equipment is made available.

Recommendations

1. To introduce detailed Quality Control (QC) and Quality Assurance (QA) manual into laboratories.
2. To obtain good reference strains are very important – at least *M.tuberculosis* H37Rv or similar.
3. To provide training for key personnel in Quality Assurance after Draft of Quality Assurance Manual or Instruction for Internal Quality Control procedures. This kind of training course could be organized on basis of Latvian National Reference Laboratory in February 2009 as 1 week training.
4. To introduce NALC-NaOH decontamination method in all 3 laboratories with providing proper centrifuges with bio-safety covers, relative centrifugation force at least 3000Xg and with cooling option at 8-10 °C. Low detection rate of TB by culture may be due, partly, to outdated decontamination and concentration techniques used in laboratories but good culture is basis for MDR TB case detection. Introduction of proper centrifugation would increase positivity rate of cultural and microscopy examinations.
5. To standardize drug susceptibility testing to one method and to one source of pure substances. This should be controlled by IQC with standard strain H37Rv. When one method is established, materials for this provided on regular basis to sustain it in long term and IQC is in place with good results, External Quality Assessment could be provided from Latvian National Reference Laboratory.
6. To recognize fact that good laboratory with quality assured DST is very important but also the smallest thing for excellent MDR TB treatment and management – changes in TB treatment policies and establishment of Infection Control principles into clinics is of the highest priority.

7. To find resource that could maintain and check most important equipment in the laboratories – BSCs, centrifuges, autoclaves etc.
8. To ensure biological material import and export permits with respective legislative system (customs, MoH, other?). Also question on principal recipient of should be discussed as if only Ukrainian National Reference Laboratory is made recipient it may be problematic for other laboratories to receive EQA panels. Best variant would be that any laboratory with established and recognized (by whom?) Biosafety level can receive biological materials and send them out.
9. To start *M.tuberculosis* strain collection and conservation into deep freeze freezers respective instruction should be provided. At least one strain from each TB case should be stored. Such collection in future can demonstrate effectiveness of treatment and infection control measures taken.
10. To improve data collection for drug resistance surveillance connection between laboratory and case registration unit should be established so that DST obtained for specimen at beginning of treatment can be identified and also unique patient identifications should be found.

Biosafety and Infection Control

There are overall low understanding of infectious nature of tuberculosis – tuberculosis is mainly transmissible via airborne particles and main Infectious Control (IC) principles are prevention of tuberculosis transmission.

To increase general understanding of IC principles for tuberculosis general training is needed for all levels of health care professionals – starting with high level management (head doctors, head nurses, representatives from MoH etc.) I would recommend ask for help in providing such training for Paul Jensen (e-mail: pej4@cdc.gov) who has vast experience in introducing IC measures in many countries with limited resources in health systems such as Russia, Peru, India, Vietnam.

He can also help with indications and technical specification for most important technical equipment for IC – UV lamps and respirators. Also it would be very good to find resources for initial procurements of proper UV lamps and organizing IC trainings. Help in organization of IC trainings also could be obtained from dr Andra Cirule (e-mail: Andra.Cirule@tuberculosis.lv), she is responsible for IC in Latvian State Agency for TB and give lectures on this topic at WHO Collaborating Center in Latvia.

This kind of education is very important also in light of future reconstruction of TB related buildings.

IC in Laboratories

This needs official recognition and instruction of minimal technical requirements (BSC, centrifuges and autoclave). This is an area of concern in all visited laboratories. Bio Safety Cabinets (BSC) class II have been installed. Still there is issue of proper installation and future maintenance.

Main (minimal) principles of safe working in TB laboratory are:

1. Specimens should be delivered in primary containers with screw caps, preferably made from plastic.
2. All actions involving specimen container or culture tube opening and manipulations with materials should be performed INSIDE working Bio Safety Cabinets (BSC) class I or II which have been properly installed and annually checked.
3. Centrifuges used for infectious specimens should be equipped with Protective BioAerosol covers.
4. All waste should be contained into waste containers placed inside BSC. Waste containers should be securely closed inside BSC and then moved out and autoclaved.
5. Room with BSC should be made with restricted access especially where work in it is performed.

All personnel should be trained in biosafety issues, including personal protection measures; Recommendations on biosafety principles based on international guidelines should be issued in country and accepted by Sanitary Epidemiological Units and MoH.

The issue of biosafety should be recognized by the MoH and the necessary budget line should be approved.

Human resources and training

During visit lack of human resources or lack of continuation of education for laboratory workers were recognized in all laboratories visited. This problem should be recognized in several levels – lack of human resources indicates low prestige and low reward that should be addressed in ministry level.

Continuation of education for laboratory workers should also be addressed at all levels by organizing trainings where important part should be motivation and recognition. At least one reporting conference would be good for all TB laboratory people to meet and exchange opinions.

Motivation of laboratory staff at PHC laboratories – it is important that they need keep up their proficiency in AFB microscopy because they serve their own neighbourhood and each undiagnosed pulmonary TB case can affect their own children or relatives.

Activities and sites visited by mission:

September 22, 2008	Arrival to Kiev Meeting in the office of PATH with O. Radzievska and T. Ivanenko
September 23, 2008	Visit to MOH "AIDS, TB and drug abuse committee" - V. Petrenko, O. Stelmah. Visit to Kiev City TB Hospital Meeting with Dr.N.B.Goncharenko, Head of Laboratory; Meetings in the PATH office Olena Radzievska, Tamara Ivanenko
September 24, 2008	Visit to Kharkiv Oblast TB Hospital Meeting with Dr Tatiana Sencheva Head doctor ,Dr. Kalmikova, Deputy director; Dr. M.F. Novohatskaja, Head of Microbiology Laboratory.
September 25, 2008	Visit to Dnipropetrovsk Oblast TB Hospital Meeting with Dr.Dmitriy Kryzhanovskiy, Head doctor; M.M. Fonareva Head of Laboratory;
September 26, 2008	Meetings in PATH office with representatives from TB laboratory at IFP MAC Ukraine: Prof A.Zurilo, Dr A. Barbova Final Discussion with PATH TB Team: Katya Gamazina, Olena Radzievska, Tamara Ivanenko



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FIRST YEAR

IN-COUNTRY MONITORING CHECKLIST

THE GLOBAL DRUG FACILITY

FIRST YEAR IN COUNTRY MONITORING CHECKLIST

All recipients of GDF in-kind grants of first-line tuberculosis drugs agree, as a condition of support, to: Regular assessments of program performance (including case finding & treatment outcomes), financing and drug management, to be carried out by an independent technical experts (Tuberculosis and Drug Management), with a complete assessment report provided to the GDF.

This check-list will form the basis of the assessment report on the performance of GDF grantees within the *first year* of support. Depending on a country's satisfactory adherence to terms and condition for support during the 1st year, the monitoring mission may give 'green light' for approval of 2nd year support. This report will be reviewed for completeness by an independent agent appointed by the GDF. In case the monitoring mission does not give 'green light' for approval of 2nd year grant, this check-list together with the desk audit report will be submitted to the Technical Review Committee, for review and decision.

Country Visited:	___Ukraine_____
Date:	From: January 21 to January 25, 2008
Data Collector(s) Name(s):	(1) <u>Andrey Zagorskiy</u> (2) <u>Archil Salakaia</u>
Data Collector(s) Signature(s):	(1) _____ (2) _____
Date report submitted to GDF Secretariat:	dd/mm/yyyy

Note: To determine the best source of information for different questions in this checklist, ask the NTP manager. If additional pages are needed for any section of this checklist please append to this document, clearly indicating the section number to which the additional page corresponds.

CONTENTS

- Main achievements and constraints/problems in the year of the monitoring visit
- National TB program management
- Financial management
- Port clearance
- Drug registration and quality
- Stock management
- TRC recommendations
- Recommendations from the pre-delivery visit
- Country request to GDF for next year
- Monitoring team decision for approval of 2nd year grant
- Monitoring team feedback
- Annex: GDF Terms and Conditions of support for 1st term Grant

Main NTP achievements and constraints since the last GDF visit /previous year

1. Main achievements :

- a) In 2007 National TB Programme 2007-2011 was approved as a Law by Ukrainian Parliament.
- b) The Ministry of Health of Ukraine Committee Against HIV/AIDS and other Socially Dangerous Diseases was established in 2007; the National Centre for Tuberculosis is a part of this Committee. Although the terms of references of these entities in regard of TB control in the country are not defined yet, the first steps to create a national coordinating body for TB control activities have been made.
- c) The focal person, Dr. Kirill Chasovski – a TB physician and senior specialist of the Committee has been identified as a focal point for communication with the GDF.
- d) The staff of the medical services of the penitentiary system is committed to use of FDC anti-TB drugs supplied by GDF;
- e) Consignee for the GDF drugs – “UkrVaccina” has skilled personnel, good storage facilities and the capacity to rapidly distribute medicines countrywide;
- f) Technical assistance to TB program is available through WHO/Ukraine and a USAID-funded project implemented by PATH;
- g) The government funding for the procurement of TB medicines is adequate for the needs; however, procurement is not transparent and prices are very high;
- h) Civil Society is widely represented among stakeholders of the TB control of Ukraine.

2. Main problems / constraints

- a) It is still a very weak program, with poor detection and treatment success rates, and low DOTS coverage
- b) Lack of the coordination of TB control
- c) There is no clear division of the responsibilities among stakeholders in the field;
- d) Although there are many diagnostic TB laboratories countywide, there is no laboratory system (NRL, quality control, supervision, HR development plan, etc)
- e) Direct Observation of Treatment (DOT) is not done in most of the country;
- f) The list of centrally procured TB medicines, especially second-line TB, includes drugs and unique drug formulations not recommended by WHO, and all fluorquinolones that may be used in TB treatment: drug selection does not seem to be rational and evidence based, and does not leave any medicines in reserve to treat XDR TB;
- g) Treatment guidelines for MDR TB are vague; there are, however, guidelines at the WHO pilot sites which were developed with technical assistance from WHO, but they are not used outside pilot sites;
- h) Reportedly, there were stock-outs in some facilities of first-line medicines during 2007 due to a combination of factors: the reserve stock is only 3 months, and it is not kept centrally; there is no mechanism to rapidly relocate medicines between different administrative territories (oblasts); the supply system utilizes a “push” distribution method.

National TB program management

3. DOTS population coverage¹ at the time of the monitoring mission: 29 %
4. Has the latest² annual WHO TB data collection form been submitted to WHO?

YES NO ;
 Date sent _____ sent by whom _____

5. Collect the latest four quarterly³ reports on case findings and treatment outcomes of the NTP in the DOTS implementing areas. Please provide comments on the data in these reports.

The mechanism for a centralized data collection is being developed by the National Centre of TB, and it is not yet fully functional. All oblasts do submit the data to the Centre, but not always in the timely manner, and the data sometimes are not accurate.

The data below were provided by the National Centre. The tables below contain data on case finding during the four quarters of the 2006, and treatment outcomes of the cohorts of the first three quarters of the same year.

So far not all TB cases were evaluated for the treatment outcomes, that is why there are differences in numbers of cases in the quarterly cohorts in the tables of case detections and treatment outcomes.

High proportion of the SS (-) cases may suggest indirectly that case detection is not good (due to problems with laboratory system organization and management), and the diagnosis is still widely based on the radiography.

Treatment success rate is low: varies between 59,9 - 62,8%.

Among Previously treated Pulmonary SS (+) cases only Relapses are included in registration. Knowing default rate (9,5 – 11,5 %) and treatment failure rate (12,5-13,6%) we can assume that the number of cases belonging to “treatment after interruption” and “treatment after failure” categories is quite substantial. But these figures are not reflected in the reports.

Table: CASE FINDING (reporting period: Q1 - 2006)

TB case category	Number	%
New Smear +ve Pulmonary TB	3185	40,7
New Smear -ve Pulmonary TB	4635	59,3
Extra-pulmonary TB	1115	12,5
Previously treated Pulmonary Smear + TB cases		
- Relapse	514	
- Treatment after interruption (Defaulters)		

¹ The percentage of population living in areas where health services have adopted the DOTS strategy. The units of population covered are usually the administrative units used for other purposes within country (e.g. districts, counties, oblasts), and the outcome is usually expressed as the percentage of the national population.

² Please specify case finding, sputum conversion and treatment outcome reporting periods

³ Please specify quarters for which reports were collected, analysed and reported in this checklist. Kindly forward the quarterly reports to the GDF secretariat with the monitoring checklist as these are an essential part of the monitoring mission report.

Annex 15

- Treatment failure		
Other cases		
Total	9449	

Table: TREATMENT OUTCOMES (reporting period : Q1-2006)

Treatment outcome new smear +ve cases	Number	%
Total number of smear + cases reported	2717	100
Total number and % of cases evaluated		
- Cure	1547	56,9
- Treatment Completed	134	5,0
- Died	289	10,6
- Treatment failure	359	13,2
- Default	261	9,6
- Transfer out	127	4,7
Treatment success rate: (cure + treatment completed)	1681	61,9

Table: CASE FINDING (reporting period: Q2 - 2006)

TB case category	Number	%
New Smear +ve Pulmonary TB	3984	45,8
New Smear -ve Pulmonary TB	4722	54,2
Extra-pulmonary TB	1212	12,2
Previously treated Pulmonary Smear + TB cases		
- Relapse	484	
- Treatment after interruption (Defaulters)		
- Treatment failure		
Other cases		
Total	10402	

Table: TREATMENT OUTCOMES (reporting period : Q2 - 2006)

Treatment outcome new smear +ve cases	Number	%
Total number of smear + cases reported	2990	100
Total number and % of cases evaluated		
- Cure	1680	56,2
- Treatment Completed	197	6,6
- Died	345	11,5
- Treatment failure	375	12,5
- Default	254	8,5
- Transfer out	139	4,7
Treatment success rate: (cure + treatment completed)	1877	62,8

Table: CASE FINDING (reporting period: Q3 - 2006)

TB case category	Number	%
New Smear +ve Pulmonary TB	3116	43,5
New Smear -ve Pulmonary TB	4052	56,5
Extra-pulmonary TB	906	11,2
Previously treated Pulmonary Smear + TB cases		
- Relapse	494	
- Treatment after interruption (Defaulters)		
- Treatment failure		
Other cases		
Total	8568	

Table: TREATMENT OUTCOMES (reporting period : Q3 - 2006)

Treatment outcome new smear +ve cases	Number	%
Total number of smear + cases reported	2612	100
Total number and % of cases evaluated		
- Cure	1372	52,5
- Treatment Completed	193	7,3
- Died	328	12,5
- Treatment failure	331	12,6
- Default	249	9,5
- Transfer out	148	5,6
Treatment success rate: (cure + treatment completed)	1565	59,9

Table: CASE FINDING (reporting period: Q4- 2006)

TB case category	Number	%
New Smear +ve Pulmonary TB	3679	43,2
New Smear -ve Pulmonary TB	4840	56,8
Extra-pulmonary TB	1236	12,7
Previously treated Pulmonary Smear + TB cases		
- Relapse	653	
- Treatment after interruption (Defaulters)		
- Treatment failure		
Other cases		
Total	10408	

6. **Is a recent independent assessment report by an NTP partner available?**

YES NO

If yes, what date and was the report collected? YES NO

- Report of a Joint Program Review of TB Control in Ukraine, Ministry of Health of Ukraine; National Institute of TB and Pulmonology; USAID; PATH; WHO; and Constella Futures Group; 13-24 February 2006
- WHO/Ukraine TB Report, December 2007
- WHO Country Office in Ukraine TB Control Programme Assessment of the laboratory network work in Ukraine 21- 25, May, 2007

(submitted as part of the GDF mission document package)

7. **What evidence is there that the drugs provided by the NTP are used only for TB patients?**

- At the time of the mission drugs were not being used. Drugs were distributed to two oblasts (Donetsk, Dnepropetrovsk), city Sevastopol and penitentiary system on December 18, 2007, but the permission to utilize these medicines was issued as a result of the mission only on January 22, 2008.

8. **What indications are there that TB drugs are provided free to TB patients?**

- According to the Ukrainian Law, TB medicines are free to patients

9. **What evidence is there that GDF drugs were only used in DOTS programmes in areas indicated in the application submitted to and approved by the GDF?**

- At the time of the GDF mission, according to the distribution documents obtained at the MOH the GDF medicines were distributed to the designated DOTS pilot oblasts:

Distribution of the GDF medicines to DOTS sites

Medicines	Number of packs				
	Donetsk	Dnepropetrovsk	Sevastopol	Penitentiary Department	Total
RHZE	891	1102	203	1004	3200
RHE	378	100	115	282	875
RH	6172	2357	255	2976	11760
HE	759	357	18	1116	2250
H	244	0	6	0	250
Z	2333	1958	46	1488	5825
E	880	357	0	2873	4110
S	2096	1990	120	3400	7606
Water	1049	996	60	1700	3805
Syringes	1049	996	60	1700	3805

10. **Does the NTP follow WHO recommended treatment regimens including drug dosage (i.e. no. of tables for different weight bands as per WHO recommendations) in areas where GDF drugs are being used.**

YES NO

If no, please explain how the regimens and/or dosage are different:

- The treatment regimens used in DOTS pilot areas are based on 60 days intensive phase (extendable to 90 days in certain cases) and 120 days continuation phase (extendable to 150 days); some drug doses are higher than recommended by WHO. These treatment regimens have been developed with the technical assistance from WHO/Ukraine.

Financial management

11. **Is there any evidence that GDF grant has displaced resources that would otherwise have been available from the government or other donors?**

- No. For 2008, the budget has been approved. The GDF medicines have not been taken into account when the budget was developed in mid-2007. The MOH will now make adjustments to use extra funds (those freed by the GDF medicines) for procurement of other TB commodities

Provide the following indicators:

- **Proportion of total financial requirements for DOTS implementation/expansion available:**
 - There is no separate budget for DOTS implementation and expansion. TB program is funded from both central sources (medicines, some diagnostics, TB program management at central level) and local government budgets (facilities, salaries, construction, maintenance, etc). The MOH claims that the available funding is adequate for TB program needs including DOTS expansion.

- Indicate the proportion of TB funding from government vs. other sources using the following table:

Table 3: PROPORTION OF TB FUNDING FROM GOVERNMENT VS. OTHER SOURCES

Budget/Expenditure (Expenditure for last year, budget for current and next year)		Last year: Year 2007		Current year: Year <u>2008</u>		Next year: Year _____	
		Amount In US \$	%	Amount In US \$	%	Amount In US \$	%
A. Total TB budget from national government (non-donor funds & interest-bearing loans)*	Drugs	20 000 000	52	24,330,000 (plus 6,000,000 for diagnostic commodities)			
	Other	19 603 960 (to re-equip TB facilities, and for capital construction – will go into 2008)	48				
B. Total TB budget from donors (Specify name of donor(s) beside amount)	Loans (non-interest bearing)	Drugs					
		Other	33 837 689 (WB) (the loan was suspended)	100			
	Grants (in-kind)	Drugs					
		Other	1 300 000 (USAID) 3 660 836 (CF Development of Ukraine)	100	2 250 000 (USAID) 1 602 329 (CF Development of Ukraine)	100	2 250 000 (USAID) 1 491 141 (CF Development of Ukraine)
C. GDF grant (equivalent \$) – the value has not yet been assigned by the MOH							
D. Total TB budget from other sources (specify)	Drugs						
	Other						
E. Total TB budget (A + B + C + D)	Drugs	20,000,000		24,330,000**			
	Other						

* The national TB budget is only for the procurement of medicines, some diagnostic reagents, and sometimes equipment (as in 2007). Other national level expenditures on TB are within overall budget for national health programs, and cannot be singled out. The actual TB program expenditures are covered by local governments; research is covered through the Academy of Sciences, no information on funding level was obtained

** GDF drugs not included. Information on the value of the supplied GDF drugs must be available at the GDF

Partners/Donors

12. Please list the NGO/Partners/Donors involved in TB control activities in the country.

NGO/Partners/Donors	Main area(s) of Collaboration with NTP
USAID	Technical assistance
World Bank	Financial support
WHO	Technical assistance
PATH	Technical assistance
Ukrainians Against TB_	Lobbying TB issues in Parliament
Coalition of HIV/AIDS Service Organizations groups	Working with HIV/TB groups and vulnerable
Ukrainian Federation of Red Cross	Working with vulnerable groups
CF "Development of Ukraine"	Financial support/ ACSM campaign
Constella Futures	Technical assistance

Port clearance

13. Report the port clearance time for the last GDF drug shipment:

Date GDF shipment arrived in port in August and September (the exact dates were not obtained*)

(-) Date drugs moved to warehouse, ready for distribution in-country: November 15 and 17, and December 15, 2007 (distributed to oblasts by December 18, 2007)

(=) Number of days to clear port. **3 – 4 months**

Reasons for the delays, as explained by UkrVaccine included:

- Documents from manufacturers that are required for importation were not received in time.
- There were more shipments than documents stated
- Svizera submitted wrong documents (name of the consignee was wrong), and it took them too long to fix this (Lupin and Cadila docs were OK)
- Three of the shipped products were not registered in Ukraine: water and S from Svizera, and Z from Cadila; Cadila refused to register its Z (was not interested in the market) but sent the required documents; Svizera never responded. UkrVaccine waited for a long time for responses before taking action on obtaining a one-time permit for importation from the MOH.
- Boxes did not come on pallets, and boxes with drugs that belonged to different batches were all mixed up; additional time and money were required to sort that out.
- Boxes were not labelled properly: they were not marked with "Humanitarian Aid. Free of Charge". All markings were in English only, not Russian or Ukrainian
- The weight of the shipments in the waybill was different from actual (500 kg more than stated in documents);
- Boxes were not on pallets, all lots mixed up, and it took time to match quantities of each lot to the documents

UkrVaccine also complained about the choice of Maersk-Ukraine as a logistics company (slow, subcontracted local organizations that were not performing) and GTZ as procurement agent (was not responding to requests for correct documents).

UkrVaccine suggested that ports other than Odessa be used for next shipments, e.g. Herson or Nikolaev (sea ports) or best – Kiev (air port), where drugs could be cleared while stored at the UkrVaccine premises, not at customs warehouses which are not equipped for storing pharmaceuticals.

See the Recommendations section for exact requirements

The logistics from the port of entry to Kiev was done by Maersk-Ukraine and it's agents; the GDF mission met only with the consignee, UkrVaccine, that does further distribution.

Future GDF missions may need to meet with Maersk-Ukraine

14. Is there evidence that the government took full responsibility for any import duties and taxes levied on drugs supplied by the GDF?

YES NO

Please explain your answer:

- All import duties and other taxes were paid by the MOH

Drug registration and quality

15. Did all the drugs provided by the GDF meet all national drug registration requirements? YES NO ; If no, please explain.

There is an official MOH document that describes requirements for full drug registration or importation of un-registered products as humanitarian aid (MOH Order #143 of May 15, 1997; amendments: July 22, 1999 #174, and January 17, 2002). The document is attached.

Lupin had its products registered in Ukraine for marketing, so there were no problems. There were problems with pyrazinamide from Cadila and streptomycin and water from Svizera.

The requirements for documentation to import medicines:

For all registered products:

- a letter from WHO stating that this a grant from WHO
- invoices, waybills, packing lists in Ukrainian (or Russian) (with exact description of dosage forms, and number of units packed)
- Certificated of origin for each product
- Analytic batch certificates

Additionally for products not registered in Ukraine, at the time of the mission Svizera's streptomycin and water, and pyrazinamide were not registered in Ukraine (all translated into Ukrainian or Russian):

- Certificate of a pharmaceutical product
- Statement of registration in the country of manufacture (licensing status)
- Free sale certificate (product can be sold in the country of manufacture)
- Instructions for use
- Statement that a product is used for the indication in the country of manufacture

All boxes must be clearly marked (in Ukrainian or Russian) – “Humanitarian Aid. Free of Charge. Not for Sale”

16. Does the government carry out quality control on drugs used in the NTP?

YES NO

If YES, please provide a brief description. Please indicate the name and number of drugs (and the manufacturers) that failed quality control testing out of the total number of drugs tested:

TB drugs are procured centrally by the MOH. All procured drugs are registered in the country, and have been tested during the registration process. Domestically manufactured medicines do not undergo any further quality control. All imported drugs are tested by the national drug quality lab (every imported batch). Some domestic manufacturers have already obtained the GMP certification from WHO or local GMP inspectors; by the Government decree, all pharmaceutical manufacturing must comply with the GMP standards by January 1, 2009.

Interviewed doctors complain about the quality of medicines procured by the MOH, but these complaints have never been documented and reported officially. There is thus no proof or evidence that TB medicines used by the TB program are of substandard quality.

The GDF medicines were tested by the national lab, and received permission to be used by the TB program. This was done in timely manner according to the MOH, and the government took care of the costs.

In - country TB drug manufacturing

17. Are any anti TB drugs being manufactured in the country

YES NO

If yes, please fill in the following table

Table 4. In-country TB drug manufacturing

TB Drug	Strength (mg)	Loose/Blister	Cost per unit ⁴ US\$**	Name of the Manufacturer
Isoniazid	0.3g		0.0116	Darnytsya
Isoniazid	0.2g			Lugansky Chemical Enterprise
Isoniazid	0.1g		0.0007	Lugansky Chemical Enterprise
Isoniazid	0,3g		0.0116	Borschagivsky Chemical Enterprise
Isoniazid 10%	5 ml		0.1306	Darnytsya; Yuria Pharm;
Rifampicin	0.15g		0.0316	Darnytsya
Rifampicin	0.15g			Borschagivsky Chemical Enterprise
Rifabutin	150 mg			Darnytsya
Rifabutin	150 mg			LvivTechnipharm
Rifapentine	150		2.574	LvivTechnipharm
Pyrazinamide	0.5g		0.0316	Darnytsya
Pyrazinamide	0.5g			Borschagivsky Chemical Enterprise
Pyrazinamide	0.5g			Lugansky Chemical Enterprise

⁴ Cost of TB drugs per unit (e.g. 100 tables) in US \$

Pyrazinamide	0.5g			Odessa, Biostimilyator
Ethambutol	0.4g		0.0316	Odessa, Biostimilyator
Ethambutol	400, 200 mg			Borschagivsky Chemical Enterprise
Ethambutol	400			Lugansky Chemical Enterprise
Ethambutol	400			Odessa Biostimulator
Ethambutol	400			Darnytsya
Streptomycin	0.5g	amp	0.1386	KyivMedpreparat
Ethionamide	250			LvivTechnipharm
Prothionamide	250		0.172	LvivTechnipharm
Capreomycin	1 g		23.76	Avant, Kiev

**** Prices are actual from 2007 national tender; prices are not manufacturer-specific as it's not known which suppliers won the tender.**

18. **Has the monitoring mission team briefed the following on the pre-qualification process for inclusion in the GDF white list of manufacturers?**
MoH NTP TB drug Manufacturers

Please detail any follow up steps and/or provide additional comments:

Only one manufacturer – Borschagovski – was briefed; the other three that manufacture TB drugs were not interested. Borschagovski is currently in the process of prequalifying its ethambutol through the WHO process, and is interested in prequalifying other medicines. However, FDCs are not manufactured in Ukraine.

Stock Management

19. **Were any TB drugs out of stock⁵ in MOH national stores, warehouses, health facilities since the GDF grant started? YES NO**

At the time of the mission, the TB program has not yet started utilizing the GDF drugs. Anecdotally, there have been some brief shortages of first-line medicines, and more pronounced shortages of second-line medicines. Non happened in the DOTS pilots (where the GDF drugs will be used). It was not possible to collect hard data on shortages as the MOH does not collect these data (or was reluctant to share with the GDF mission)

**If YES, indicate the average number of days they were out of stock _____
Please provide additional details:**

⁵ Time out of stock, or stock-out time, is defined as the number of days that a product was not present in a warehouse or health facility over a recent 12-month period (usually the 12 months preceding the one during which the monitoring takes place). To be considered a stock-out, there must have been none of an unexpired drug in stock. If even small quantities of an unexpired drug were present, the drug should be counted as in stock. Percentage of time out of stock is defined as the percentage of days during a 12-month period that a drug has been out of stock (based on inventory records).

20. What stock management tool/process is used for TB Drugs ?

Health facilities use log books to keep records of the stock. The most accurate information, however, can be found in financial records, because medicines are centrally procured and their expenditure is strictly audited by fiscal organizations. The newly established MOH Committee on AIDS and other Social Diseases currently does not collect the pipeline data; it seems that it never occurred to the Committee that such data may be needed for making managerial decisions. Previously, pipeline data were collected by a TB department of the MOH which does not exist now.

21. Did you find any expired TB drugs in the MOH national stores at the time of your visit?

YES NO

If YES, percentage of TB drugs that were expired _____

Date visited _____

Show your calculation:

22. Indicate the value and quantity of any pending TB drug deliveries from all sources, by source (donor, government procurement e.t.c) expected to be received in-country over the next 6 months.

Table 5: Value and quantity of any pending TB drug deliveries from all sources (planned 2008 procurement; medicines will be procured in March 2008; values are projected by MOH based on previous procurement)

Drug	Source*	Quantity	Value \$\$**	Expected delivery date***
INH 300	MOH	19,191,491	224,217	June-July
INH 100		10,470,825	76,717	
INH syrup, 200 ml		12,861	76,400	
INH 10% 5 ml		1,068,875	139,694	
Rifampicin 150		46,913,774	1,486,377	
Rifapentin 150		966,658	2,488,426	
Pyrazinamide 500		33,647,014	1,066,043	
Ethambutol 400		27,859,150	882,666	
Streptomycin 1g		2,225,934	312,703	
HRZE 300/600/1600/1100 (sachet, dispersible)		1,425,450	1,411,336	
Kanamycin		912,693	289,170	
Amikacin		310,424	461,025	
Prothionamide		3,917,500	674,896	
Ofloxacin		294,607	729,225	
Moxifloxacin		26,429	1,570,040	
Gemifloxacin		228,460	1,492,906	
Gatifloxacin		71,274	1,114,979	
Sparfloxacin		455,260	540,902	
PASA + INH (800 mg/23.3 mg)		795,000	425,050	
PASA (3% 400 ml)		175,945	871,015	
PASA 1 gr		4,052,380	1,524,660	
Cycloserine		314,476	996,360	
Capreomycin		93,605	2,224,277	
Clofazimine		625,153	371,378	

* Will be procured centrally by MOH

** Exchange rate used: \$1 = 5.05 UAHr

*** June-July

TB medicines are procured centrally by the MOH, and that is the only source of TB medicines. Medicines procured in 2007 have been delivered to the facilities, there are no pending deliveries. The 2008 procurement will be conducted in March-April.

The GDF medicines have been delivered to oblasts and penitentiary system.
 The GDF medicines are not included in the table above; the MOH will adjust the 2008 quantities to factor in the GDF medicines.

Technical review committee (TRC) recommendations

23. Did TRC make recommendations for follow up at the time of application approval:
 YES NO

If YES, write below the recommendations made by the TRC and the progress/expectations made by the NTP/government for fulfilling them. If no progress has been made on a specific recommendation, indicate what the NTP/government plans are to fulfil that obligation.

Table 6: TRC recommendations at the time of application approval and action taken

- TRC recommendations have been addressed by the pre-delivery mission to Ukraine in November 2005 (see the mission report)

Recommendation	Action Taken & Results

Recommendations from the pre-delivery country briefing mission

24. **Please review the recommendations made during the pre-delivery country briefing mission, using the mission report attachment to this checklist; write below the recommendations and the progress/expectations made by the NTP/government for fulfilling them. If no progress has been made on a specific recommendation, indicate what the NTP/government plans are to fulfil that obligation.**

Table 7: Pre-delivery country briefing mission recommendations and action taken

Recommendation	Action Taken & Results
Finalize a review of Prikaz #45 and revise, or develop a separate order for DOTS regions and the Penitentiary system, in order to allow full adherence to DOTS principles in the DOTS implementing regions.	Law of Ukraine “On the National TB Control Program 2007-2011” was approved in which the main elements of the DOTS strategy are reflected
Establish a monitoring procedure for the distribution of GDF drugs to ensure that they are only used in the regions implementing DOTS (Donetsk, Dnipropetrovsk, Sevastopol and the Penitentiary system)	Drugs were distributed only to Donetsk and Dnepropetrovsk oblasts, Sevastopol City and penitentiary system. There are no plans to distribute GDF rugs to other regions.
Distribute GDF drugs to oblast level upon delivery to Ukraine according to quantification estimates made during pre-delivery visit and include six moth buffer.	“UkrVaccina” has distributed the medicines according to initial quantification.
Store the remaining six months buffer stock at “UkrVaccina” so to be able to respond on unexpected increased demand from DOTS regions.	Buffer stock is not kept at “UkrVaccina”; there must be a special decision made by MOH, supported by additional funding for storage. The 2008 GDF mission reinforced this recommendation.
Oblast level to hold GDF drugs and distribute on the regular basis (quarterly) to health facilities according to new (to be designed and introduced) resupply/ordering procedures.	Drugs were not distributed to the health facilities at the time of the mission. This will be done on the basis of the established regular drug distribution, no new procedures for ordering and distribution were developed.
Establish a budget for the costs associated with the importation of the GDF drugs – clearance, customs and transfer to central storage.	There were no financial constrains to import and distribute drugs. “UkrVaccina” had sufficient budget to cover expenses related to drug importation and distribution.

GDF grant request for 2nd year (if applicable)

At the time of the mission in the end of January 2008, the GDF medicines were distributed to the sites, but the actual utilization was only planned to start in Q2 of 2008.

Because of the time it took for the agreement with the GDF to be signed and orders placed, and because there have been several changes of the Ministers of Health and reorganizations, the institutional memory of the arrangements with the GDF had been lost.

The GDF mission team had thus to explain to the new management of national TB program terms and conditions of the GDF support, and the benefits of introducing the GDF medicines into the program.

At the time of the mission, the Penitentiary Department Medical Services expressed strong interest in receiving the GDF medicines for the whole prison system – because the state budget for medicines for prisons is very low, and because FDCs are the most suitable dosage forms for prisons. It was not possible, however, to quantify the needs for 2009 as it was not clear at the time of the mission what volumes of medicines would be procured in 2008 (procurement was under way).

Oblasts will start using the GDF medicines in Q2 of 2008, and will then make a decision on the continuation of the grant. Oblasts want to first see how well the GDF medicines (FDCs) would fit into the program.

It was thus decided with the MOH that the final decision re continuation of the GDF grant would be made no later than June 2008. At that point, if the MOH would decide to continue, needs quantification for oblasts would be made and sent to the GDF. Technical assistance for the quantification exercise would be provided through a USAID-support TB program implemented in Ukraine by PATH.

25. Estimates of patients to be treated with GDF drugs. Year: _____
Date drugs required (without using buffer stocks): _____

Treatment Category	Regimen	A	B
		Total number of cases NTP expects to treat under DOTS using drugs from ALL SOURCES	Total number of cases NTP expects to treat under DOTS using drugs SUPPLIED BY GDF
1			
2			
3			
Buffer Stock required for cases under column B: YES <input type="checkbox"/> NO <input type="checkbox"/>		If YES indicate percentage here: %**	

** Kindly provide % of buffer stock in the space provided only, do not include buffer stock calculation for any treatment category under column B. The GDF secretariat will calculate the amount of buffer for each treatment category according to the % figure provided in the above table.

26. Calculation of drug needs and stock levels

Table 8: Drug requirement and stock level

Drug	(A) Drug needs for 1 year	(B) Buffer Stock needed %	(C) Drug needs until next delivery	(D) Current stock (at the time of the GDF visit)	(E) Pending ⁶ deliveries (GDF + non GDF)	(A+B+C-D-E) Total GDF drug order
RHZE 150/75/400/275						
RHE 150/75/275						
RH 150/75						
RH 150/150						
EH 400/150						
Z400						
E400						
H300						
S 1 g						
Water for injection						
Hypodermic Syringe (AD)*						

* 5ml automatic disabling feature after 2nd cycle, disposable, sterile with 21Gx1.5" needle, 100/bx

Table 9: Drug needs (formulation and strength), type of packaging and cost

Drug	Requirement	Type of packaging	# of units	Cost
Kits Cat. 1&3				
Kits Cat. 2				
RHZE 150/75/400/275				
RHE150/75/275				
RH150/75				
RH150/150				
EH400/150				
Z400				
E400				
H300				
S 1 g				
Water for injection				
Hypodermic Syringe (AD)*				

* 5ml automatic disabling feature after 2nd cycle, disposable, sterile with 21Gx1.5" needle, 100/bx

⁶ If the supply of drugs from any source is assured with absolute certainty within the next 2 months, the quantity of this supply should be added to the current stocks column D.

27. The GDF monitoring mission decision for Green Light (approval) for 2nd year GDF grant

27.1 Adherence to GDF Terms and conditions

27.1.1 National TB program management
YES FULLY YES PARTIALLY NO UNKNOWN

27.1.2 Financial management
YES FULLY YES PARTIALLY NO UNKNOWN

27.1.3 Port clearance
YES FULLY YES PARTIALLY NO UNKNOWN

27.1.4 Drug registration and quality
YES FULLY YES PARTIALLY NO UNKNOWN

27.1.5 Stock management
YES FULLY YES PARTIALLY NO UNKNOWN

27.2 Adherence to recommendations made by the pre delivery country mission
YES NO

27.3 Adherence to TRC recommendations made at the application approval time
YES NO

Based on above the 1st year monitoring mission recommends

Green Light (approved and no need for TRC review)**

To be reviewed by TRC
(Please explain reasons for the TRC review/decision)

The monitoring mission recommendation is to approve the second year of grand supply. The rationale: GDF is the only source of WHO compliant FDCs in Ukraine, and the mere presence of the GDF products is likely to change the mindset of physicians. The grant is also leverage for StopTB to put pressure on Ukrainian TB program and promote proper reporting.

It should be noted, however, that the final decision on the continuation of the grant for the civil sector (Donetsk, Dnepropetrovsk oblast, and the City of Sevastopol) will be made by the recipient in June 2008.

The Penitentiary Department, on the other hand, firmly requested the continuation of the GDF grant, and is asking the GDF to increase its support to cover all drug needs of the penitentiary system.

In this situation the GDF Secretariat may want the final decision to be made by the TRC.

28. Monitoring mission main recommendations

Please list below the main recommendations from this monitoring mission to the MOH/NTP, Donors/Partners, GDF and Others. The recommendations should be prioritized and time bound. Please list them in numerical order ("1" as the most important) and indicate the quarter (**Q1**: January - March, **Q2**: April - June, **Q3**: July -September, or **Q4**:October- December) and year when *each* recommendation should be implemented.

MOH/NTP

Recommendation	Due date	Person responsible
Quantification of needs for 2009 and placement of order: <ul style="list-style-type: none"> ○ Collect pipeline data (as soon as it's known what and how many drugs have been procured for each of the recipient oblasts) ○ Using average monthly consumption establish when the stock must be replenished; take into account buffer stocks (must clarify with the MOH and MoF re allowable volumes of the buffer – 3 months or one year) ○ Adjust to national budget and procurement cycles ○ Establish the date when the GDF drugs will be needed ○ Take into account the GDF lead time – 6 months average, plus 2 months extra for customs clearance, Pharmaceutical Committee quality control, and distribution 	End of Q2 (June 2008)	MOH Committee for AIDS and Other Socialy Significant Diseases, Dr. Kirill Chasovski kirill@moz.gov.ua
Establish a mechanism for regular reporting of medicines pipeline and stock levels	Q2	MOH Committee for AIDS and Other Socialy Significant Diseases, Dr. Kirill Chasovski kirill@moz.gov.ua
Develop a policy for building a buffer stock of TB medicines, and keeping it at the central level (UkrVaccine?)	Q4	MOH Committee for AIDS and Other Socialy Significant Diseases,
<i>Other recommendations made by the mission, but not directly related to the GDF medicines (this is just for the information of future GDF mission to Ukraine):</i>		
Draft a policy for procurement from international sources – like GLC, GDF, etc., and present to the MOH and the government		
Develop TEF for the National TB Centre, clearly		

define its role (as a National Centre responsible for all programmatic, management issues and coordination of TB control in UA), and divide responsibilities with Committee on HIV		
Develop and implement MIS for TB (patient register, lab management system, monitoring drug supply)		
Quantify financial needs and existing gaps for program management and laboratories		
Limit and optimize the number of medicines for TB by levels of the health system, especially second-line (currently all possible SLDs are being used, which may lead to super resistance because of lack of drug utilization control and enforcement of regimens) – one way is through the development of a National Formulary of TB commodities		
Promote and disseminate Protocols for Diagnosis and Treatment of MDR TB developed by WHO for Donetsk pilot in 2006		

Donors/Partners

Recommendation	Due date	Person responsible
Provide TA assistance to develop TOR for the National Centre of TB, calculate and lobby a budget needed for effective functioning of the Centre as a coordinating body for TB control activities.	Q2	PATH Dr. E. Gamazina
Provide technical assistance to establish MIS for TB (patient register, lab management system, monitoring drug supply)	Q2	MSH J. Keravec
Provide TA assistance to develop a master plan to organize a laboratory system and then to implement it	Q4	WHO/Kiev
Support the local authorities to organize trainings for the TB doctors in use of FDC anti-TB drugs	Q4	WHO, PATH

GDF

Recommendation	Due date	Person responsible
Follow-up with the MOH re the 2009 supply and quantification of needs; contact person: Dr. Kirill Chasovski kirill@moz.gov.ua	June 1, 2008	
Make sure that the GDF suppliers send all documents required for the importation to the consignee UkrVaccina at once 40 days ahead of shipments arrival:		

Annex 15

<p>For all registered products:</p> <ul style="list-style-type: none"> - a letter from WHO stating that this a grant from WHO - invoices, waybills, packing lists in <u>Ukrainian (or Russian)</u> (with exact description of dosage forms, and number of units packed) - Certificated of origin for each product - Analytic batch certificates <p>Additionally for products not registered in Ukraine, at the time of the mission Svizera’s streptomycin and water, and pyrazinamide were not registered in Ukraine (<u>all translated into Ukrainian or Russian</u>):</p> <ul style="list-style-type: none"> - Certificate of a pharmaceutical product - Statement of registration in the country of manufacture (licensing status) - Free sale certificate (product can be sold in the country of manufacture) - Instructions for use - Statement that a product is used for the indication in the country of manufacture <p>All boxes must be clearly marked (<u>in Ukrainian or Russian</u>) – “Humanitarian Aid. Free of Charge. Not for Sale”</p> <p>Boxes must arrive on pallets, and boxes with drugs that belong to different batches should not be mixed on one pallet</p>		
<p>Requests from MOH and consignee</p>		
<ul style="list-style-type: none"> • If possible, change the port of entry from Odessa to Herson or Nikolaev (if by sea), or – best of all – Kiev by air; that way customs clearance will be much faster; • The GDF uses services of Maersk-Ukraine for logistics; Maersk-Ukraine had sourced out the contract to two local subcontractors who are very inefficient; this must be changed. 		

Others (please specify)

Recommendation	Due date (e.g. Q2/06)	Person responsible

Feedback to the GDF

The independent consultant collecting these data will provide the following information as feedback to the GDF. The GDF will use the information to modify the data collection tool for future monitoring.

If you had difficulty collecting data for a particular item above, indicate the item below and the reason. From the possible *reasons* given below, choose the one most appropriate or indicate a different one in the space provided

Problem: Financial data were not readily available **Reason:**_____

Problem:_____ **Reason:**_____

Problem:_____ **Reason:**_____

Reasons:

- A. Data not made available to you
- B. Data not easily retrievable
- C. Question not clear
- D. Other, indicate: _____
- E. Other, indicate: _____

Annex 1.

Report distribution list:

1. Director TBP
2. Director STB (high burden countries only)
3. Operations Manager, GDF
4. Co-ordinator TBS (high burden countries only)
5. Regional Focal Point STB
6. Regional Director/Regional Advisor
7. WR
8. NTP Manager
9. All In - country TB Partners (NGO/Donors)
10. GFATM Portfolio Manager
11. Registry
12. DAP Co-ordinator, EDM
13. PAR Co-ordinator, EDM
14. Co-travellers

(Distribution of the report is responsibility of GDF secretariat however mission members have to specify the names and titles for country level officials i.e. from 7 to 9. Kindly indicate to the extent possible the respective **email addresses where relevant.)**

Report distribution Country level officials list:

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Dr. Ekaterina Gamazina - Ukraine Country Program Director, PATH
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Annex :

GDF TERMS AND CONDITIONS OF SUPPORT FOR FIRST-TERM GRANTS

The terms and conditions of GDF support are the following:

1. **All drugs supplied by the Global TB Drug Facility (GDF) will ONLY be used:**
 - a. for treatment of TB patients;
 - b. free of charge to patients;
 - c. in treatment regimens following WHO guidelines;
 - d. in programmes following national guidelines for DOTS implementation;
 - e. in accordance with a multi-year plan for DOTS expansion and sustainability to reach the global targets for TB control.
2. **The applicant is responsible for the drugs beyond the agreed point of delivery.** The applicant will arrange for the payment or waiver of any import duty or tax, storage fees or insurance levied on drugs supplied by GDF in a timely fashion so that the drugs are released from customs and supplied for programmatic needs as required. The applicant is responsible for the in-country distribution and monitoring of drugs provided by GDF.
3. **Where registration is required,** GDF drugs will be expeditiously registered and the applicant will facilitate this process, so that drugs are released from registration and supplied for programmatic needs as required.
4. **For purposes of in-country registration by the National Drug Authority** (where applicable) of the anti-TB drugs to be supplied by GDF, the following actions are necessary:
 - The NTP is required to provide GDF with the contact details of the persons at the National Drug Authority and the NTP/Ministry of Health responsible for drug registration in country. This information will be provided to our suppliers.
 - A copy of the Guidelines for Submission to the National Drug Authority, along with an indication of the time required for registration should be provided to GDF for the suppliers; Further, it should be indicated whether it is possible to obtain a waiver to registration or if a fast-track mechanism for dossiers exists in country. If so, the terms or conditions under which either of these provisions could be exercised should be provided to GDF to be shared with suppliers.
 - Suppliers will submit dossiers (where possible) in accordance with the Guidelines provided. The National Drug Authority should review the documents and inform the suppliers if they are sufficient for the purposes of registering all anti-TB drugs to be shipped. If all requirements are not met, the suppliers should be informed of any additional documentation that is required.
 - Where necessary, additional registration documents will be sent by the suppliers.
 - The NTP should indicate to GDF whether it is possible to ship and import the products while the registration process is ongoing.
5. **Regular assessments of the NTP performance,** including anti-TB drug management, will be carried out by an independent technical agency, and the complete assessment report provided to GDF. The applicant will also provide the following reports to the Stop TB Partnership secretariat:
 - a. a regular annual report on TB programme performance in accordance with WHO guidelines;
 - b. quarterly reports on case finding, smear conversion and treatment outcomes;

- c. date of arrival of GDF drugs at port;
 - d. time taken to register drugs (if applicable); and
 - e. date drugs received in central drugs store.
6. **Proven sustained political commitment:**
- a. Where a budget line or earmarked public sector funds for anti-TB drugs do not exist, Government beneficiaries must establish a multi-year budget line for anti-TB drugs or earmark multi-year public sector funds for anti-TB drugs with annual increases in dedicated funds and furthermore demonstrate expenditure of the dedicated funds during the period of GDF support.
 - b. Where a budget line or earmarked public sector funds for anti-TB drugs do exist, Government beneficiaries must make annual increases in dedicated funds for anti-TB drugs and demonstrate expenditure of the dedicated funds during the period of GDF support.
7. **Additionality:** Government beneficiaries must provide annually to the GDF, evidence that GDF anti-TB drugs and/or related supplies are additional to what would have been provided by the recipient government, other donors and agencies (including non-governmental organizations) in the absence of the GDF Grant. To this end, the evidence will include, but not be limited to, the following:
- a. Baseline data with respect to the annual number of courses of treatment being provided by all non-GDF sources – national government and other donors – during the year prior to the arrival of GDF-supplied drugs in the country;
 - b. The annual number of courses of treatment being provided by all non-GDF sources – national government and other donors – following the arrival of GDF supplied drugs in the country.
 - c. Where this information does not exist, and where the Government has exhausted all reasonable avenues in its efforts to obtain this information, the Government will provide estimates supported by the empirical evidence used to arrive at these estimates.
8. **Co-financing and technical cooperation** are available from other governments/donors for non-drug aspects of the multi-year plan (including DOTS expansion).

TB MIS in Ukraine
March 17th to 21st: Trip Report

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March 2008



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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

During this visit, an evaluation of the context and conditions was conducted with the MOH, Committee on HIV/AIDS and other Socially Dangerous Diseases Control and main stakeholders for the potential implementation of an electronic TB MIS, which was initially developed for MDR TB and implemented in a number of countries by RPM Plus during 2004 - 2008. A working group of all stakeholders involved in the program was created, activities defined and a matrix of responsibilities agreed among all counterparts and donors for the process of design and implementation of this MIS.

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Key Words

Tuberculosis, TB, MDR-TB, DMIS, First and Second-line Drugs Management, GLC

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ACRONYMS

DMIS	Drug Management Information System
DOTS	WHO TB Control Strategy
DOTS Plus	DOTS strategy for MDR-TB
DST	Drug Sensitivity Test
E&E	Bureau for Europe and Eurasia [USAID]
IPP	Institute of Phthisiology and Pulmonology,
FDC	Fixed Dose Combination
FY	Fiscal Year
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
GLC	Green Light Committee (WHO)
MDR-TB	Multi-Drug Resistant Tuberculosis
MOH	Ministry of Health
MSH	Management Sciences for Health
NTP or NTCP	National Tuberculosis Control Program
PATH	Program for Appropriate Technology in Health
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
TA	Technical Assistance
TB	Tuberculosis
SPS	Strengthening Pharmaceutical Systems Program
USAID	U.S. Agency for International Development
WHO	World Health Organization
WG	Working Group

BACKGROUND

By definition, Multi-Drug Resistant Tuberculosis (MDR-TB) patients have developed resistance to at least isoniazid and rifampicin, currently the most powerful anti-TB medicines. The number of MDR-TB cases in many parts of the world is increasing due to poor treatment, noncompliance of patients, and poor access to pharmaceuticals. Moreover, the growing incidence of HIV/AIDS is expected to further impact the increasing number of MDR-TB patients. If MDR-TB continues to spread, treatment costs will increase, additional global health resources will be required to combat TB, and patients will suffer for longer periods, or worse, die.

To confront this growing public health menace, the World Health Organization (WHO) and its partners have established the DOTS Plus strategy, which provides technical support to countries and regions to build on existing DOTS programs (for primary TB). The WHO DOTS Plus strategy provides technical support through the Green Light Committee (GLC) and concessionary prices for second-line medicines needed to treat MDR-TB. Medicines to treat one MDR-TB patient can cost upwards of US\$ 10,000 or more per treatment if purchased on the open market. By purchasing through the GLC procurement agent, a country program can reduce costs to as little as US\$ 2,000 per patient.

Management Sciences for Health (MSH) and its Rational Pharmaceutical Management Plus Program (RPM Plus) are partners with the WHO Stop TB program and the GLC. One of the RPM Plus streams of activities is to provide support in pharmaceutical management of MDR-TB medicines in collaboration with the GLC and its partners. Financial support is provided by the U.S. Agency for International Development (USAID).

RPM Plus has developed, field tested and implemented in Brazil a management information system (MIS) for improving diagnosis and case management of multi-drug resistant and extensively drug resistant tuberculosis (MDRTB/XDRTB) patients and stock management of the required medicines for treatment.

The MIS system consists of a computer application accessible over the Internet which can be used by designated regional level MDRTB/XDRTB treatment centers to register new patients, treatment schemes, medicine orders, distribution from central levels to periphery levels, and medicine dispensing to patients throughout the course of treatment. Consolidated reports allow each level of management to access online information about the quantities of medicines in stock, ordered or consumed by recipient or cost of treatment as well as the total quantity of medicines dispensed to each registered patient.

The various versions of the MIS have been presented in conferences during FY06 and Ukraine has requested the possibility of adapting the MIS for TB and MDR/XDR-TB control in its local context. In response to this need, RPM plus plans to develop and adapt a generic version of the MIS for managing TB and MDR/XDR cases plus 1st and 2nd line drugs in Ukraine to strengthen TB and MDRTB control activities within the country.

Purpose of Trip

The purpose of this visit was to collect information for the development and adaptation of a generic version of the MIS for managing TB and MDR/XDR cases and 1st and 2nd line medicines in Ukraine, and to outline possible activities aimed at strengthening TB control through improved data management.

Scope of work for Rita Seicas and Ricardo Memoria for this visit is as follows:

- Collect information to specify the needs for changes to develop and adapt a TB MIS generic version to meet the local requirements in Ukraine context: case management and treatment guidelines, drug management practices, information flows at all levels, required system lay-out, required collection and presentation of data, required system functionalities to be incorporated to the generic version.
- Identify all TB partners who may be involved in this project (MoH, NTP and TB program coordination, Laboratory Network, Universities, International Agencies, WHO, GLC, GFATM) to further establish a working group for project development, monitoring, follow-up, and evaluation.
- Brief/debrief USAID mission and WHO WPRO offices as requested.
- Prepare the next steps for implementing a full functional TB MIS and define a roll-out strategy in accordance with the scaling up programmatic plan for MDRTB patients treatment expansion.

ACTIVITIES

MSH/RPM Plus Consultant, Software Development Specialist, Brazilian DMIS development, Ricardo Memoria and RPM Plus Pharmaceutical Consultant, Rita Seicas conducted the following activities (Annex 1, 2 and 3):

- 1) Introduced the scope of the mission to the MOH, the expected activities for the trip and the benefits of the TB-MIS software as a solution for TB/MDR management;
- 2) Presented and discussed functionalities of Romanian version of Drug Management system and Brazilian version of Case Management;
- 3) Defined all functionalities, variables and reports needed for 1st line drug in the Drug Management module of the TB-MIS for the context in Ukraine. Please refer to Annex 6 for key findings and recommendations on MIS for regular TB/DR case management and TB drug management in Ukraine from the trip:
- 4) Defined all functionalities, variables and reports needed for the case management module of the TB-MIS for the context in Ukraine. The findings from the survey and TB MIS implementation in Ukraine can be found in Annex 5;
- 5) Introduced and explained the purpose of the Memorandum of Understanding (MOU) regarding intellectual property of the TB-MIS;
- 6) Initiated a process to form a multi-disciplinary working group (WG): discussed the WG's objective, composition, and matrix of the members' responsibilities. (Annex 4 -Draft of the regulation concerning establishment of Working Group);
- 7) Briefed Visit to the State Pharmacological Center (STC) about Drug Management in Ukraine;
- 8) Visited Kiev City TB Hospital #1 to collect information about case management and softwares in use to support case and drug management;
- 9) Briefed Ukrvaccine about FLD and SLD receiving from manufactures and its distribution to Oblasts;
- 10) Debriefed with USAID office in Kiev;

NEXT STEPS

1. Officially nominate the members of the WG with all local counterparts;
2. Approve the MOU regarding intellectual property of the TB-MIS between MSH/RPM Plus and MOH;
3. Develop a workplan for MIS development and implementation;
4. Define specifications for data entry forms, system functionalities and reports/indicators;
5. Prepare a pilot version (draft version) and release for workgroup evaluation, testing and final customizations of the system;
6. Use this first pilot MIS as a model to validate with all partners at all levels the procedures on data collection, information flows and drugs management reports;
7. Develop guidelines for MIS use at TB facilities and for Training of Trainers (TOTs) training courses;
8. Organize training of trainers;
9. Conduct an evaluation of the performance of the draft version of TB MIS.

Recommendations

Considering the lack of a comprehensive system for TB and MDRTB case management and TB drugs management, lack of clear regulations for MDRTB case management, RPM Plus recommends giving a special attention for TB case management and first line TB drugs and use as benchmark for MDRTB cases management and second line TB drugs the generic version of MIS.

Since the MIS is WEB based software, it's recommended to evaluate the existing infra-structure considering that the following:

- The TB-MIS software will be installed in a centralized computer denominated server. This computer will be the host of the system, nominated WEB Server;
- Every user of the TB-MIS will also need a computer with a WEB browser installed and this computer must be able to connect to the WEB Server through a network;
- The network available for connecting the users to the software may be a local network, an Intranet or, as a recommended solution, the Internet;

Agreement or Understandings with Counterparts

The principle and matrix of responsibilities of the WG has been fully accepted by all stakeholders for the implementation steps of the new MIS for TB/MDRTB case management and first and second line TB drugs management. The stakeholders agreed on the implementation steps of the new MIS for case and first second-line TB drug management.

The program to strengthen TB MIS will be implemented in close collaboration with PATH bilateral program in Ukraine. It is expected that responsibilities and joint implementation strategy will be defined during the next visit to Ukraine.

Important Upcoming Activities or Benchmarks in Program

Following the experience of implementation of two models of MDRTB MIS in Brasil and Romania, RPM Plus will provide a generic versions of MDRTB MIS that will be adapted according to the requirements of the MOH and NTP.

ANNEX 1: AGENDA FOR THE MISSION TO UKRAINE

Management Sciences for Health Rational Pharmaceutical Program Plus

Mission to Ukraine – Agenda March 17-21, 2008

Participants:

Ricardo Memoria Lima, IT specialist, Consultant, Management Sciences for Health/RPM Plus /Brazilian office

Ph. Rita Seicas, Consultant, MSH/RPM Plus, Moldova.

<i>March 17, Monday</i>		
<i>Institution / Program</i>	<i>Name and position</i>	<i>Suggested duration – Topics discussed</i>
Ministry of Health	Prodanchuk M. – First Deputy Minister, Chief Sanitary Doctor of Ukraine, Petrenko V. , Members of TB/HIV and Other Socially Dangerous Diseases Committee	9:15-10:15 Briefing-debriefing Presentation of purpose RPM Plus missions and MIS for MDRTB case and second line TB drugs Strategic discussion for workplans and activities of SPS/ MSH continuing support for case and TB drugs management
PATH, Institute of Phthysiology and Pulmonology, MOH specialists	Olena Radziyevska , Vicedirector PATH Ivanenco Tamara , Laboratory specialist PATH, Alexei Bogdamov, IT specialist PATH Smetanina O. Chief of the Organizational / Method Department of the Institute of Phthysiology and Pulmonology, Chasovskiy K., Tb doctor, TB/HIV and	11:00am-17:00pm Presentation of RPM Plus DMIS, Evaluation of the relevance of the DMIS model in the Ukrainian context, Strategic discussion for workplans and activities, WG approach.

	<p>Other Socially Dangerous Diseases Committee</p> <p>Nedospasova O. Medical Statistical Department of the MOH</p> <p>Tarasenko Elena NTP, TB Control Center</p> <p>Mutrici Ina, TB Doctor, Organizational / Method Department of the Institute of Phthisiology and Pulmonology,</p> <p>Larisa Artiuskina TB specialist , DPI</p>	
<i>March 18, Tuesday</i>		
<i>Institution, program</i>	<i>Name and position</i>	<i>Suggested duration</i>
State Pharmacological Center of MOH Ukraine	<p>Olga Baula, First Deputy Director SPC, Director, pharmaceutical Activity Board,</p> <p>Morozov Anatoly, First Deputy Director</p>	<p>11.00 -12.00 a.m.</p> <p>Assessment of the current DMIS.</p>
USAID Ukraine	<p>Lesley Perry, Director , Office of Health and Social Transition</p> <p>Alina Yurova, Infectious Disease Programs, Office of Health and Social Transition</p>	<p>01.30 -02.20 pm</p> <p>Briefing-debriefing Strategic discussion for workplans and activities of MSH to support the MOH and NTP of Ukraine to strengthen MIS for TB/ MDRTB case and first and second line TB drugs.</p>

PATH Institute of Phthysiology and Pulmonology,	<p>Ivanenco Tamara , Laboratory specialist PATH,</p> <p>Alexei Bogdamov, IT specialist PATH</p> <p>Smetanina O. Chief of the Organizational / Method Department of the Institute of Phthysiology and Pulmonology,</p> <p>Mutrici Ina, TB Doctor, Organizational / Method Department of the Institute of Phthysiology and Pulmonology,</p>	<p>03.30-17.30 pm.</p> <p>Assessment of current forms for case management and information flow. Establishment of the information flow and fields for the new MIS. Identify data entry forms for TB case management.</p>
<i>March 19, Wednesday</i>		
Kiev City TB Hospital # 1	L. Stadnik Chief Doctor	10:00am-13:00 pm Assessment of current information systems, recording and reporting forms for case and first and second line TB drug management practice.
Ministry of Health	Povelco N, Chief of the State Procurement Department	Assessment of procurement, distribution and reporting practice of first and second line TB drug management.
<i>March 20, Thursday</i>		
State Enterprise “Ukrvaccine”	Oleksandr Kuznetsov general director of Ukrvaccine	12:30-14:00 pm Assessment of the pharmaceutical warehouse’s role in procurement, distribution, recording and reporting systems of first and second line TB drug management.
PATH Institute of Phthysiology and Pulmonology,	<p>Olena Radziyevska , Vicedirector PATH</p> <p>Ivanenco Tamara , Laboratory specialist PATH,</p>	<p>15.00 – 17.30 pm</p> <p>Identify data entry forms for MDRTB case management Presentation of the preliminary results of the mission</p>

<p>TB/HIV and Other Socially Dangerous Diseases Committee</p>	<p>Alexei Bogdamov, IT specialist PATH</p> <p>Smetanina O. Chief of the Organizational / Method Department of the Institute of Phthisiology and Pulmonology,</p> <p>Chasovskiy K., Tb doctor, TB/HIV and Other Socially Dangerous Diseases Committee</p> <p>Nedospasova O. Medical Statistical Department of the MOH</p> <p>Mutrici Ina, TB Doctor, Organizational / Method Department of the Institute of Phthisiology and Pulmonology,</p>	<p>Planning of the next steps.</p>
<p>March 21, Friday</p>		
<p>Ministry of Health</p>	<p>Petrenko V., Members of TB/HIV and Other Socially Dangerous Diseases Committee</p> <p>Olga Nedospasova Members of TB/HIV and Other Socially Dangerous Diseases Committee</p>	<p>9:15-10:15 Briefing Presentation of first conclusions and next steps for MIS development and implementation. MOU</p>
<p>USAID/ Ukraine</p>	<p>Lesley Perry, Director , Office of Health and Social Transition</p> <p>Alina Yurova, Infectious Disease Programs, Office of Health and Social Transition</p>	<p>12:30-13:00 Briefing-Debriefing</p> <p>Presentation of results of first conclusions and next steps</p>

	Oleksander Cherkas Senior Social and Health Advisor	
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ANNEX 2: AGENDA FOR THE WORKING GROUP MEETING

1. Presentation of the RMP Plus DMIS: Brazilian DMIS, Romanian version of DMIS and generic DMIS.
2. Identify MOH and NTP requirements for strengthening the case and drugs management information systems: assessment current data collections forms for TB and MDRTB cases, drugs management and information flow; establishment of the information flow and fields for the new MIS.
3. The Working Group Approach: validation of the Working Group concept and the member's roles and responsibilities matrix
4. Next steps

ANNEX 3: LIST OF PARTICIPANTS AT THE WORKING GROUP MEETING

**Kiev Ukraine
March 18, 20, 2008**

1. Olena Radziyevska , Vicedirector PATH
2. Chasovskiy K., Tb doctor, TB/HIV and Other Socially Dangerous Diseases Committee
3. Smetanina O. Chief of the Organizational / Method Department of the Institute of Phthysiology and Pulmonology,
4. Nedospasova O. ,Medical Statistical Department of the MOH
5. Tarasenko Elena,NTP, TB Control Center
6. Ivanenco Tamara , Laboratory specialist PATH,
7. Alexei Bogdamov, IT specialist PATH
8. Mutrici Ina, TB Doctor, Organizational / Method Department of the Institute of Phthysiology and Pulmonology,
9. Larisa Artiuskina, TB specialist , DPI
10. Rita Seicas, Consultant, Management Sciences for Health /RPM Plus, Moldova
11. Ricardo Memoria Lima, IT specialist , Consultant Management Sciences for Health/RPM Plus /Brazilian office

ANNEX 4: MEMORANDUM OF UNDERSTANDING

Memorandum of Understanding for the Creation of a Partners Working Group for TB And MDRTB cases Management and TB drugs information system

The goal of the working group is to coordinate the development and to and implement the Data Information system for TB and MDR- TB and to rationalize all efforts of different stakeholders involved in this process, also avoiding duplications of different strategies and information models used in data collection and reporting for TB and MDR- TB at different levels.

The specific objectives are the following:

- To review the current system for TB and MDR- TB case notification
- To define and to test a pilot TB and MDR- TB patients surveillance system for case management and transfer of relevant data at all levels: Central Unit, Ministry of Health, Oblasti level, MDR- TB reference Centers.
- To establish the monitoring indicators for case TB and MDR- TB management and monitor standard epidemiological data and operational research.
- To offer data for monitoring and operational research.
- To establish forms for the registration of drugs regarding the distribution and use of first and second line drugs.

Main tasks of the working group would be:

- To evaluate and revise the diagnostic procedures and standard treatment procedures and case management practices for TB and MDR- TB patients.
- To evaluate the current procedures for data collection
- To identify the needs of NTP and MoH for a new Information System for Data management (DIMS).
- To develop the forms to be used for data collection and follow-up for TB patients
- To establish the information flow and indicators for standardized monitoring and reporting
- To organize training courses for implementation of the new TB and MDR- TB case management system.

The working group needs to be an interdisciplinary team, consisting on representatives of different organizations involved in DOTS and DOTS Plus strategy implementation.

Main role and responsibilities of key stakeholders:

Ministry of Health/ Committee of TB/HIV and other Socially Dangerous Diseases:

- To monitor the steps in development of DMIS in close collaboration with MSH/SPS Plus.
- To approve the modules and procedures of DMIS.
- To validate the strategies for implementation of DMIS at all levels and the training modules.
- To coordinate the implementation of the system at all levels.

Institute of Phthisiology and Pulmonogy:

- To evaluate the diagnostic and treatment protocol, procedures and management practices of TB and MDR- TB cases.
- To revise the diagnostic, standard treatment protocols, notification and TB and MDR- TB case management procedures
- To identify the needs for DMIS according to the GLC, WHO and other partners recommendations.
- To evaluate the current system for TB and MDR- TB data collection
- To establish the data needed for TB and MDR- TB management taking into consideration all aspects: diagnosis, enrollment, treatment, laboratory management, drug management reporting.
- To elaborate the forms for data collection and information flows
- To establish the indicators and the reports forms
- To monitor the implementation of the new DIMS
- To maintain and update the DMIS.

PATH:

- To ensure assistance in revision of the diagnostic, standard treatment protocols, notification and TB and MDR- TB case management procedures
- To ensure assistance in elaboration and implementation of new software for TB and MDR- TB.

- To ensure assistance in elaboration the training modules.
- To ensure assistance in maintaining and long term roll-out strategy of the DMIS

WHO:

- To ensure technical assistance for elaboration, revising and elaboration of diagnostic, case management, treatment protocols and notification procedures for TB and MDR- TB case management
- To ensure technical assistance for selection of indicators
- To ensure technical assistance for elaboration of training modules
- To ensure technical assistance in training courses organization

MSH- SPS:

- To coordinate the working Group (WG) activities at each step level
- To establish and monitor the work plan and activities
- To offer a software model for TB and MDR- TB case management
- To ensure technical assistance in adjustment and integrate the software in the current systems used
- To ensure technical assistance in development of the drug management component of the system.
- To coordinate the elaboration of DMIS.
- To ensure technical assistance for elaboration of the training modules
- To ensure technical for training course organization.

Nomination of Working Group members:

Committee TB/HIV and other Socially Dangerous Diseases, MOH

- Vasyl Petrenko, Head, Committee TB/HIV and other Socially Dangerous Diseases, MOH
- Olga Stelmakh, Deputy Head of the Committee TB/HIV and other Socially Dangerous Diseases,
- Kirill Chasovsky,

Centre for Medical Statistics, Ministry of Health

- Olga Nedospasova, Chief TB specialist, Centre for Medical Statistics

Institute of Phthiology and Pulmonogy:

- Yuriy Feschenko, Director, National Institute of Phthiology and Pulmonogy
- Oksana Smetanina, Head of the Department, National Institute of Phthiology and Pulmonogy
- Svitlana Cherenko, Chief Scientific Worker, National Institute of Phthiology and Pulmonogy
- Inna Motrych, National Institute of Phthiology and Pulmonogy
- Anna Barbava, Laboratory Specialist, National Institute of Phthiology and Pulmonogy

TB Health Units from Oblasti:

- Halyna Koval, Deputy Head Director Kherson Oblast TB Hospital,
- Natalya Shvets, Deputy Head Doctor, Zaporizhzhya Oblast Territory Medical Amalgamation, Phthiology,,

MSH- SPS program:

- Joel Keravec, Technical Programme Coordinator
- Ricardo Memoria Lima, IT specialist, Brasilia.
- Rita Seicas, Pharmaceutical Consultant.

PATH:

- Olena Radzyevska , Deputy Director of the TB Control Partnership Project, PATH Representative Office in Ukraine;

Pharmaceutical area / Warehouse:

WHO Office:

-

Steps to be followed in order to reach the goal are described in the working plan.

This memorandum is signed by all partners in order to insure the success of proposed activities/ objectives.

Kiev, March , 2008 .

ANNEX 5: TB-MIS IMPLEMENTATION IN UKRAINE

TB-MIS Introduction

The TB Management Information System (TB-MIS) is WEB based software developed by MSH to act in the following modules:

- **TB and MDR-TB case management** – Registering of TB and MDR-TB cases, including patient data, treatment regimens, laboratory exams, medical examinations, and as a result of these clinical data, the system generates indicators like incidence indicator, cohort indicator, demographic indicators, and others;
- **1st and 2nd line medicine management** – Registering of every medicine movement in every TB unit, segmented by medicine sources, including batch control, FIFO control, medicine forecasting and estimation.

The system is currently in development phase and will include the best practices for TB management acquired from the implementation of a proprietary solution for MDR-TB management in other countries.

Collected Information

The Information collected was acquired from different entities in Ukraine. Following are the entities involved in the related information collected by TB-MIS modules:

Collected Information	Entities Interviewed
Case management	MoH Institute of Phthiology and Pulmonology Kiev City TB Hospital # 1
Medicine management	MoH Institute of Phthiology and Pulmonology Kiev City TB Hospital # 1 State Enterprise “Ukrvaccine”

With the information collected from these entities, it was possible to map the processes involved in case and medicine management. What follows bellow are an overview of the process concerning the TB-MIS implementation:

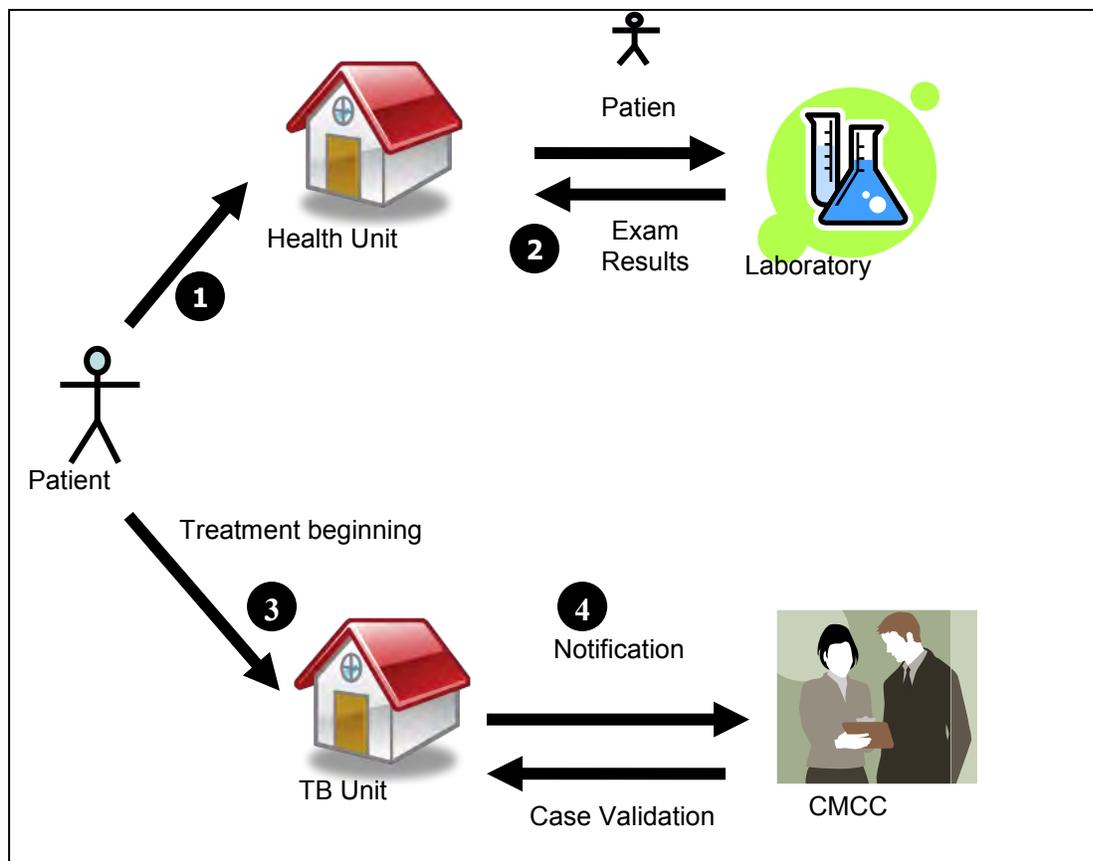
Case Management Process

The case management process is composed of the following points:

1. Case notification;
2. Case treatment;

3. Case outcome;

Case Notification - The case notification is the most complex of the 3 phases. The diagram below displays the phases of the notification:



1. The patient arrives in a Health Unit;
2. The doctor suspects he is a TB case and redirect him to laboratory exams;
3. If the laboratory exams confirms he is a TB case, the patient is redirected to a TB unit;
4. The TB Unit notify the case to the CMCC (Rayon level, which analyses the TB cases), where it's validated;

The case treatment and outcome follows the regular treatment of a TB and MDR-TB case (regimen changes, patient transfer, exam results, etc). At this point these are the relevant points:

- By the cases notified to CMCC, in a quarterly basis the Rayons reports to Oblasts about a summary of the cases (new cases, cases in treatment, outcomes);
- The Oblasts, consequently, report in a quarterly basis to the Institute of Phthisiology and Pulmonology and MoH a summary of the cases in management;

Medicine Management Process

Following is a brief overview of the medicine management in Ukraine. Concerning the TB-MIS implementation, these are the processes regarding medicine management that deserve attention:

1. **Medicine forecasting and procurement** – The forecasting and procurement of TB medicine is executed by the MoH. The MoH calculate the medicine forecasting based on request from Oblasts. The procurement is done once a year. The MoH procures both 1st line and 2nd line medicines;
2. **Medicine distribution** – After procurement the medicines are sent from the manufactures to Ukrvaccine (The state enterprise responsible for the distribution). The Ukrvaccine doesn't store the medicines, but distribute them directly to the Oblasts, which distribute them to Rayons and finally, distribute them to health units;
3. **Medicine orders and transfers** – Health units order medicines to Rayons. The objective of the order is to supply TB health units with medicines for the cases in treatment, but there is no guideline or rule about the how often an order must be placed or validation if the quantity ordered is compatible with the quantity of cases in treatment. Medicine transfers may occur from a health unit to another (example: Unit with an excessive quantity of medicine may be transferred to another unit in a medicine shortage).
4. **Reports** – Information are sent in a consolidated report from one level to another (Rayon to Oblasts and Oblasts to MoH) on a quarterly basis. The Ukrvaccine generates reports about quantity delivered and its costs, while Oblasts generates reports about quantity dispensed.

Actors and the TB-MIS

Actors are anyone or anything that interact with the system. For the TB-MIS implementation in Ukraine, these are the following actors that will interact with:

Actor	Interactions with the TB-MIS
Institute of Phthisiology and Pulmonology	<ul style="list-style-type: none">• Monitors TB and MDR-TB cases (case searching and surveillance);• Consult medicine forecasting for the procurement;• Generates indicators about TB and MDR-TB cases;• Checks stock position of Rayons and Health Units;• Generates indicators about medicine management;
MoH	<ul style="list-style-type: none">• Monitors 1st and 2nd line medicines movements in Oblasts, Rayons and Health Units;• Checks stock position of Rayons and Health Units;• Generate medicine forecasting for the procurement;• Generates indicators about TB and MDR-TB cases;

CMCC	<ul style="list-style-type: none"> • Monitors TB and MDR-TB cases in Rayon level; • Validates TB and MDR-TB cases; • Generates indicators about TB and MDR-TB cases in Rayon level;
Ukrvaccine	<ul style="list-style-type: none"> • Registers 1st and 2nd line medicine receiving from manufactures; • Transfers medicines to Oblasts; • Generates medicine movement reports containing financial information (medicine costs);
Oblast and Rayon	<ul style="list-style-type: none"> • Receives medicines from Ukrvaccine; • Deliveries medicines to health units; • Transfers In/Out of medicines; • Forecasts medicines for the procurement; • Generates medicine movements reports (medicine input/output);
Health Unit	<ul style="list-style-type: none"> • Notifies TB and MDR-TB cases; • Update TB and MDR-TB case information (regimen changing, exam results, medical examination, patient data, etc); • Transfers patient to another health unit; • Received patients transferred out from another health unit; • Places new orders to Rayons; • Receives medicines from Rayons; • Registers medicines dispensing to patients; • Transfers In/Out of medicines; • Generates medicine movements reports (medicine input/output) in health unit level;

TB-MIS New Functionalities and Improvements

Below is a list of changes to be made on the TB-MIS as a result of the Ukraine trip:

1. Improvements

- a. **Incorporate new fields for case notification** – The TB-MIS is following the standard forms of WHO, but most countries include extra information, such as patient citizenship, phone number, security number, etc.

- b. **Record exam results and medical examinations for case management** – There is a possibility to include new exam results during the treatment and data from medical examination (height, weight, etc);

2. New Functionalities

- a. **TB management** – The TB management in the system was planned to be incorporated in a second version, but due to a lack of standards in MDR-TB treatment, we consider the importance of including TB management for the pilot version of the system;
- b. **Patient history** – This feature will not only record the TB cases, but will also incorporate the exam results of patients during pre-notification, when patients were TB suspected. Annex 7 (excel form) reflects the drafted forms with key specialist from Ukraine for notification and follow-up of TB patient, based on forms applied by the NTP Moldova. In accordance with the request of the key specialist from Ukraine, data collected for the notification and follow-up of MDRTB patients should be based on the form TB/01/MDRTB;
- c. **Medicine Forecasting** – This will help the MoH with the working of forecasting medicines for the procurement;
- d. **Financial reports about medicine movements** – Reports will be generated by Ukrvaccine to the MoH;

3. Indicators

- a. TB and MDR-TB Incidence;
- b. Cohort indicator;
- c. Bacteriological evolution;
- d. Demographic characteristics;
- e. Drug resistance pattern;
- f. Previous treatment;
- g. TB and MDR-TB prevalence;
- h. HIV/AIDS among TB cases;

TB-MIS Impacts in Ukraine

Below is a list of positive impacts for a successfully implementation of the TB-MIS in Ukraine:

1. **On-line reports for 1st and 2nd line management** – Most of the medicine management reports are produced on a quarterly basis. With the TB-MIS the medicine management reports will be generated at any moment with the possibility to be consolidated by country, oblasts, rayon or health unit.
2. **On-line indicators** – Today, indicators are consolidated from information sent on a quarterly basis from the Oblasts to the MoH. With the TB-MIS, the moment a new case is validated in the system; this information will be included in the indicators the next time they are generated.

3. **Real time information about TB and MDR-TB cases** – As new cases are registered in the system, such information will become available to the central level;
4. **Distributed system with a centralized database** – A centralized database gives to the data administrator several possibilities to generate their own indicators at any time he/she wants (without having to wait for any quarterly report, as it is done today);
5. **Better order estimation** – The TB-MIS automatically estimates the quantity of medicine necessary for an order based on the number of patients under treatment in the health unit. Today there is no validation of the orders placed by the health unit to the Rayons;

Recommendations for Implementing the TB-MIS implementation

1. **Clear guidelines for 1st and 2nd line management** – Today the Oblasts have a great administrative autonomy, resulting in a lack of clear rules on how medicine orders and distributions are done;
2. **Clear guidelines for MDR-TB management** – Lack of guidelines for treatment of MDR-TB, like standard regimens, notification forms, etc.
3. **Team Leader to conduct the project in Ukraine** – It's very important to choose someone from the Ukraine side playing the role of a team leader. This person will be in charge of taking decisions, answering questions and helping the planning of the implementation of the system in Ukraine;
4. **Infrastructure** – To run the system adequately, an entry level computer connected in the same network as the server computer is necessary (the server computer is where the system is installed). The best option is to use the Internet as the "bridge" to access the system, but other (affordable) solutions are available, such as a wide area network, for example.
5. **Define Drugs Management Indicators**

Next Steps

1. Development of a pilot version;
2. Demonstrate and implement the pilot version;
3. Execute a training for future trainers;
4. Execute adaptations in the system (evaluation of the pilot version);

ANNEX 6: KEY FINDINGS ON MIS FOR REGULAR TB/DR CASE MANAGEMENT AND TB DRUG MANAGEMENT

The summary on results of MIS TB/ DR assessment is formulated based on the key elements of drugs management:

TB Case Management

1. There is regulation on management of TB according DOTS Strategy (National protocol on implementation of DOTS strategy in Ukraine approved by the MOH order № 318 from May 24, 2006 and Protocol on medical assistance for TB patients (№ 384 of the MOH from June 9, 2006).

In practice the classification of patients by categories differs from the WHO recommendations.

2. There is no comprehensive and unique data management information system for regular TB management. Currently the TB Units use two information systems: “medstate” (system developed and implemented in the former system) and “EPI INFO,” developed during implementation of DOTS strategy. DOTS strategy has been implemented in pilot projects from 8 regions. Correspondingly the remaining Oblasts use only one system: “medstate”.
3. There is no unique unit for data collection, monitoring and evaluation on TB case management at the central level.
4. There is no information system for monitoring of the laboratory activities.

MDRTB Case Management

1. There are no national protocols for MDRTB management, except the protocol on diagnosis and treatment of MDRTB in Donetsk oblasti, Ukraine developed by the Medical State University from Donetsk with support of the WHO.

Currently the Working Group of the Committee of TB/HIV and Other Socially Dangerous Diseases is working on development of national protocols. At the moment there are general recommendations on MDRTB management as part of the Protocol on medical assistance for TB patients (№ 384 of the MOH from June 9, 2006).

2. MOH procures second line TB drugs based on the request of TB units.
3. There is no National Reference Laboratory in the country. The laboratory system faces problems with supply of equipment, laboratory items etc.
4. There is a lack of recording and reporting system for DR TB.

Drug Management

Management:

1. There is a lack of coordination of the whole TB drugs supply procedures by the central unit of the TB program. Currently management of TB drugs supply is shared by different stakeholders and institutions and there is no well established mechanism of collaboration between them.

Selection of medicines

1. Selection of single dose TB medicines is prioritized. The treatment schemes are composed from single dose drugs and are not oriented to include FDC. Moreover the list of drugs selected includes pharmaceutical formulations (for instance: solution for infusion/injection) that are not included in the WHO's schemes.
2. There is a lack of regulations and protocols of treatment of DR Tuberculoses. At the same time a wide range of second line TB drugs is a part of selected drugs list for procurement (source – list of TB drugs from the visited unit). Moreover delays of financing create premises for delays of drugs supply and correspondingly the prescription. As a result, the adjustment of treatment schemes of second line TB drugs is performed in accordance with available stock of drugs. This practice may be a reason for development of resistance since there is no possibility to prescribe drugs following the amplification of resistance principle.

Procurement of medicines

1. There is no unique tool for estimation of TB drugs and capacity to evaluate the requests on medicines of the TB units.
2. Specifications for drugs require improvements to ensure fulfillment of international quality standards.
3. There is a lack of the current regulation concerning the maintaining of the buffer stock level at the central and local level. Delays of financing is impediment for regular, continue supply of drugs to TB health units.

Medicine Storage and Distribution

1. The current regulation does not foresee maintaining of buffer stock at the central level. The TB units from Oblasti receive the total quantity for one year inclusive the buffer stock. Correspondingly, the oblast distributes medicines to all Rayons, which is the final point where drugs are stored during the year.
2. There is no practice of TB drugs distribution on quarterly bases. From the information shared by the central warehouse in some oblast/rayon there is no warehouse with adequate space for storage of one year stock
3. There is lack of practice to formulate medicine distribution plan. Medicine distribution plan is approved by the MOH following the medicine requests of oblasti and tender's

results. The lack of the system for estimation of the necessity and monitoring of consumption as well as a lack of reliable case management system may be an issue for development of medicine requests. At the same time, each transfer of medicine should be approved by the MOH, which requires additional time and may be a reason of delay and interruption.

4. There is no a well defined mechanism of reallocation of medicines from one oblast to another.
5. There is no a central warehouse for receiving and storage of TB medicines on behalf of NTP.

Recording and Reporting system

1. There is no unified practice of recording drugs movement over the country. The system used by the pharmacies and warehouses is a system developed for accountancy department.
2. NTP does not have a system for monitoring and evaluation of TB drug movement. Consolidated report with data on consumption, remained stock and cost of drugs is sent by the “UKRVACCINE” to the Financial Department on regularly basis. To the MOH, the report is sent only on upon a request and there is no official regular procedure of reporting.

Use of TB drugs

1. Treatment protocols include schemes with FDC TB drugs prescription. The prescription is provided according to the available stocked drugs. According to the list of TB drugs procured by the MOH and dispensed to TB units, there were no procured FDC formulations (source: information on the TB drugs stock from the municipal TB hospital, Kiev).
2. There is no system of monitoring and evaluation of consumption of TB drugs by patients, category and health units. Reporting system on drugs consumption is not implemented.
3. There is a system of monitoring of side effects in place. Reporting on side effects is collected by the State Pharmacological Center of MOH Ukraine.

Recommendations:

TB and MDRTB Case Management

1. Revision and adjustment of the current regulation/protocols on DOTS implementation.
2. Harmonization of the recording/ reporting system with WHO recommendations and national request into one unified recording and reporting system. Development of MIS for TB/DR Case Management.
3. Implementation of unified recording system over the country.
4. Establishment of central unit in charge for monitoring and evaluation on TB case management and drugs management at the central level.
5. Development and incorporate laboratory module within MIS for TB/DR .
6. Strengthen Laboratory service prior to starting of DR TB treatment.
7. Development and approve national regulations concerning TB DR management.

Drug Management

Management:

1. Establishment of one unit at the central unit in charge for management of TB drugs supply.

Selection of medicines

1. Revise the current practice of drugs selection and prioritize FDC prescription.
2. Develop and approve treatment protocols on MDR TB. Establish clear criteria for selection of drugs for DR treatment.

Procurement of medicines

1. Establishment of unique tool of TB drugs estimation and application over the country.
2. Improve tender specifications concerning the drugs quality requests.
3. Revision of the current regulation concerning assuring all TB units with adequate buffer stock level during the year.

Medicine Storage and Distribution

1. Establish a central medicine warehouse responsible for storage and maintaining of the TB drugs procured by the MOH inclusive buffer stock.
2. The current regulation should be revised and adjusted to international recommendations concerning management of TB drugs stock.

Recording and Reporting system

1. Central unit should unify recording and reporting practice on TB drugs.
2. The DMIS should be developed to ensure monitoring and evaluation of TB drug movement at each stage and level being linked to case management information system.

Use of TB drugs

1. 1. Evaluation of prescription and use of second line TB drugs should be undertaken.
2. Revision of the current practice of prescription first line TB drugs and second line TB drugs.
3. A system of monitoring of medicines consumption should be implemented.

ANNEX 7: PATIENT HISTORY FORMS

A:

Ministry of Health

Medical documentation
Formular Nr _____
approved by _____

_____ name of health facility

Notification of new case / relapse and results of treatment monitoring

Part A. Notification of new/relapse TB cases

1	Specialized Health Unit where patient will be recorded	name _____
		cod _____

demographics and social data:	
2	individual number of TB patient _____ (generated automatically)
2a	registration number TB-03 _____
3	first name _____ last name _____ Patronymic _____
4	Identification number _____
5.a	Address: _____
5.b	town /village _____ street, home, apartment _____ 1 urban 2 rural
5.c	
5.d	
6	Sex 1 M 2 F
7	Birth date / / date month year
8	
9	Factors of risk B.20 ARV treatment Cotrimoxazol therapy alcoholism use of injection drugs contact 9.a co-morbidities 9.b unemployed medical profession refugee/immigrant prison 9.c homeless
10	Have been out of the country more than 3 months during last 12 months 1 yes 2 no
11	have been in prison 1 yes 2 no
12	send to Tb cabinet by: 71 family doctor, symptomatic 72 family doctor, prophylactic control 81 other specialist, symptomatic 82 other specialist, prophylactic control 2 direct
13	Number of contacts within the family _____
13.	from them children up to 18 years old _____
13.b	come from the focar 1 yes 2 no

history of disease:	
date of first symptoms / / day /month /year	
date of confirmation / / day /month /year	
diagnosis _____	
date of registration / / day /month /year	
14	Date of treatment start / / day /month /year
15	localization 1 pulmonar _____ Clinic,s form _____ name _____ cod _____ extrapulmonar _____ localization _____
16	
17	
17a	Morphological confirmed 1 0 2 yes
18	Stage 1 infiltrati on 2 destruction X ray 0 not done 1 2 3 cavern yes no
19	Microscopy result 1 positiv 3 no data 2 negativ 5 not done
19.a	positive (+) 1- 9/100 1+ 2+ 3+
20	culture results 1 positive result 3 no data 2 negative result
20.a	positive degree (+) 1+ 2+ 3+
21	MBT Sensibility to drugs S -sensible, R - resistant H R E S Z Et Km O Cs 22 group dispensary evidence 1 2 3 4 5
23	received anti TB treatment previously, exception drugs 1 yes 2 no
23.a	if yes, starting date / (month and year)
24	type of patient 1 new case 21 relapse BAAR neg. 2 relapse BAAR poz. 22 relapse extrapulmonar 3 after abandon 4 failure 5 chro nic 6 initiated the treatment abroad (documented)
24.a	1 2
25	1 2
26	Date of treatment start / /
27	treatment category 1 I treatment scheme per phasis _____
28	HIV investigation 1 no 2 test result
29	co-morbidities (could be marked several) 1 HIV 2 diabetes 3 hypertension 4 other chronic diseases 5 other

IS Office: Currently patient does not have this number.

Rita: include all drugs

Rita: MDRTB
Rita: Cronics

Ukraine asked to make link between category and drugs and weight in the system

30	Doctor /name _____ signature _____
31	date of fill in the form / / (zz/ll/aaaa)

fill in form from programme Date: _____ Facility: _____
Operator: _____

Ministry of Health

B:

name of health facility

Notification of new case / relapse and results of treatment monitoring

Part B. Follow up of treatment

Se completează pe parcursul tratamentului și la sfârșitul acestuia

1	Specialized Facility where patient is kept on evidence	1.4	name	cod	1.3	name	cod	1.2	name	cod	1.1	name	cod			
Patient:																
2	Individual number of TB patient	2	(generated automatically)		2	(generated automatically)		2	(generated automatically)		2	(generated automatically)				
3	first and last name, patronymic	3			3			3			3					
4	personal numerical cod	4			4			4			4					
7	birth date	7	/	/	7	/	/	7	/	/	7	/	/			
History of disease:																
17	Clinic form	17.4	name	cod	17.3	name	cod	17.2	name	cod	17.1	name	cod			
18	Xray	18.4	yes	2 no	18.3	yes	2 no	18.2	1	2	18.1	1	2			
			close of the cavity			4 close of the cavity			4 close of the cavity			4 close of the cavity				
19	Microscopy result	19.4	1 positive	2 negativ	19.3	1 positive	2 negativ	19.2	1 positive	2 negativ	19.1	1 positive	2 negativ			
			3 no data	5 not done		3 no data	5 not done		3 no data	5 not done		3 date absente	5 nu s-a efectuat			
19.a	level of positivity (+)	19.a.4	1 - 9/100	1+ 2+ 3+	19.a.3	1 - 9/100	1+ 2+ 3+	19.a.2	1 - 9/100	1+ 2+ 3+	19.a.1	1 - 9/100	1+ 2+ 3+			
20	Culture result	20.4	1 pozitiv	2 negativ	20.3	1 positive	2 negativ	20.2	1 positive	2 negativ	20.1	1 positive	2 negativ			
			3 no data	5 not done		3 no data	5 unfinished result		3 no data	5 not done		3 no data	5 not done			
			4 unfinished result			4 unfinished result			4 unfinished result		4 unfinished result					
20.a	level of positivity (+)	20.a.4	1	2 3	20.a.3	1	2 3	20.a.2	1	2 3	20.a.1	1	2 3			
21	MBT Sensibility to drugs S -sensible, R - resistant	21.4	H	R	E	S	Z	E	t	K	m	O	Cs	Ps		
22	group dispensary evidence	22.4	1A	1B	1C	E1	E2	S	22.3	1A	1B	1C	E1	E2		
28	HIV investigation	28	1 no	2 yes/+	3 yes/-	4 no/unknow	28	1 no	2 yes/+	3 yes/-	4 yes/unknow	28	1 no	2 yes/+	3 yes/-	4 yes/unknow
32	Number of days and number of doses	32.4			32.3			32.2			32.1					
33	Transfer	33.4	1 to other regio	2 to penitentiary	33.3	1 to other regio	2 to penitentiary	33.2	1 to other regio	2 to penitentiary	33.1	1 to other regio	2 to penitentiary			
	Facility where is transferred		3 from other reç	4 from penitentiary		3 from other reç	4 from penitentiary		3 from other reç	4 from penitentiary		3 from other reç	4 from penitentiary			
	date		date			date			date			date				
34	confirmed side effects to specific drugs		1 yes	2 no	3 lack of information											
35	date		/	/	date /month /year											
35.a	treatment of side effects		X	nonths												
	Modification of the treatment scheme		1 yes	2 no	3 lack of information											
36	treatment results															
	1 cured (smear, or culture, clinic results)		2 completed treatment													
	3 failure															
	41 abandon															
	died HIV															
	51 died TB		52 died due to other reason													
	6 non confirmed TB diagnose		7 non evaluated													
	81															
	82															
37	Date of treatment finishing		/	/	date /month /year	it is completed at the 5th months from the start of treatment		it is completed at 3-4th months from the starting of the treatment (on the necessity if patient is still positive to microscopy at the 2-3th months after initiating of treatment)		it is completed at the 2-3th months from the starting of treatment						
It is completed at the end of the treatment 6-9, mandatory 12 month and repeatedly for those which continue treatment more then 12 month																
x	Doctor and signature	x			x			x			x					
34	Date of fill in the form	34.4	/	/	date /month /year	34.3	/	/	date /month /year	34.2	/	/	date /month /year			

fill in form from programme

Date: _____

Facility: _____

Operator: _____

Date: **36**

Facility: _____

Operator: _____

Date: _____

Facility: _____

Operator: _____

Date: _____

Facility: _____

Operator: _____

C:

Ministry of Health

_____ name of facilities

Notification of new case / relapse and results of treatment monitoring

Part C. Treatment results note

is completed at the moment of taking out from the group of dispensary surveillance

(from contingent)

1	Specialized Facility where patient will be recorded	1.5	_____ name _____ cod
---	--	-----	-------------------------

Patient:

2	Individual number of TB patient	2	_____ (it is generated automatically)
3	First, last name and patronymic	3	_____
4	personal numerical cod	4	_____
7	Birth date	7	_____/_____/_____ date month year

History of disease

36	treatment results	36.1	21 treated under DOTS+ 22 treated with individual scheme 51 died TB 52 died, other reasons 42 abandon
37	date of taking out from the group of dispens	37.1	_____/_____/_____ date month year
x	doctor,s name	x	_____
31	Date	31.5	_____/_____/_____ date month year
x	signature	x	_____

Date: _____

facility _____

Operator: _____

Remark

Cod clinic form

MBT Sensibility to drugs

H	Izoniazidă	1,0	Et	Etionamidă
R	Rifampicină	40,0	Km	Kanamicină
E	Etambutol	2,0	O	Ofloxacină
S	Streptomicin	10,0	Cs	Cicloserină
			Ps	PAS

Summary of actions to improve TB/HIV services at oblast level

- Strengthening of the coordination mechanism and improving of strategic planning in the TB/HIV domain at the oblast level. The formation of the regular functioning working group was proposed. It will be analyzing the situation based on the monitoring data and offering the activities to improve the situation.
- Formation of coordination algorithm and referral system.
- Formation and support of monitoring groups to implement the coordination mechanism by oblast coordination councils.
- Formation and distribution of educational programs for nongovernmental organizations' (NGOs) staff and their clients.
- Implementation of joint regular meetings system (TB medical facilities, AIDS centers, social services, NGOs) to discuss problems and possible ways of solving them.
- Implementation of regular clinical examinations of TB/HIV co-infection cases into everyday practice (multidisciplinary method) with the involvement of TB specialists, infectionists, physicians, narcologists, and other medical specialists with the aim of improving the effective treatment of TB/HIV co-infection.
- Trainings for TB specialists and infectionists (jointly) on clinical issues of TB/HIV co-infection cases' detection and observation, including the peculiarities of TB/HIV co-infection and requirements to in-patient control of HIV-positive patients in TB-epidemic environment.
- Implementation of screening interviewing (the questionnaire was worked out and tested by PATH) in medical facilities network and in NGOs.
- Meeting of the expanded coordination councils with the aim of analyzing the existing activities and planning of further activities.