

Support to Ukraine in Implementing Its National TB Program

Midterm Evaluation Report:

**External Evaluation Conducted July 4-16, 2005
and
Annual Report for October 2004 – September 2005**

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List of Acronyms

AIDS	Acquired immune deficiency syndrome
AFB	Acid-fast bacilli
ART	Antiretroviral therapy
BCC	Behavior change communication
CDC	Centers for Disease Control and Prevention
CSHGP	Child Survival and Health Grants Program
DIP	Detailed Implementation Plan
DOTS	Directly Observed Treatment, Short-Course
DRRS	Data recording and reporting system
DRRF	Data recording and reporting forms
DST	Drug susceptibility testing
EU	European Union
FGD	Focus group discussion
FIND	Foundation for Innovative New Diagnostics
GFATM	The Global Fund to Fight AIDS, Tuberculosis, and Malaria
GHC	General health care
HIS	Health information system
HIV	Human immunodeficiency virus
HLWG	High-level working group
IDU	Injection drug users
IEC	Information, education, and communication
INH	Isoniazid
IPC/C	Interpersonal communication/counseling
IRB	Institutional review board
ITP	F.G. Yanovsky Institute of Tuberculosis and Pulmonology of Academy of Medical Sciences of Ukraine
KAP	Knowledge, attitudes, and practices
KMAPGE	P. Shupik Kyiv Medical Academy of Post-Graduate Education
KNCV/KIT	Royal Netherlands Tuberculosis Association/Royal Tropical Institute
KPC	Knowledge, practices, and coverage
LTBI	Latent TB infection
MDR	Multi-drug resistance
M&E	Monitoring and evaluation
MIS	Management information system
MOH	Ministry of health
MOU	Memorandum of understanding
MTB	Mycobacterium tuberculosis
MTE	Midterm evaluation
NGO	Nongovernmental organization
NIS	Newly Independent States
NRL	National Reference Laboratory
NTP	National Tuberculosis Control Program
PACG	Policy and Advocacy Consulting Group
PATH	Program for Appropriate Technology in Health
PDR	Primary drug resistance
PHC	Primary health care

PIU	Project implementation unit
PLHA	People living with HIV or AIDS
PVO	Private voluntary organization
QA	Quality assurance
QC	Quality control
SDR	Secondary drug resistance
SES	Sanitary epidemiological station
STI	Sexually transmitted infection
TAG	Technical advisory group
TB	Tuberculosis
TB EMIS	TB Electronic Management Information System
TB-ESCM	TB Electronic Surveillance and Case Management
TIMS	TB Information Management System
TOT	Training of trainers
URCS	Ukrainian Red Cross Society
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
VAT	Value-added tax
VCT	Voluntary counseling and testing
WB	World Bank
WHO	World Health Organization

Summary

Description of Program and Its Objectives

In 2003, the United States Agency for International Development's (USAID) Child Survival and Health Grants Program (CSHGP) provided PATH with US\$1.5 million for the period October 2003 through September 2006. An additional \$1 million was committed in 2005 by the USAID Regional Mission based in Kyiv. The objectives of the PATH project are to:

- Improve capacity for the directly observed treatment, short-course (DOTS) expansion by advocating for political support, including appropriate legislation and assistance in developing pilot sites.
- Improve the quality of diagnostic services in selected oblasts.
- Improve the use of monitoring and surveillance data for TB program management.
- Reduce diagnostic delay, increase case detection, and improve treatment adherence.
- Improve provider practices by improving capacity to diagnose and treat TB based on the DOTS strategy and enhance knowledge and response to TB/human immunodeficiency virus (HIV) interactions.

The full report of the external evaluation conducted by Dr. Fabio Luelmo in July 2005 is provided in Annex A.

Main Accomplishments: October 2004 through September 2005

The PATH strategy has been to support national, oblast, and city TB control efforts, and by doing so, demonstrate the feasibility and appropriateness of the DOTS strategy. PATH has continued and complemented support from other agencies (World Health Organization [WHO] and Royal Netherlands Tuberculosis Association/Royal Tropical Institute [KNCV/KIT]) and taken leadership in collaboration with oblast authorities. According to midterm evaluation findings, the PATH strategy has proved to be appropriate and the changes observed in the pilot areas for DOTS implementation are substantial in comparison with the status of the new areas selected for expansion. Kyiv and Donetsk Oblast have integrated case detection in general facilities, increased ambulatory treatment, improved TB laboratory functioning, and developed an information system for monitoring. The Ukrainian Red Cross Society (URCS) provides a good model for expansion of outpatient care to the community, in particular for high-risk populations. The progress achieved in the country in comparison with the previous situation, described in the joint evaluation in 1999¹ and in consultant reports,² is quite satisfactory.

Main Constraints, Problems, and Areas in Need of Further Attention

The main constraints at the national level include:

- Absence of a TB unit/team to develop comprehensive guidelines, to plan and to coordinate all sources of funding and technical cooperation, and to monitor and supervise activities.

¹Joint Review of Tuberculosis in Ukraine. WHO/EURO, 6-15 December 1999.

²TB surveillance assessment mission to Ukraine. WHO/EURO, 20-24 May 2002.

- Survival of obsolete laws, which prohibit implementation of modern strategies (e.g., mass screening by x-ray and mandatory hospitalization).
- Resistance of TB specialists to adopt more effective TB control strategies and simpler instruments to allow monitoring and evaluation; the present Policy and Advocacy Consulting Group (PACG) is probably not fully appropriate to advise the Ministry of Health (MOH) on DOTS implementation.
- Lack of comprehensive and patient-friendly TB control guidelines from the MOH, based on effectiveness and efficiency, and overruling previous norms.
- Insufficient coordination of the technical partners (PATH, WHO, World Bank) to support the MOH in its capacity to make decisions that further implement the DOTS strategy and facilitate health sector reform (for instance, converting TB hospital beds to other purposes and changing the financing system for hospitals).
- Separate drugs, no reserve stocks (several month stock-outs of pirazinamide were observed in a TB hospital during the mission), lack of clear national decision-making and guidelines for standard regimens (multiple alternatives observed during the mission), and use of second-line drugs with irregular supply or private purchase without national guidelines.
- An excessive number of TB beds and TB hospitals for the existing caseload (e.g., one TB specialist for 14 new TB patients per year and more than one TB bed per TB patient).

The main constraints at the oblast and city level are as follows:

- Insufficient staff knowledge of the efficacy of interventions to reduce TB transmission and mortality (different from individual patient diagnosis), and inclusion of patients cured of TB and persons only infected with TB in “TB prevalence data.” This leads to excessive hospitalization and labeling of healthy children and cured adults as TB patients.
- Inadequate use of the laboratory capacity; reading (in theory) 300 fields; cultures made for diagnosis in all three samples but not taken into account by the specialist making the diagnosis; lack of analysis of the proportion of outpatients examined and the positivity to evaluate detection of suspects (less than 0.5 percent positive observed in a polyclinic).
- Insufficient use of available information on trends related to smear conversion and treatment outcomes to monitor program effectiveness and to take corrective actions.
- Excessive hospitalization; very limited use of the polyclinics and hospital outpatient services for ambulatory treatment.
- Lack of program supervisors at all levels to ensure compliance with national guidelines (also lacking) and quality of care, and to complement training.

Conclusions and Recommendations Resulting from the Evaluation

Conclusions

- The PATH strategy has shown to be appropriate and the changes observed in the pilot areas for DOTS implementation are substantial in comparison with the status of the new areas selected for expansion and with the previous situation as described in national assessments and reports.
- The impact on national policy change has been much more limited, due to the lack of a TB program counterpart in the MOH and resistance from specialists to revise

current practices, simplify procedures, and implement monitoring. Although formal coordination groups have been established, the information exchange and participatory decision-making is insufficient. Major factors are the absence of a TB management unit with the MOH—essential for program sustainability, coordinating and monitoring activities, and coordinating with the cooperating institutions—and the absorption of some of the roles of the MOH by specialized institutions and experts. Strong leadership is needed from the MOH to make decisions, utilizing a full-time TB control team plus a technical advisory group of recognized specialists with hands-on experience in DOTS implementation in Ukraine, supported by the international partners.

- Coordination among the external partners to support TB control policy changes is essential, particularly now that the MOH has given priority to health reform. Major policy changes include the abolition of obsolete laws and regulations (such as screening of the general population and mandatory hospitalization); changing the system of financing TB hospitals according to the number of beds; and redefining the functions of existing hospitals and separating their role in TB patient management from other reasons for hospitalization. A comprehensive guide for TB control activities, including policy (DOTS), technical (such as standard treatment regimens), and operational components (recording, reporting, training, supervision and monitoring), is indispensable to avoid the current uncertainty of field staff regarding procedures.
- HIV/TB co-infection is the main challenge for the future. To meet this challenge, control programs should be closely coordinated. The TB program includes offering voluntary HIV testing and counseling (VCT) to all patients. This should be complemented with referral for antiretroviral treatment (ART) when indicated, and possibly, co-trimoxazol prophylaxis. The HIV program should intensify early detection of TB cases (all forms) and provide INH prophylaxis (six months of INH) to those without active TB as part of the package of care. New, confirmed TB patients should constitute a group for regular HIV infection surveillance.
- The level of financial support from USAID to PATH seems adequate. However, the continuity of support is indispensable to achieve full implementation of DOTS and ensure sustainability and impact of the strategy.

Recommendations

To USAID:

- Maintain support to PATH for the current project and consider expansion of the project after 2006 to consolidate the progress achieved.
- Promote close coordination between external partners (USAID, WHO, PATH, and World Bank) to obtain political commitment and support implementation of DOTS as a national policy, with priority to ownership of the program, establishment of a TB management unit in the MOH, and abolishment of obsolete regulations.

To PATH:

- Coordinate with WHO to support the MOH in establishing a TB management unit (first component of the DOTS strategy), to abolish obsolete laws and regulations (mass screening, mandatory hospitalization), and to prepare comprehensive TB program guidelines (policy, technical and operational).
- Support a joint national TB program evaluation and the preparation of a new national medium-term TB plan of action.

- Support retraining and supervision in the pilot areas to ensure strict compliance with standard procedures and recording and to achieve model results, monitoring progress through the trends in smear conversion and treatment outcomes. In particular, analyze the reasons for deterioration of the outcomes in the Donetska Oblast and test corrective actions, monitor the quality of medical diagnosis (proportion of cases diagnosed that were smear positive), and support quality control of smears through re-reading of a sample of slides.
- Support quality control of smear examination by re-reading a sample of slides (particularly negative slides in polyclinics); obtain data on trends of the number of patients examined for diagnosis and the positivity rate for each oblast.
- Support operational research (cost-effectiveness of reading 300 fields, doing several cultures, the real proportion of adults with cough over three weeks attending general health facilities for any reason, and of long-term hospitalization).
- Continue training and DOTS expansion. Data on the prevalence of MDR is important but must wait for the development of capacity in one of the laboratories and the capacity of the national program to select a representative sample of patients.
- Maintain and expand support to DOTS in additional oblasts, monitor outcomes through quarterly analysis of smear conversion, and take rapid corrective actions.

PATH's Response to the Midterm Evaluation Recommendations

Recommendation: Coordinate with WHO to support the MOH in establishing a TB management unit (first component of the DOTS strategy), to abolish obsolete laws and regulations (mass screening, mandatory hospitalization), and to prepare comprehensive TB program guidelines (policy, technical, and operational).

Response: To support the MOH in developing a fully functional National TB Program, including the revision of key legislation and policies, PATH is cooperating closely with WHO, USAID, the World Bank, and the Futures Group's Policy Project. PATH was a key participant in a series of meetings with key stakeholders regarding the draft NTP plan for 2006–2010. PATH, along with other international agencies, submitted in writing to the MOH its main comments and concerns regarding the existing draft. Further, PATH staff participated in a meeting with Deputy Minister Rybchuk to discuss next steps regarding finalization of the new program. Finally, PATH was instrumental in the establishment of a country coordinating group on TB, which is likely to evolve into a more formal country coordinating mechanism for TB over the next year. PATH was elected by its peer organizations to sit on the coordinating group, representing the international NGO constituency in Ukraine. This body is expected to be influential in the development of the new NTP plan. Unfortunately, with President Yushchenko's recent dismissal of the government, the Minister of Health and his two key deputies have been replaced. It is currently unclear to what extent the new Minister and deputies will be supportive of DOTS implementation.

Recommendation: Support a joint national TB program evaluation and the preparation of a new national medium-term TB plan of action.

Response: A key outcome of the consultations and meetings noted above has been that the MOH has agreed to participate in a joint national TB program review, with the stated outcome of revising the proposed 2006–2010 plan of action. PATH, in collaboration with WHO, the World Bank, Policy Project, and USAID, will be heavily involved in organizing

this assessment, which is now tentatively scheduled for January 2006. We hope that recent political changes will not negatively affect these plans.

Recommendation: Support retraining and supervision in the pilot areas to ensure strict compliance with standard procedures and recording and to achieve model results, monitoring progress through the trends in smear conversion and treatment outcomes. In particular, analyze the reasons for deterioration of the outcomes in Donetska Oblast and test corrective actions, monitor the quality of medical diagnosis (proportion of cases diagnosed that were smear positive), and support quality control of smears through re-reading of a sample of slides.

Response: Following the midterm evaluation (MTE) recommendations, PATH has reviewed its MIS training curriculum to enhance the analytical skills of oblast-level TB statisticians for TB program monitoring. Specifically, PATH has added sessions on analysis of individualized data to identify risks and predict likely treatment outcomes, as well as for problem identification and strategic planning. Further, MIS implementation protocols were clarified to ensure proper use of indicators, which include indicators on treatment monitoring and outcomes. In addition, a team of MIS field coordinators was recruited and trained on the revised M&E tool, and further trainings are planned for the coming months to strengthen monitoring of outcomes and corrective actions taken.

Finally, PATH has developed and will help implement the following recommendations at the oblast level to address key, ongoing challenges regarding problem identification and follow-up action:

- Facilitate and assess effectiveness of providing social and monetary support for previously treated TB cases (second category) during the continuation phase.
- Strengthen coordination mechanisms among HIV and TB programs, especially regarding clinical care and surveillance.
- Strengthen HIV prevention and detection among TB patients (HIV testing and counseling; HIV prevention and ART for TB/HIV patients).
- Improve detection and treatment of TB among PLHA (active TB case detection and treatment of latent TB infection [LTBI]).
- Assess readiness to implement DOTS-Plus.

Recommendation: Support quality control of smear examination by re-reading a sample of slides (particularly negative slides in polyclinics); obtain data on trends of the number of patients examined for diagnosis, and the positivity rate for each oblast.

Response: Consistent with the MTE recommendations regarding laboratory strengthening, PATH is now working with Donetska Oblast TB Hospital specialists to continue implementing an external QC system that requires re-reading positive and a portion of negative AFB smear microscopy slides stained by Zeiss-Nielsen.

Recommendation: Support operational research (cost-effectiveness of: reading 300 fields, doing several cultures, the real proportion of adults with cough over three weeks attending general health facilities for any reason, and of long-term hospitalization).

Response: Due to questions raised by PATH and its consultants, the MOH has recently issued a new order that lowers the number of required fields to be read from 300 to 100 per slide. As for the other topics, PATH is currently considering the cost and time requirements

to conduct such studies to determine their feasibility. It likely will not be possible to conduct new research with existing CSHGP funds; however, new funds being accessed through TB TASC may be sufficient to support one to two studies.

Recommendation: Continue training and DOTS expansion. Data on the prevalence of MDR is important but must wait until the development of capacity of one of the laboratories and the capacity of the national program to select a representative sample of patients.

Response: PATH is currently accelerating its trainings for primary health care providers to accelerate DOTS expansion. Regarding MDR surveillance, data collection on MDR has already been initiated among new cases in Donetsk Oblast. Expanding MDR surveillance will be contingent on factors noted above.

Recommendation: Maintain and expand support to DOTS in additional oblasts, monitor outcomes through quarterly analysis of smear conversion, and take rapid corrective actions.

Response: PATH's laboratory specialist, Dr. Tamara Ivanenko, is a key member of an MOH working group that is developing legislative and policy documents that will guide DOTS expansion in additional oblasts. Specifically, the working group is focusing on legislation to support the establishment of a TB laboratory network, to develop regulations and methodological recommendations on laboratory QC and state sanitary rules, to supplement reporting and recording forms on TB, and to develop national guidelines on TB control. Further, as noted above, PATH's MIS specialist, Dr. Andrei Dadu, is working closely with oblast-level data analysts to strengthen monitoring of outcomes and develop action plans to correct identified problems.

PATH's Action Plan and Revised Timeline for Year 3 can be found in Annex B.

Assessment of Progress Toward Achievement of Program Objectives

Technical Approach

This project aims to improve the capacity for DOTS-strategy expansion by advocating for political support; strengthening TB diagnostic capacity and quality control procedures for smear microscopy, culture, and drug sensitivity testing; strengthening TB surveillance capacity; improving provider capacity; and increasing public awareness and patient support. The project is currently active in Donetsk, Dnipropetrovsk, and Kharkivsk Oblasts, and Kyiv and Sevastopol Cities. This is a 100 percent TB project. The general program strategy focuses on close collaboration with key national and oblast-level stakeholders, as well as other international agencies such as WHO, the World Bank, and the Futures Group's Policy Project to support the Government of Ukraine to adopt internationally recommended approaches to TB control based on DOTS.

Progress by Intervention Area

A table listing the progress by intervention area can be found in Annex C. Further description is as follows.

Objective 1: Improve capacity for DOTS expansion within Ukraine by advocating for political support for DOTS at all levels of government, including facilitating the development of an appropriate legislative base in support of newly introduced TB control approaches and by assisting the government with DOTS "expansion preparedness" to pilot sites.

In collaboration with national and international stakeholders and partners, PATH has accomplished the following activities as part of its TB control policy and advocacy reform efforts:

Development of TB Control Legislative and Policy Documents

PATH, in collaboration with the MOH and the F. G. Yanovsky Institute of Tuberculosis and Pulmonology (ITP), established a Policy and Advocacy Consulting Group (PACG) to identify and prioritize necessary revisions or additions to a wide range of TB control legislative and policy documents. After consultations with leading TB specialists, politicians, health authorities, and international agencies such as WHO, KNCV, USAID, and the World Bank, the PACG decided to focus on two main activities. First, the group focused on improving the legislative base that dictates the state sanitary norms for TB health care service activities and epidemiologic surveillance. Second, the PACG has been working on developing recommendations for the new National TB Control Program for 2006–2010.

With regard to the development of state sanitary norms and epidemiologic surveillance, PATH is facilitating the development and/or revision of the following documents:

- State sanitary norms guiding the organization and maintenance of TB facilities.
- State sanitary norms guiding ongoing and emergency control of TB outbreaks.
- Methodological recommendations regarding epidemiologic surveillance.
- Field standards on sterilization and disinfection of medical equipment, supplies, and biohazardous material.
- Regulations regarding microbiological diagnostic laboratories.
- State sanitary norms guiding organization, maintenance, and job safety of microbiological diagnostic laboratories.
- A ministerial order regarding TB prevention among medical personnel in TB facilities.

In August 2005, drafts of these documents were sent to the MOH and ITP for review. At the last PACG meeting held in September 2005, Deputy Minister of Health, V. Rybchuk, proposed that the documents be finalized by early November for review and approval by the third roundtable meeting on TB control. PATH is currently preparing for this meeting.

With regard to development of recommendations for the new National TB Control Program for 2006-2010, as a result of PACG discussions, PATH co-convened a national symposium on the proposed program which was held in May 2005 in Kharkiv with the MOH and the Kharkivsk Oblast TB Dispensary. Subsequently, PATH and other international partners proposed that the MOH invite national and international experts to conduct a national assessment of the TB program, with the goal of finalizing a new NTP plan. The assessment is currently slated for January 2006 and will focus on evaluating the effectiveness of current TB control efforts; identifying strengths, gaps, and constraints; and developing a technically sound NTP plan for the coming five years. A further goal will be to identify strategies for

optimizing the integration of a national TB control plan into overall health care system reform, as well as ensuring consistency with the DOTS approach, and more broadly, with the Millennium Development Goals.

Development of TB Proposal to Global Fund to Fight AIDS, TB, and Malaria (GFATM)

PATH was significantly involved in providing assistance to the MOH to develop a round-five proposal on TB for the GFATM. As part of this process, a series of meetings was convened that led to the establishment of a National Coordination Group on TB. PATH, represented by Dr. Katya Gamazina, was elected to sit on the Coordination Group as the international NGO constituency representative. Although the proposal was not submitted, significant progress was made in building consensus regarding the development of a new National TB Plan.

Collaboration with International Partners

PATH continued its close collaboration with the WHO Office for TB Control in Ukraine. Currently, PATH and WHO staff are finalizing a joint plan to expand DOTS implementation to three additional regions within the country: Crimea, Zaporozhye, and Kherson Oblasts.

During the first and the second years of the project, PATH continued to cooperate with KNCV until the conclusion of KNCV's project in April 2005. Both PATH and KNCV participated in quarterly steering committee meetings, meetings of working groups on developing data reporting and recording forms, a study tour to Mariupol City and Donetsk Oblast organized for TB specialists from Kyiv City, as well as roundtables dedicated to World TB Day. The KNCV TB Team used the information, education, and communication (IEC) materials developed by PATH for dissemination within Kyiv. Further, PATH supported six officials, representing Dnipropetrovsk, Donetsk, and Kharkiv Oblasts, Kyiv and Sevastopol Cities, and the ITP, to attend the final conference on KNCV's project, convened in Kyiv in April 2005.

Project Technical Advisory Group (TAG) and Annual Stakeholder Meetings

To ensure effective coordination of project activities, approximately 40 people representing PATH's key local partners and stakeholders comprise the project's TAG, which meets annually. The function of this group is to discuss project progress, develop proposals to improve project implementation, and assist PATH in overcoming barriers to progress. TAG members suggest topics for discussion during the annual stakeholders' meeting when the annual progress report is presented.

The second roundtable meeting was originally scheduled for September 2004 but was postponed until April 2005 due to political events and the "Orange Revolution." During the April meeting, the following issues were addressed: (1) progress on project implementation during 2004 and the plan of activities for 2005, (2) discussion of presentations and proposals for cooperation to increase efficacy of project implementation in 2005, and (3) lessons learned from implementation of DOTS in initial pilot sites. Members of the World Bank assessment mission also took part in the roundtable meeting.

Selection of New Pilot Sites

As noted previously, with the additional funds from the USAID mission in Ukraine for fiscal year 2005, PATH expanded the original CSHG-supported program to include three additional pilot oblasts. PATH worked closely with national (MOH and ITP) and local health authorities, as well as KNCV, WHO, USAID, and the World Bank, to move the DOTS scale-up plan forward in Ukraine and to develop specific criteria for selection of “expansion oblasts.” Criteria included the following and were rated on a weighted point system:

- Degree of local political support among regional health authorities for the WHO-recommended approach to TB control.
- Level of interest among local TB hospital authorities in being involved in project activities.
- Degree of participation of local health care staff in workshops related to DOTS and/or in international technical assistance projects (WHO, USAID, and others).
- Efforts already underway by local TB health facilities to apply the DOTS strategy.
- Local TB health facilities laboratories are equipped or will be provided with modern laboratory equipment in the near future by the World Bank-funded TB/HIV/AIDS control project.
- Local TB health facilities are using the WHO data recording and reporting system (DRRS) and have or will be provided with computers in the near future by the World Bank project.
- Primary health care and family doctors are involved in TB case detection. Local TB health facilities collaborate with HIV/AIDS centers.
- Local health authorities have experience collaborating with nongovernmental organizations (NGOs) concerning patient and community support.
- The incidence and mortality rates of TB and HIV/AIDS are high relative to other regions of the country.
- Regional peculiarities exist that distinguish the site from others in terms of the presence of ethnic minorities, refugees and illegal migrants, prison TB hospitals, and others.

In addition to reviewing existing data, a questionnaire was developed and disseminated to 25 oblasts. Based on responses received, combined with the criteria noted above, a shortlist of five oblasts was developed. Site visits to these oblasts to finalize the list had to be postponed until late January due to the Orange Revolution. Ultimately, Dnipropetrovsk and Kharkiv Oblasts and Sevastopol City were selected.

Execution of Memoranda of Understanding (MOUs)

After extensive consultative discussions, PATH was finally able to sign an MOU with the ITP. The delay may be attributed to the strong and well-known resistance to DOTS on the part of Prof. Yuriy Feschenko, ITP Director. PATH also signed MOUs with the oblast health administrations in the expansion sites in April and May 2005.

Additional MOUs with the MOH, World Bank TB/HIV/AIDS Control Project, and the WHO Office for TB Control in Ukraine are still in process. The main reasons for the delay in signing these additional MOUs are as follows:

- MOH: A general MOU between PATH and the MOH is currently being renewed and the TB component will be part of this new MOU.

- World Bank: The MOU will be signed once the Ukrainian Government has approved the World Bank pilot oblasts for 2005.
- WHO: This MOU will be renewed once WHO's new TB control project in Ukraine, supported by the USAID Mission, has been initiated.

Improved Access to Literature on International TB Control

Results from baseline data indicated that many TB providers, as well as TB and general health authorities, lack up-to-date information on the WHO-recommended strategy, specifically regarding diagnosis and treatment standards and global progress in combating the disease. Since the start of the project, PATH has been providing translated abstracts and articles to TB specialists affiliated with the MOH, ITP, and medical universities, as well as to TB health care providers in all oblast TB dispensaries and health authorities. In addition, PATH continues to expand its TB-info listserv and has supported access to the internet in its pilot sites, enabling them to access the listserv, among other resources. Moderated by PATH, the listserv provides new materials, articles, and documents from national and international sources on a weekly basis. An electronic TB library, which contains more than 1.5 GB of data, was distributed on CD-ROM.

Objective 2: Improve the quality of TB diagnostic services in at least two oblasts by designing, implementing, and building capacity to sustain QC procedures for smear microscopy, culture, and drug sensitivity testing, and if possible, evaluating improved technologies for TB case detection.

During the second year of the project, PATH's key accomplishments related to improving the quality of TB diagnostic services include the following:

Development of Methodological Recommendations

PATH collaborated with the P. Shupik Kyiv Medical Academy of Post-Graduate Education (KMAPGE) laboratory specialists to develop methodological recommendations, entitled "TB Laboratory Diagnostic Quality Assurance Program: Sputum Examination for TB by Direct Microscopy," for general health care (GHC) clinical diagnostic laboratories. It is important to note that until now, no national recommendations on TB diagnosis QA and QC have been developed. Therefore, the guidelines developed by PATH and local partners constitute the only comprehensive, ready-to-use document on this topic in the country. Donetsk Oblast health authorities have approved these guidelines, and they formally recommended that they be published and widely disseminated among GHC facilities throughout the Donetsk Oblast. Highlights of these recommendations include a description of optimal physical conditions of the laboratory, staining methods, microscopic examination of sputum smears, recording and reporting results, QA, and other key components of the sputum microscopy process. In addition, the guidelines include a description of key biosafety measures necessary for safe practice in laboratories where sputum samples are being handled.

The guidelines also were reviewed during trainings of 51 laboratory specialists from six oblasts at the KMAPGE and were very well received. Many specialists were not familiar at all with DOTS and the WHO-recommended approaches to TB diagnostics based on direct-smear microscopy. The topic of biological safety generated particular interest among the participants and has formed the basis of the new state sanitary norms on safety described under Objective 1. KMAPGE (supervised by the MOH) also plans to use these guidelines as

the basis for in-service training for medical personnel. This will greatly enhance the dissemination of the recommendations throughout the country's health facilities.

Development of Laboratory QA Training Materials and Curricula

PATH finalized a set of training materials and curricula in collaboration with consultant Ms. Carolyn K. Wallis and in cooperation with laboratory specialists of KMAPGE. The curricula comprises guidelines for training of trainers (TOT) and an adapted version for rollout training. The materials include handouts, PowerPoint slides, overhead transparencies, and a video. Much of the content was based on existing materials from WHO and the U.S. Centers for Disease Control and Prevention (CDC) and adapted for conditions in Ukraine. The objective of these QA trainings is to enhance knowledge and proficiency in conducting smear microscopy, primarily focusing on the QC aspects. The workshops comprise classroom and laboratory components and cover all aspects of smear microscopy internal and external QC, including development of a QC manual that outlines the general QC approaches and procedures for equipment, media, reagents, susceptibility testing, and personnel in the laboratory. Standard operating procedures, accurate reporting of results, self-assessment, panel testing, and blinded rechecking of results also are addressed. In addition, participants are trained in accurate reporting of results.

Initiation of Laboratory QA Training

PATH developed a detailed training schedule for laboratory specialists in Donetsk Oblast, which was approved by the Donetsk Oblast Administration in September 2004. During this reporting period, eight three-day trainings were conducted for level I and II laboratory specialists from Donetsk City and Donetsk Oblast; 115 specialists were trained. Thus, all trainings planned for Donetsk Oblast were successfully conducted. As noted above, on April 26–27, 2005, a two-day training also was conducted for 51 lab specialists from six oblasts at KMAPGE. Collaboration with national laboratory specialists from the ITP continues to improve, and several training sessions have now been jointly conducted by PATH and ITP experts. These training courses included content on external quality control of culture and QC of drug sensitivity tests. In addition, in May 2005, PATH and the ITP jointly conducted a five-day TOT for 13 specialists from the Dnipropetrovsk and Kharkivsk Oblast TB dispensaries and the Sevastopol, Kyiv, Mariupol'''' and Gorlovka (Donetsk Oblast) City TB dispensaries.

Establishment of Protocol for Panel Testing

With supervision from PATH's TB team, a protocol for external QA using panel testing, as well as a set of panel testing smears, was developed by local laboratory consultants affiliated with the Donetsk Oblast TB Clinical Hospital and in cooperation with laboratory specialists of the Donetsk City TB Dispensary. All 20 Donetsk City TB microscopy laboratories have received the protocols, containers for glassware storage, and panels (of a batch of six smears) for the first stage of external QA proficiency testing. The first external QA was conducted in September 2004, and by April 2005, 70 level I-II laboratories had taken part. As planned, all the laboratories got the panels, and the results were sent to the clinical laboratory of the Donetska Oblast TB Hospital. For a report of the panel testing results, please contact PATH.

Laboratory Follow-up and Monitoring Plan

In cooperation with WHO and Dr. Elena Yann, head of the Donetsk Oblast TB Hospital laboratory, PATH developed a plan and schedule for external QC visits and monitoring. These monitoring visits focus on observing all relevant QC procedures for smear microscopy. The goal of this monitoring is to produce objective, valid, and reliable data on smear microscopy performance. In addition to visiting laboratories, treatment effectiveness is also reviewed. The laboratory is currently unable to do this monitoring on its own due to difficulties with transportation, lack of fuel, and shortages of specialists; therefore, PATH continues to provide assistance and will advocate for local support as PATH's role is phased out.

Guidelines for Introduction of QC of Culture and Identification Tests for MTB

PATH held consultations with laboratory specialists affiliated with the ITP, the National Reference Laboratory, and the KMAPGE focusing on the development of national guidelines for QC of culture and identification tests for MTB at selected level II and III laboratories. This activity will be finalized next year in accordance with the project timeline.

PATH and ITP specialists are also collaborating on the development of training materials addressing organizational and QC issues related to culture and drug sensitivity testing. Much of the content is based on existing materials from WHO and the CDC and is adapted for conditions in Ukraine.

Potential Evaluation of New TB Diagnostic Test or Approach

During the reporting period, PATH has continued to gather data on the performance needs, required level of simplicity, and acceptability of new diagnostic approaches. The results of this investigation are that, while some rapid serological diagnostic tests exist and providers are interested in using them, the per-test costs are unaffordable for the Ukrainian health system. For example, PATH looked into the QuantiFERON-TB Gold test, but the cost is estimated to be US\$10 to US\$35 per specimen, depending on volume. The VScan TB kit also was explored, but per-test costs are approximately US\$2.50, which is still out of range for government-supported laboratories. PATH currently continues discussions with the Foundation for Innovative New Diagnostics (FIND), based in Geneva.

Objective 3: Improve use of monitoring and surveillance data for TB program management by introducing and institutionalizing methods to monitor program performance at all health service levels.

Key accomplishments in improving the use of monitoring and surveillance data for TB program management are as follows:

Revisions to Existing Recording and Reporting Forms

PATH has worked diligently with WHO, regional and national health authorities, the MOH/World Bank project implementation unit, and KNCV (until the end of its project) to develop a standardized TB MIS based on the WHO-recommended approach. As part of this effort, PATH staff reviewed all pertinent legislation concerning the TB MIS and followed up with negotiations with local TB authorities and local and international partners. Ultimately, a

set of revised forms was introduced. These forms are currently in use for registration, case management, and reporting in all project sites except Kyiv City, where forms developed by KNCV and the ITP are still being used. As part of ongoing efforts to enhance cooperation, PATH's MIS specialist participated in numerous meetings with World Bank project implementation unit coordinators. Throughout the first half of 2005, PATH was engaged in difficult discussions regarding the standardization of the forms, with the World Bank in Kyiv and ITP insisting on excessive numbers of forms and extraneous content. Common agreements concerning the total number of forms were finally achieved, but negotiations and consultations regarding design and content still continue. Outstanding concerns include case definition at registration and treatment process monitoring and outcomes.

Surveillance Tools and Technical Support

Two components of the TB MIS tool were addressed during the reporting period: the development of surveillance tools and a plan for technical support. The surveillance tools include revised forms, computer hardware, electronic communication using the internet, and computer software to allow for an electronic MIS program. Technical support included the development of guidelines for the use of forms and training.

Training in Use of New TB EMIS

PATH/USAID funding has been instrumental in establishing a TB Training Center in the Donetsk Oblast TB Hospital to train data entry clerks and data analysts, as well TB doctors and laboratory specialists. The center includes two rooms and eight workstations equipped with computers connected to a local area network. Two types of users use the TB EMIS at three territorial-administrative levels: data entry clerks, who are present at the rayon, city, and oblast level (depending on the site), and data analysts, who are present at all three levels. The PATH team, in collaboration with local partners, determined who should be trained during the first set of TB EMIS workshops at the oblast and national levels. The TB EMIS training plan was divided into three stages: training of oblast coordinators, TB EMIS expansion, and follow-up.

The first stage of training was held in cooperation with WHO, the Donetsk Oblast TB Hospital, and the Network Academy "AMI." Two categories of TB service staff (data entry clerks and TB control analysts) totaling 31 people were trained.

The second stage of training included TB EMIS users from 13 administrative units (rayons/cities) of Donetsk Oblast, Sevastopol City TB Dispensary, and Kharkiv Oblast TB Dispensary. The training curricula included the following content:

- An overview of the global TB situation as well as the situation in Ukraine.
- A review of computer functions.
- A review of the surveillance system in public health (based on CDC's lessons) related to TB control.
- Information on TB epidemiology based on Hans Reider's book, *Epidemiologic Basis of TB Control* (risks of infection, disease, and outcome).
- The data reporting and recording system based on the new forms.
- The methodology for monitoring and evaluation of the National TB control program at the rayon and oblast levels.
- Information on TB database entry and use of the analysis modules in the TB EMIS.

- Information on database management (database backup, sending-receiving), software installation, and updating techniques.

All trainings were well received, with participants noting the professionalism of the courses.

Introduction and Use of the New TB EMIS

PATH staff supported the installation of the TB EMIS on 15 computers (13 in the field and 2 at the Donetska Oblast TB Dispensary) provided by WHO in Donetsk Oblast. The next training workshops are scheduled for October–November 2005. These workshops will focus on the use of the TB EMIS in daily practice and will address the recommendations made in the midterm evaluation report.

Tools for Monitoring of Diagnostic Efficiency and Effectiveness of New TB Screening Methods and Strategies

Tools and indicators for routine monitoring of diagnostic efficiency and effectiveness of existing and new TB screening methods and strategies have been developed and were presented during the MIS trainings for data entry clerks and TB control analysts of Donetsk and Kharkiv Oblasts and Sevastopol City.

Coordination of Information Systems for TB and HIV Programs

To ensure that TB-HIV co-infection surveillance eventually can be linked, and in order to improve referral systems among facilities initiated, PATH initiated the introduction of an addition to the TB-01 Form (where TB risk factors are listed) to include the HIV status of the patient. Existing AIDS legislation in Ukraine requires that all data regarding a patient's HIV status be kept confidential. Therefore, the DRRF Revision Discussion Group decided that this attachment should include no personal identifiers but rather use a numeric code. The form, with the attachment, has been approved by local health authorities of Donetsk and Kharkiv Oblasts and Sevastopol City and is now being used by TB health facility staff.

In April 2005, PATH specialists Katya Gamazina and Andrei Dadu participated in a training course organized by the WHO Collaborating Centre for Tuberculosis and Lung Diseases and the S. Maugeri Foundation held in Tradate, Italy. The course covered topics such as the epidemiology of TB, HIV and TB/HIV; TB and HIV/AIDS control and TB/HIV program collaboration; surveillance of TB and HIV/AIDS; clinical management and service delivery for TB and HIV/AIDS; capacity building for TB/HIV; TB/HIV monitoring and evaluation; and costing and budgeting for TB/HIV program planning. A report and draft work plan for TB-HIV collaborative activities for Ukraine was developed and presented at the course.

Objective 4: Reduce diagnostic delay, increase case detection, and improve adherence to TB treatment by stimulating timely and appropriate health-seeking behavior for TB symptoms; implementing specific community mobilization strategies; increasing awareness and understanding of TB transmission, symptoms, treatment, and cure among the general public, as well as among specific populations at risk; and introducing culturally sensitive treatment support strategies for TB patients and their families.

Completion of Comprehensive Behavior Change Communication (BCC) Strategy for TB Control

In fall 2004, based on the results of the baseline work, PATH finalized its BCC strategy, which will continue to guide activities for the duration of the project.

IEC Materials Development Workshops

In October 2004, PATH BCC specialists Dr. Natalya Zaika and Ms. Svitlana Okromeshko conducted a training workshop on IEC message and materials development for 20 local health education and medical specialists in Donetsk Oblast. The goal of the workshop was to increase local capacity to develop and maintain public information dissemination. Specifically, participants were trained in the use of formative research to develop an IEC strategy and to design, pretest, produce, and disseminate key materials and messages. The PATH TB team collaborated with local health authorities to choose participants for the workshop.

Development of Educational Materials

Based on the KAP survey results, PATH reviewed existing IEC materials for the public and developed new designs for the poster, leaflet, and brochure for the general population. With assistance from Donetsk Oblast Health Center specialists trained as part of the previous WHO TB project, PATH held the first round of pretesting among 96 people in Donetsk Oblast. Specifically, PATH pretested a three-fold brochure for the general population and a 16-page booklet for TB patients and families. Two additional pretests were conducted during January-February 2005. Based on the pretest results, the patient booklet was revised and a draft of the brochure for TB patients was developed with local partners. Both were reviewed and approved by TB specialists in Donetska Oblast and Kyiv City. The brochure was then pre-tested among patients and family members (46 people). Pre-test results indicated that the materials for patients and families were useful and that the information was easy to understand. All participants highlighted the necessity and urgency of such information to help them better understand TB and the importance of adherence to treatment.

Outreach to Homeless Populations in Kyiv City and Donetska Oblast

On September 30, 2004, PATH and KNCV/KIT co-convoked a roundtable meeting with local NGOs that work with homeless populations in Kyiv City. The goal of the meeting was to determine the most appropriate approaches for reaching homeless people with key TB information and referral contacts. As a result of this meeting, PATH and KNCV/KIT developed a specific IEC outreach strategy aimed at the homeless. The plan was finalized in November, with implementation beginning in March 2005, led by PATH.

During the last quarter of 2004, KNCV and PATH reviewed the roles of existing organizations working with the homeless (NGOs and public service) and developed subcontracts with the Kyiv City Committee of Ukrainian Red Cross Society (URCS) and Donetsk Oblast Committee of URCS. URCS was selected because the basic direction of its activities includes medical and social support of socially vulnerable people, a visiting nurses service for elderly people living alone, a network of Red Cross centers providing medical and social support, and information dissemination on various medical problems. As outlined in the work plan, PATH conducted two TOTs with URCS personnel on effective TB

communication. The main goal of this work is to improve the counseling skills of visiting nurses and volunteers to decrease of stigma towards TB patients, to provide correct information on TB, and to encourage adherence to TB treatment. The training courses were enthusiastically received. In June 2005, Dr. Alla Khabarova, Executive Director of the URCS Central Committee, asked PATH to conduct the same training for URCS project coordinators from other oblasts of Ukraine, at their expense.

In May 2005, PATH initiated the development of a model for involving the URCS Visiting Nurses Service in Kyiv City and Donetsk Oblast to carry out DOT of TB patients during the continuation phase. The main goals of this work are to determine the needs of TB patients during the continuation phase and to develop effective methods of collaboration between local NGOs and medical facilities involved in TB care and support.

Objective 5: Improve provider practices by strengthening provider capacity to diagnose and treat TB based on DOTS, improving systems to support appropriate referral of TB cases, and enhancing knowledge of and response to HIV/TB interaction, with emphasis on appropriate counseling and client-provider interaction with emerging populations at risk.

Under the current program, PATH's efforts have been aimed at improving provider practices in DOTS implementation in the pilot sites, including clinical management. PATH has been cooperating closely with WHO-trained trainers from Donetsk to expand these trainings to the new sites. Further, PATH continues to provide training to strengthen interpersonal communication and counseling (IPC/C), as well as HIV-related voluntary counseling and testing (VCT) skills to TB specialists. Key activities include the following:

Adaptation of IPC/C Curricula and Launch of Training in Donetsk Oblast

During this project period, Dr. Zaika and Ms. Okromeshko adapted the curricula and other materials for conducting training on VCT and effective communication for TB specialists. A total of five trainings were conducted in Donetsk Oblast and two in Kyiv City, involving a total of 107 TB specialists. Evaluations from the training sessions indicated that:

- The contents of the training curricula are relevant and useful for practical work.
- All training aspects are important for conducting successful patient consultations.
- The role-playing exercises were considered very helpful in developing the participants' counseling skills, as well as in stimulating and motivating a desire to change existing approaches.
- The training helped participants realize the importance of counseling as a crucial element in communication with patients and to promote informed decision-making among patients regarding TB treatment and adherence.

Modification of TB Clinical Training Curriculum

In consultation with project partners in Donetsk Oblast, and led by PATH's clinical training consultant, Dr. Oleksandr Klochkov, PATH reviewed and modified the WHO curriculum. As part of this process, PATH convened a roundtable meeting with all project partners, international collaborators, and USAID on April 21, 2005, in Kyiv. In May 2005, the DOTS Training Curriculum and DOTS Training Modules/Guidelines were finalized.

TOT and Roll-out Training on TB Diagnosis and Ambulatory Treatment Follow-up

The purpose of this training is to provide primary health care providers with training on TB diagnosis and ambulatory treatment follow-up in order to ensure readiness of the system for proper referral of patients. To select TOT participants, a questionnaire was developed and distributed among TB specialists in the pilot sites. PATH then conducted interviews with potential TOT trainees during site visits in April and May 2005, which led to the first TOT for the new pilot sites held in early June 2005. This training was led by the DOTS Training Team from Donetsk (individuals trained by WHO).

Training for TB Providers on TB Detection, Diagnosis, Treatment, and Follow-up

The first regional trainings were held during the period June to August 2005 in Kharkiv, Sevastopol, and Dnipropetrovsk. A total of eight trainings were conducted and more than 150 health providers were trained. Trainers will continue to provide DOTS implementation trainings in the new sites with PATH support and supervision. It should be noted that chief doctors of health facilities and health authorities were invited to participate in the first round of training, with the goal of informing them properly about DOTS and gaining their support.

Factors That Have Impeded Progress During Year Two and Actions Taken

Factors	Influence on Implementation Plan	Proposed Solution or Action Taken	Technical Assistance Required
<p>Presidential election on October 31, 2004, and Orange Revolution. Because many stakeholders were involved in or would be affected by the presidential election, PATH was requested to postpone the first annual stakeholder meeting.</p>	<p>Delay in conducting annual stakeholder meeting originally planned for September 2004.</p>	<p>A set of meetings took place with the MOH, ITP, Donetsk Oblast and Kyiv City health authorities, WHO, and other stakeholders to settle the issue of timing of the annual stakeholders meeting. The group agreed that it would take place at the end of November (after the presidential elections).</p>	<p>Not required.</p>
<p>Resistance of ITP authorities to any changes in approaches to TB control system in Ukraine, including DOTS implementation.</p>	<p>Policy Advocacy Consulting Group meeting was not held in July as planned.</p>	<p>PATH worked with WHO to negotiate with the ITP and MOH regarding the importance of adopting modern approaches to TB control and of having TB legislative support for such changes. MOH now has asked PATH to provide technical assistance in developing the scope for the new National TB Control Program for 2006–2010.</p>	<p>Technical assistance regarding analysis of economic issues related to TB control in Ukraine planned (PATH staff member, Dr. Christy Hanson, will lead this effort).</p>
<p>Lack of TB laboratory specialists and staff in Donetsk Oblast due to high staff turnover. This turnover occurs because of low salaries and fear of</p>	<p>Delays in implementation of external QA and monitoring in Donetsk City and Donetsk Oblast. Specific reasons for the delay include: A number of laboratory specialists trained as trainers left their jobs; it is</p>	<p>PATH continues to negotiate staffing problems with Donetsk Oblast health authorities and the TB laboratory working group members. PATH will continue to conduct trainings while other solutions are sought.</p>	<p>Ongoing efforts to streamline and appropriately target laboratory training workshops.</p>

Factors	Influence on Implementation Plan	Proposed Solution or Action Taken	Technical Assistance Required
contracting TB, due in part, to the prevalence of outdated equipment and work overload.	difficult to choose new candidates to replace them. Specialists do not have time to prepare panel of smears for QA. Often, only one specialist works in a laboratory, so it is impossible for him/her to attend two- or three-day workshops.		
Poorly equipped laboratories.	Delays in implementation of external QA. Laboratories lack funds to buy glassware and other supplies needed for external QA implementation. The ongoing renovation of the Donetska Oblast TB clinical hospital also has interfered with smooth operations of the TB laboratory as well as external QA program implementation.	PATH has procured and delivered the containers for glassware storage. Additional glassware will be purchased before the end of 2004.	World Bank TB/HIV/AIDS Project needs to proceed with purchase of new laboratory equipment as soon as possible.
Difficulties in reaching vulnerable groups (homeless people, ex-prisoners, PLHA).	The need to develop a specific strategy for homeless populations became evident through baseline research.	Collaboration with URCS, State Penalty Execution Department, NGOs working with homeless people, KNCV, and PLHA has led to the development of a specific plan for this population.	
High cost of TV and radio broadcasting of educational spots in Ukraine.	PATH lacks funds to cover the costs of regular TB mass media campaigns on popular TV and radio stations during prime time.	PATH negotiated with Donetsk Oblast health authorities and health centers regarding broadcasting on local TV and radio channels and received their support for discounted	Support of PATH and USAID in negotiations with World Bank authorities regarding fund allocation for

Factors	Influence on Implementation Plan	Proposed Solution or Action Taken	Technical Assistance Required
		or pro-bono distribution. In addition, PATH has negotiated an agreement with the World Bank whereby the broadcasting costs for the PATH-developed spots will be covered by the World Bank project.	broadcasting.
Outdated DRRFs are still used in most of the country to record TB statistical data. This recording system is not accepted by WHO.	In pilot sites, TB personnel are still required to use the old system in parallel with the new one being introduced by the PATH project and WHO.	PATH created a DRRF Revision Discussion Group consisting of MOH, WHO, ITP, and KNCV to help resolve the problem. Trainings on TB EMIS were held in several pilot oblasts. PATH expects that as more experience is gained with the new forms, health authorities will be more receptive to abandoning the old system.	Assistance from PATH experts and CDC specialists required to help promote and finalize the new TB EMIS.
Lack of and advanced age of field TB statisticians.	Delays in implementation of TB EMIS in Donetsk and Kharkiv Oblasts and Sevastopol City. Specific reasons for the delays include: A number of TB statisticians trained as trainers left their jobs; it is difficult to find new candidates. There are no specialists in the statistical department of Sevastopol City. Specialists are overloaded with routine statistical work, which can be attributed	PATH continues to negotiate staffing problems with field health authorities and the TB working group members. PATH also is providing support for cross-monitoring of project sites whereby TB statisticians from one site are used as consultants to other sites.	Assistance on promoting importance of information system for TB program M&E and decreasing number of DRRFs.

	Influence on Implementation Plan	Proposed Solution or Action Taken	Technical Assistance Required
	to implementation of the parallel DRRS.		
World Bank project implementation behind schedule: Equipment procurement has not been launched yet. Pilot oblasts for the first round of equipment have not been selected yet.	Laboratory equipment and computers for TB and health care facilities have not been provided. This has caused some minor delays in PATH's laboratory QA and MIS technical assistance schedule. Selection of expansion oblasts also was delayed with the expectation that the World Bank would clarify where it will focus implementation.	PATH staff regularly engages World Bank, MOH personnel, and WHO regarding this situation.	Not required.
Death of Dr. Oleg Karatayev, Chief Doctor for the Donetsk Oblast TB Hospital.	Dr. O. Karatayev was PATH's TB Project Coordinator in Donetsk and a principal backstop for PATH TB team activities in Donetsk Oblast.	Donetska Oblast health authorities are currently determining who will replace Dr. Karatayev.	Not required.
Location of authority over the National TB Reference Laboratory in Ukraine still undecided.	This caused difficulties during development of the methodological recommendations on the TB laboratory QA program and also resulted in delays in development of the guidelines on culture and identification tests for MTB.	PATH and WHO are in frequent discussions with the MOH and the ITP and have offered technical assistance to help organize the National Reference Laboratory.	Not required.
KNCV project delays laboratory equipment delivery to Kyiv City TB Laboratories because of custom clearance difficulties.	This resulted in a delay in implementing the laboratory QA component in Kyiv City.	Resolved. Equipment was installed in April 2005.	Not required.

Cross-cutting Approaches

Community Mobilization

PATH's main community mobilization activities have been undertaken in collaboration with URCS chapters in Kyiv City and Donetsk Oblast. Specifically, as noted earlier, PATH has provided training to the URCS's visiting nurses to conduct outreach to vulnerable populations, observe treatment, and reduce treatment default. In the coming year, this model will be extended to the new pilot sites.

Communication for Behavior Change

To ensure that the project achieves maximum effectiveness and appropriateness of all activities, the following guiding principles articulated in the strategy are now being applied:

- Content and approaches are based on findings from the formative research.
- Development of communications activities is participatory, involving members of the target populations.
- Materials and BCC activities are participatory, involving relevant international and local partners to enrich the quality of those materials and activities and avoid duplication.
- Messages and materials are pre-tested and revised prior to use.
- Curricula and other capacity building materials are developed taking into account data from the baseline survey and cultural characteristics.
- All messages, materials, and BCC activities are planned and articulated in light of Ukrainian social and cultural norms.
- The BCC strategy planned and articulated is in accordance with the goals of the National TB Program in Ukraine.
- Activities and materials are monitored and evaluated.

Please see the updated work plan and description of accomplishments to date under Objectives 4 and 5 in the previous section for further details.

Capacity-building Approach

Strengthening the PVO

PATH's local TB team continues to strengthen its ability to effectively implement the program. All specialists have had the opportunity to participate in national and regional conferences and training courses to enhance their knowledge and skills. During the last year, PATH's role in supporting the government to strengthen its national TB program has become more prominent, as evidenced by PATH's increasing involvement in key working groups and consultations. PATH clearly is viewed as a key technical resource on TB in the country and region. Further evidence includes its participation in the planning of the national TB program assessment and its role as the international NGO constituent representative on the National TB Coordination Group. PATH's technical teams routinely receive positive feedback on project activities, including training courses, materials, roundtables, and strategic input to the MOH. In September, the MOH requested that PATH assist them with developing a TB drug supply management system—again, evidence of the confidence that key stakeholders have in the abilities of the PATH team.

Strengthening Local Partner Organizations, Health Facilities, and Health Worker Performance

The primary participants in PATH's capacity-building activities include the network of TB laboratories and clinical facilities specializing in TB, GHC laboratories and polyclinics, health education centers, and URCS chapters in the target oblasts. PATH is seeing progress towards building capacity among all participants across all key objectives. For example, cadres of visiting nurses from URCS chapters in Donetsk and Kyiv City have been trained and are supporting TB patients to adhere to drug treatment by increasing the number of access points where treatment can be provided (polyclinics and URCS centers), offering food support and other incentives such as hygiene packets (provided with funds from the oblast health administration) to needy patients, and offering information and emotional support to patients and families. In the coming year, these trained nurses will share their experiences and lessons learned with their counterparts in the new target regions.

Laboratory capacity has also been dramatically improved due to the project's training on internal QC for smear microscopy, external QA using panel testing, and improved safety procedures and lab organization. Trained laboratory specialists from Donetsk and Kyiv will provide training to their counterparts in other regions in the coming year. Strengthening sputum microscopy at general polyclinics also has improved access to diagnosis.

TB specialist clinical skills are being enhanced through clinical training in the new pilot oblasts. Strengthening MOH capacity at the central level is more challenging, given the political instability and frequent turnover of ministers and deputies. Nevertheless, PATH has provided consistent support for strategic planning, realignment of TB program goals and objectives, knowledge enhancement by facilitating working groups and consultations, and improving access to up-to-date information and literature on international TB control standards.

Training

During the last year, the project has trained the following cadres of professionals:

- 107 TB specialists in VCT and effective communication.
- More than 150 TB specialists and general health doctors in DOTS implementation.
- More than 200 lab specialists in QC of sputum smear microscopy.
- More than 50 TB statistics specialists in data entry and analysis using the new electronic data recording and reporting system for TB cases.

Sustainability Strategy

Although difficult at times, PATH is committed to working with existing MOH leadership and structures across all project objectives, since the strengthening of political will in favor of DOTS is perhaps the most important element for ensuring maximum sustainability over time. In addition, nearly all Ukrainians seek health care through government facilities. For these reasons, PATH continues to focus intensively—and now in collaboration with the Futures Group's Policy Project—to encourage reform of the fundamental national and oblast-level legislative base in support of DOTS. PATH also has forged important collaborative relationships with other key groups working to improve TB control, such as WHO and the World Bank, so that our collective efforts might speed the advance of DOTS acceptance at the national level, as well as accelerate implementation in the regions. In addition, PATH has sought to prepare local trainers in all technical areas so that local capacity will continue to be available after the project has ended. Examples of local ownership and investment include Donetsk's commitment to supply food packages and hygiene kits to low-income TB patients.

This is important as the project specifically decided against supplying such support due to sustainability concerns. Finally, PATH is closely collaborating with the KMAPGE and the Kharkiv Medical Academy of Postgraduate Education to adopt DOTS-related curricula, as these institutions are used by the MOH to systematically organize postgraduate (in-service) courses for doctors, nurses, and medical laboratory staff.

It is important to note that the USAID Mission in Ukraine has recognized the importance of longer term support to Ukraine to successfully adopt the DOTS strategy. The Mission has made additional investments in the program—\$1 million in 2005 through CSHGP, as well as an additional \$1 million through TB TASC for fiscal year 2006. Further investment through fiscal year 2010 is likely. Given this situation, “phase-out” plans per se have not yet been developed—although, as described, each activity has been designed with maximum sustainability in mind.

Program Management

Planning

All relevant governmental, international, and local entities have been involved in planning. For example, for fiscal year 2006 activities, PATH, the World Bank, Futures Group, USAID, and senior MOH officials met to outline key priorities and determine roles and responsibilities. Further, all proposed plans, as well as progress to date, are discussed at our annual stakeholders meetings and quarterly at various conferences, symposia, and roundtables at the national and regional levels. The program’s objectives are clearly understood by all parties. Support for some of the DOTS-related interventions is still conditional—for example, MOH authorities still insist on hospitalization periods that are longer than required by international standards—but MOH officials are not impeding our overall ability to implement DOTS. Changes to the work plan have been detailed in previous sections of this report and have been completely supported—and in some cases, driven, by the USAID mission and local partners. Factors affecting progress towards objectives have also already been presented.

Staff Training

Local PATH staff based in Kyiv have participated in the following trainings, meetings, and conferences:

- 35th International Union Against Lung Diseases Annual Meeting, and 5th DOTS Expansion Working Group Meeting, October 28–November 1, 2004, Paris, France. (A. Bishop, K. Gamazina, A. Tsarenko).
- Sondalo Course for Programme Managers on TB/HIV Collaborative Activities, April 9–13, 2005, Sondalo TB Hospital “E. Morelli,” Tradate, Italy (K. Gamazina and A. Dadu).
- KNCV and Kyiv City Health Administration TB Control Project, Final Conference, April 2005, Kyiv, Ukraine (all staff).
- Flagship Summer School on Health Sector Reform and Sustainable Financing, August 28–September 2, 2005, Budapest, Hungary (K. Gamazina and A. Tsarenko).
- WHO TB Control Project in Donetsk, Final Conference, September 22–23, 2005, Donetsk, Ukraine (all staff).
- WHO/European Union (EU) Meeting on TB Collaboration in the NIS Region, Copenhagen, Denmark, November 17–21, 2004 (N. Zaika).

- CDC Epidemiology course, Atlanta, Georgia, September 24–October 25, 2004 (A. Dadu).

Dr. Tsarenko, Dr. Gamazina, and Dr. Dadu also completed the PATH-required training course on the protection of human subjects as part of research.

During the midterm evaluation, Dr. Fabio Luelmo provided important feedback to the team on its performance and met with each technical specialist to review their components. This input was considered extremely valuable by the entire team.

Supervision of Program Staff

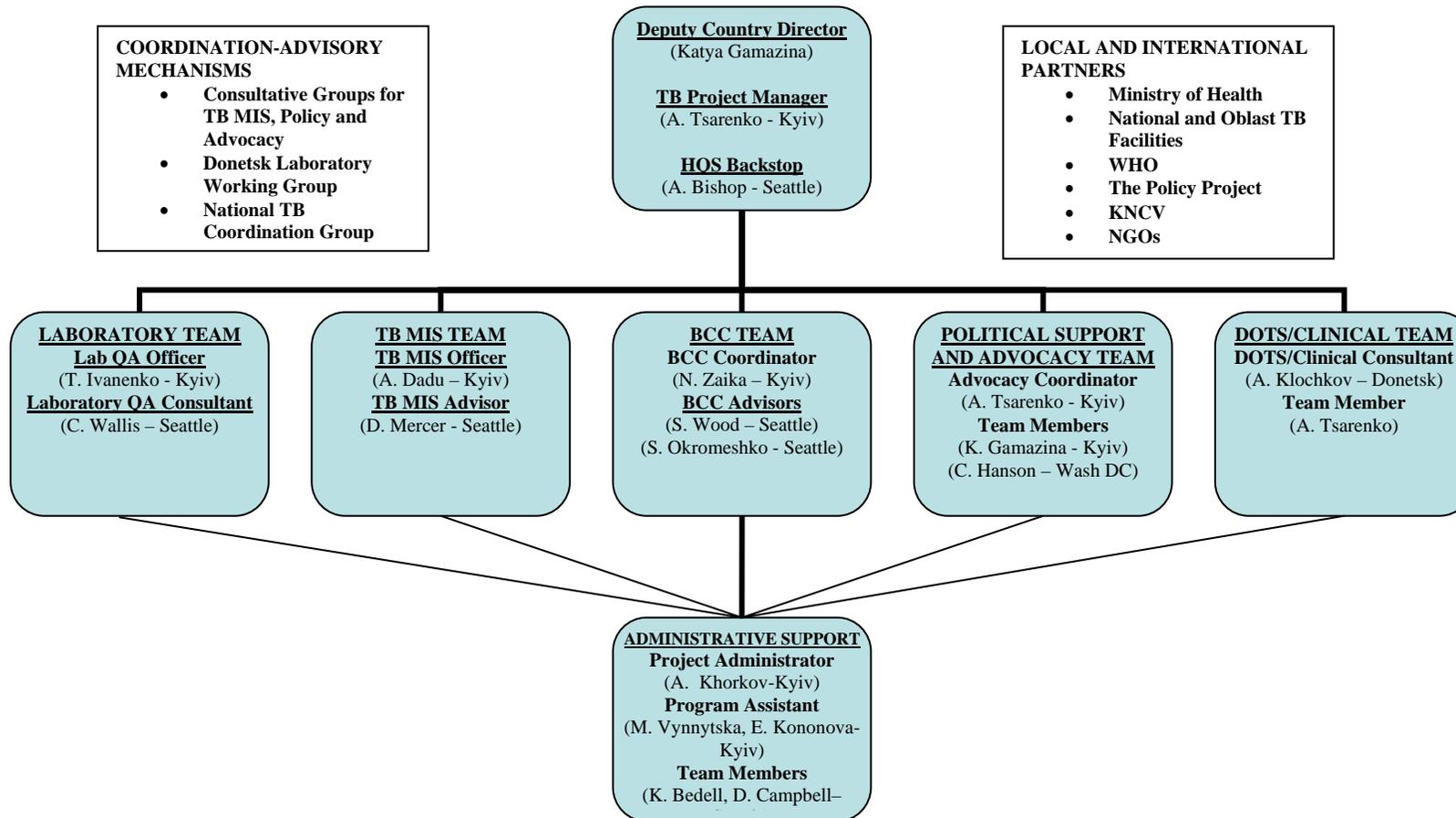
Dr. Tsarenko, as Project Director, has immediate responsibility for supervising the project team based in Ukraine. Dr. Gamazina, as Deputy Country Director for PATH in Ukraine, and Amie Bishop, as Country Director, also play important supervisory roles to ensure that the project is progressing smoothly. PATH staff in Kyiv convene monthly staff meetings and weekly TB team meetings. Email and conference calls also are regularly used.

Human Resources and Staff Management

During the second year of the project, PATH hired additional staff and consultants to accommodate the expanded scope of work supported by the USAID Mission. Specifically, a DOTS/TB clinical management specialist was hired as a consultant in April 2005, a new program assistant was hired in September 2005, and several consultants at the regional level (coordinators and trainers) were hired over the course of the year. Staff turnover has been minimal—only one program assistant has left. All other original team members remain. Workloads are very heavy, and additional hiring may be necessary in the coming year. Please see the updated organizational chart on the following page.

**PATH PROJECT: SUPPORT TO UKRAINE IN IMPLEMENTING
ITS NATIONAL TB PROGRAM**

ORGANIZATIONAL CHART – Updated: 10/07/2005



Financial Management

PATH staff in Kyiv provide local financial management for the project. All USAID requirements concerning procurement, financial transactions, reporting, and VAT exemption have been followed. Staff in PATH's headquarters in Seattle backstop the project and prepare all financial reports before submission to USAID.

Logistics

PATH staff in Kyiv oversee all the logistics necessary for project implementation. They are responsible for procuring local equipment and training supplies, as well as making travel arrangements and training logistics arrangements. The PATH office successfully follows well established procedures regarding all logistics arrangements.

Information Management

PATH's project team is tracking progress towards objectives at multiple levels. Standard and well-defined approaches to cohort analysis are used for implementation of DOTS. The PATH MIS specialist, in particular, has led the development and adoption of a TB MIS that conforms to international standards and generates data for cohort analysis. This system is part of the government structure, and PATH is providing support to government counterparts to enter and analyze the data, troubleshoot, and monitor progress. This system should remain in place after the project is completed. For more details, see Objective 3 in the Program Accomplishments section.

In addition, PATH regularly monitors objective-specific indicators as outlined in the project's monitoring and evaluation matrix. (Please see updated matrix in Annex D.)

Technical and Administrative Support

The TB team has benefited from ongoing technical and administrative support from PATH headquarters in Seattle; PATH's Strategic Program on HIV/AIDS, TB, and Malaria in Washington, D.C.; and from external consultants such as Ms. Carolyn Wallis (laboratory). Further, project staff routinely discuss technical approaches with USAID personnel from the Europe and Eurasia Bureau (Ms. D'Arcy Richardson) and from the Mission, as well as with WHO, World Bank, and STOP TB Partnership colleagues.

Conclusions and Recommendations

Please see pages 2–6 for a review of midterm evaluation conclusions, recommendations, and responses.

Results Highlight

Among the project's successes thus far, we are particularly pleased with the model developed by the project and its partners for increasing support and improving treatment adherence, especially among vulnerable populations. Through the URCS's Visiting Nurses Program, the project has stimulated local ownership of and investment in supporting interventions to improve treatment adherence, care, and support in both Kyiv City and Donetsk. In the coming year, the project will expand this model to other regions, facilitating peer-to-peer training among various URCS personnel. Further, within the next year, the project will conduct a follow-up evaluation to determine its potential impact on reducing treatment default and improving treatment outcomes. Once evaluation results are available, we will provide a more detailed results highlight to USAID/CSHPG.

Annex A: Midterm Evaluation Report by External Evaluator: Dr. Fabio Luelmo

PATH Support to Ukraine in Implementing Its National TB Program

**Mid-term Evaluation Report
4-16 July 2005**

Cooperative Agreement No. GHS-A-00-03-00010-00

Project Location: Ukraine

1.1.1.1 Project Duration: October 1, 2003 – September 30, 2006

Evaluation Team

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Annexes

- I. Areas and institutions visited and main persons interviewed
- II. Maps of Ukraine
- III. Report of MoH Ukraine meeting to review the results of TB service in 2004 and National symposium to discuss draft National TB Control Program for 2006-2010 (Kharkiv, 25-26 May 2005)
- IV. Main documents consulted

Executive Summary

Tuberculosis is a major health problem in Ukraine. In the last 15 years reported incidence has increased from 32 per 100 000 in 1990 to 76 per 100 000 in 2002, doubling every ten years. Almost all the increase has occurred in adults, and reported incidence under 15 years of age is stable. The main reasons for increase are socio-economical, breakdown of health delivery (irregular drug supply until recently 2001) and inadequate TB control strategies. The increase of HIV infection -now estimated at 1% of the general population- and probable high rates of resistance to TB drugs as a result of irregular treatment and of availability of TB drugs over the counter are important factors.

The national government commitment has improved: there is a budget line for TB, sufficient drug supply since 2002 and a World Bank loan of US\$28.7 million for TB for 5 years including activities in prisons, part of a loan for TB and HIV control (2002 –2006). The process of government approval was delayed so WB loan funded activities started late in 2004 and only a small fraction has been used so far. The loan includes equipment, supplies (mainly for laboratory), training and patient incentives to treatment that will be used to facilitate TB case management in primary health care facilities.

The Minister of Health of the new national government has stated the high priority of health care reform. TB is under the first Vice-Minister of Health and falls within the responsibility of the Department of Socially Dangerous Infectious Diseases. There is at present a focal point for TB and HIV, but no TB management unit in the Ministry of Health to plan, coordinate and monitor programme activities and to advise on the use of the WB funds.

Many of the current TB strategies are not consistent with international recommendations and are not effective to reduce TB transmission, and the use of resources is not cost-effective (such as case detection using mass photo-fluorography, hospitalisation of most patients for long periods, excessive number of TB beds, very little integration of patient management in general health facilities, long-term follow-up of patients after completion of treatment, no cohort evaluation of treatment outcome except in pilot areas). Guidelines for TB control are ad-hoc and partial, obsolete laws are currently valid and procedures in different Oblasts and facilities are not standardized.

The Institute of Tuberculosis and Pulmonology is under the Academy of Medical Sciences. It has high clinical capacity and recognition but it is oriented to individual case management, costly interventions of low impact on TB transmission and complex information systems. Oblast governments are more receptive to adopt modern effective interventions for TB control (the DOTS strategy) but are constrained by the lack of national guidance in that direction, by inappropriate legislation and difficulty to redirect resources. In general there are no reserve stocks of TB drugs and stock-outs were observed during the mission.

External partners supporting TB control in Ukraine are PATH, WHO and the World Bank. USAID is the main source of external funds. The KNCV/KIT (Royal TB Association and Royal Tropical Institute, The Netherlands) with funding from the European Commission supported a project in Kyiv for two years (until April 2005). Follow up co-operation activities in Kyiv have been continued by PATH. The DOTS project in the Donetsk Oblast was supported initially by WHO; PATH was a WHO subcontractor for BCC and later provided direct support to all components. National partners in TB control include the Ministry of Health, the TB Institute, the Oblast and city authorities of the pilot sites (Donetska,

Dnipropetrovska, Kharkovska, Kyiv and Sevastopol), the Ukrainian Red Cross Society and local NGOs.

USAID has supported TB control in Ukraine through PATH and through WHO. In 2003 USAID CSHGP supported a PATH proposal with US\$1.5 million for 3 years (October 2003-September 2006). This is the project now under mid-term evaluation. An additional \$1 million was committed in 2005 by the USAID Kyiv office. The objectives of the PATH project are to:

1. Improve capacity for DOTS expansion by advocating for political support including appropriate legislation and assistance in developing pilot sites.
2. Improve the quality of diagnostic services in selected oblasts
3. Improve the use of monitoring and surveillance data for TB programme management
4. Reduce diagnostic delay, increase case detection and improve treatment adherence
5. Improve provider practices by improving capacity to diagnose and treat TB based on the DOTS strategy, and enhance knowledge and response to TB/HIV interaction.

The DIP was approved in April 2004¹. A report on PATH activities of the first year of the project is available². The report of activities achieved by mid term of the project is attached.

The PATH strategy has been to support Oblast and City TB control programmes as a method to show feasibility and appropriateness of the DOTS strategy, and to support government adoption of effective TB control practices. PATH has continued and complemented support from other agencies (WHO, KNCV/KIT) and taken the leadership in collaboration with Oblast authorities.

In conclusion, the PATH strategy has shown to be appropriate and the changes observed in the pilot areas for DOTS implementation are substantial in comparison with the status of the new areas selected for expansion. Kyiv and Donetsk Oblast have integrated case detection in general facilities, increased ambulatory treatment, improved TB laboratory functioning, and developed the information system for monitoring. The Red Cross provides a good model for expansion of outpatient care to the community, in particular for high-risk populations. The progress achieved in the country in comparison with the previous situation, described in the joint evaluation in 1999³ and in consultant reports⁴ is quite satisfactory.

The main areas for improvement of delivery of care in the pilot areas include:

- quality control of smears through re-reading (particularly of smear negative),
- quality of data recording (mainly in the patient cards),
- quality of medical diagnosis and use of hospital beds (hospitalization of children without TB and of TB smear negative adults) and, in particular,
- analysis and use of indicators for action (the proportion of defaulters is increasing to unacceptable levels in Donetsk, the demonstration area).

The impact to change national policies has been much more limited, due to high resistance to revise current practices, simplify procedures and implement monitoring. Although formal coordination groups have been established, the information exchange and participatory decision making is insufficient. Major factors are the absence of a TB management unit at the

¹ PATH support to Ukraine NTP. Detailed implementation plan 2003-2006, supported by CSHGP, USAID. April 30, 2004.

² Support to Ukraine in implementing its national TB program, Cooperative Agreement GHS-A-00-03-00010-00. PATH Annual Report, October 30, 2004.

³ Joint Review of Tuberculosis in Ukraine. WHO/EURO, 6-15 December 1999.

⁴ TB surveillance assessment mission to Ukraine. WHO/EURO, 20-24 May 2002.

Ministry of Health -essential to coordinate and monitor activities (including all sources of funds) and to act as counterpart for the cooperating institutions- and the absorption of some of the roles of the Ministry by specialized clinical institutions and experts. Coordination among the external partners to support TB control policy changes is essential, particularly as the new Minister of Health has noted the priority of health reform and tuberculosis.

The level of financial support from USAID to PATH seems adequate. However continuity of support is indispensable to achieve full implementation of DOTS and ensure sustainability and impact of the strategy.

Recommendations

To USAID.

- Maintain support to PATH for the current project and consider expansion of the project after 2006 to consolidate the progress achieved.
- Promote close coordination between external partners (USAID, WHO, PATH, WB) to obtain political commitment and support implementation of DOTS as a national policy, with priority to ownership of the programme, establishment of a TB management unit in the Ministry of Health and abolishment of obsolete regulations.

To PATH

- Coordinate with WHO the support to the Ministry of Health to establish a TB management unit (first component of the DOTS strategy), to abolish obsolete laws and regulations (mass screening, mandatory hospitalisation), and to prepare comprehensive TB programme guidelines (policy, technical and operational).
- Support a joint national TB programme evaluation and the preparation of a new national medium-term TB plan of action.
- Support retraining and supervision in the pilot areas to ensure strict compliance with standard procedures and recording and to achieve model results, monitoring progress through the trends in smear conversion and treatment outcomes. In particular, analyse the reasons for deterioration of the outcomes in the Donetsk Oblast and test corrective actions, monitor the quality of medical diagnosis (proportion of cases diagnosed that were smear positive) and support quality control of smears through re-reading of a sample of slides.
- Support quality control of smear examination by re-reading of a sample of slides (particularly negative in polyclinics); obtain data on trends of number of patients examined for diagnosis and positivity rate for each oblast;
- Support operational research (cost effectiveness of reading 300 fields, of doing several cultures and on the real proportion of adults with cough over 3 weeks attending general health facilities for any reason, and of long-term hospitalization);
- Continue training and DOTS expansion. Data on the prevalence of MDR is important but must wait the development of capacity of one of the laboratories and the capacity of the national programme to select a representative sample of patients.
- Maintain and expand support to DOTS in additional Oblasts, monitor outcomes through quarterly analysis of smear conversion and take rapid corrective actions.

**PATH Support to Ukraine in Implementing Its National TB Program
Mid-term Evaluation Report
4-16 July 2005**

1. Terms of reference

- To assess PATH's progress in implementing its Detailed Implementation Plan (DIP) submitted to USAID in June 2004;
- To assess PATH's progress towards achievement of objectives and annual benchmarks;
- To determine whether interventions are sufficient to reach desired outcomes;
- To identify barriers to achieving objectives; and
- To recommend actions to guide the program during the remaining project period.

2. Evaluation Team

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The areas and institutions visited and main persons interviewed are included in Annex I and maps of the country in Annex II.

3. Introduction and background

a. TB in Ukraine: epidemiology

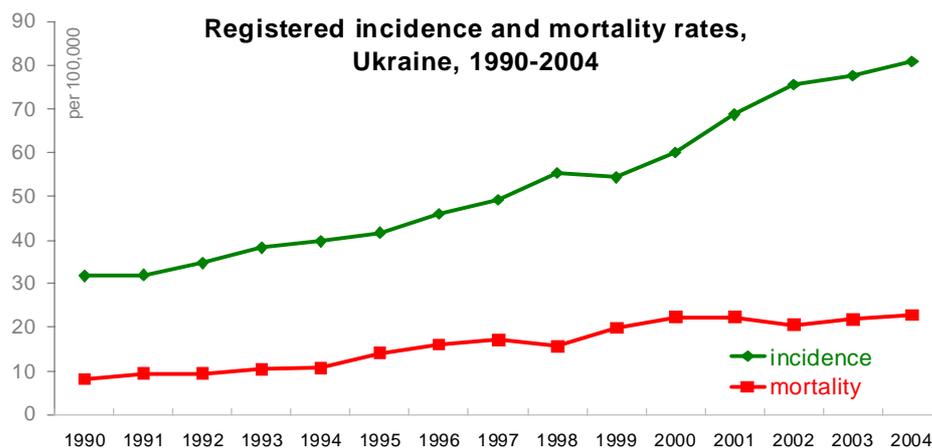
TB reported incidence has increased in Ukraine over the past 15 years, from 16 465 cases (32.0 per 100 000 population) in 1990⁵ to 38 403 in 2004⁶ (81 per 100 000). This excludes TB cases registered among the Ukrainian Armed Forces, Ministry of Internal Affairs and Security Service employees or prisoners—populations served by separate health care systems. In 2002, an incidence rate of 4 585 cases per 100 000 was registered in the penitentiary system.⁷

Of the new TB cases registered in 2004, 72 percent were among men. The highest reported incidence rates in 2004 were reported in the oblasts of Khersonska (166 per 100 000) and Nykolayevska (115). The lowest incidence was registered in the city of Sevastopol. The proportion of cases under 15 years old was 1.8% (rate 9.3 per 100 000). 88.7% of the newly diagnosed cases were pulmonary and 12.3% extra-pulmonary.

⁵ Melnyk, V.P., Workshop national NTP managers, Budapest, October 2003.

⁶ Ministry of Health TB statistical Report, 2005.

⁷ Melnyk, V.P., Workshop national NTP managers, Budapest, October 2003.



A notable fact is that although reported incidence has increased, incidence below 15 years old has kept almost steady. This suggests that transmission is not increasing much and that breakdown to disease in previously infected persons is the main reason for the trend (due to socio-economical factors, HIV and irregular drug supply).

The mortality rate also rose during this period, from 8.1 per 100 000 in 1990 to 22.9 in 2004. Nearly 9 percent of deaths due to TB disease were identified postmortem⁸. High rates and increase in mortality as well as high number of deaths during treatment (about 10% in Donetska Oblast) are likely due to late case detection (resulting from poor accessibility to appropriate care and poor TB awareness among general providers), shortages and irregular supply of TB drugs until 2002, multi-drug resistance and, more recently, HIV infection.

Data from 1999 suggest that approximately 30 percent of all TB patients in Ukraine were in prison where infection rates are believed to be very high. There was a prison amnesty in 2001 and a new one is expected in August 2005. This may release a number of TB patients and infected persons into the community. However the prisons have already initiated TB control according to the DOTS strategy, so the problem may become more of follow up (while avoiding unnecessary hospitalization) than increased transmission.

As in all former Soviet countries, conventional TB case detection in Ukraine relies on active case finding based on mass screening using miniature chest x-ray (photo-fluorography). Since 1996, the MOH established annual x-ray screening for all citizens over 15 years old. Children under 15 are required to have an annual tuberculin skin test⁹. All individuals with suspected TB are referred to TB dispensaries or rayon hospitals for chest x-ray and microscopy. Despite substantial evidence that x-ray mass screening is inefficient and extremely costly, most Ukrainian health authorities continue to advocate it and it is still mandatory by law (1996). The majority of TB cases, however, are detected passively through self-referral to specialized institutions.

Most new TB patients are hospitalized for six to eight months. Health authorities argue that hospitalization is needed to tailor the patient's treatment plan, determine how contagious the person is, provide the initial course of chemotherapy, and provide food for undernourished patients. A large proportion of TB beds are used for non-TB reasons. This is fostered by the

⁸ Feschenko, Y.I., TB epidemiology in Ukraine during the last 3 years, 11/14/2000.

⁹ Ukraine Ministry of Health's Order #233 from 07.29.1996, *About approval of guidelines for medical and sanitarian help for TB cases.*

system of funding institutions according to the number of beds. Children without diagnosis of active TB disease (only TB infection) are often hospitalized in pediatric TB hospitals and controlled by TB dispensaries, wasting resources and incorrectly labeling healthy persons as TB patients. Surgical treatment for forms of disease that respond poorly to conservative treatment is common. Preventive treatment (6 months isoniazid or isoniazid plus pirazinamide or ethambutol) is administered to family contacts of smear-positive patients, to children with strong tuberculin skin test reactions, and to children with skin test conversion.

HIV/AIDS. The first HIV cases in Ukraine were registered in 1987. Ukraine has seen the AIDS epidemic advance rapidly since independence in 1991, and it is the only country in Europe and Eurasia with an estimated 1% prevalence rate among adults (around 500 000)¹⁰. Until 31 December 2003, 62 365 cases had been registered, including 3 590 deaths. About 10 percent of all HIV cases registered are among children under age 15. In 2003 the HIV incidence rate was 20.8 per 100 000 population¹¹. While injection drug use is linked with over half of HIV infections in Ukraine, transmission via sexual contact is growing, and about 40 percent of known infections are among women¹².

Most cases of TB-HIV co-infection are not detected, due to substandard diagnosis and poor linkages between the HIV and TB systems, which are implemented vertically and remain very separate. Data about co-infection rates are unreliable, resulting in contradictions between official statistics and operational reporting. Operational data from 2003 indicates that there were 913 known HIV-TB cases among the 36 471 registered TB cases in Ukraine.¹³ The highest incidence rates of TB and HIV co-infection were registered in Odeska (9.1 per 100,000), Dnipropetrovska (6.8), and Donetska (5.3). TB develops in almost half of the HIV infected persons under observation.

TB Drug Resistance. There is no national data regarding drug resistance in Ukraine. Data from the TB Institute reflect a selected patient population, and no survey according to internationally agreed protocols has yet taken place. In 2001 Kyiv City reported a primary drug resistance rate of 26 percent and a secondary drug resistance rate of 15 percent among new pulmonary smear-positive TB cases. Among new cases 2.9 percent had MDR-TB¹⁴. MDR resistance appears to be more common among marginalized social groups largely due to under-treatment, poor compliance and treatment interruptions. Self-medication is common, as all drugs are available over the counter in pharmacies.

b. Health care delivery and TB Control

The two key national structures currently responsible for TB control are the MOH (Department of Socially Dangerous Infections Diseases) and the F.G. Yanovsky Institute of Tuberculosis and Pulmonology (ITP), Academy of Medical Sciences of Ukraine (AMS). The ITP has defined policy and trained staff for the national TB control program. Regional (oblast-level)

¹⁰ UNAIDS, World Health Organization. *AIDS Epidemic Update*, December 2001.

¹¹ Ukraine MOH website, <http://www.moz.gov.ua/en/main/siterubr>.

¹² Ukraine National HIV/AIDS Center, 2002.

¹³ Alexandrina, T.A., Epidemiological situation regarding TB in combination with HIV and AIDS in Ukraine, *Ukrainian Journal of Chemotherapy*, #3-4, 2003.

¹⁴ Trnka, L., Leimane, V., Falzon, D., Miskinis, K., *Tuberculosis Surveillance Assessment Mission to Ukraine*, 20-24 May 2002.

and city/rayon TB dispensaries are supervised by the MOH and the oblast health administrations, which regulate the TB budget. Each oblast has an oblast TB hospital / dispensary, including clinical and diagnostic laboratories with bacteriological departments to diagnose TB. Oblast TB dispensaries, together with the SES, analyse epidemiological data, plan and organize TB screening and immunizations, and provide laboratory diagnosis. Treatment for most TB patients is provided at dispensaries, specialized regional hospitals, or departments of general hospitals.

At the district (rayon) level, health care is provided by a central rayon hospital and polyclinics, which have integrated TB dispensaries, TB day hospitals, TB departments or TB consulting rooms. Rural populations are served by the rayon and inter-rayon TB dispensary and clinical and diagnostic laboratories or centers for AFB microscopy (depending on the population and availability of resources). Outpatient clinics are used for treatment follow-up. Rayon TB facilities report to oblast TB dispensaries. In villages, patients are assessed at a feldsher/nurse point (FAP) or a village ambulatory, both of which serve as primary health care facilities¹⁵. According to 2001 data, there were about 3 000 TB specialists, 147 TB dispensaries, 98 TB sanatoria, and about 30 000 TB beds in dispensaries and hospitals.

The human resources for general health have been constant from 1990 to 2004 and include about 223 000 physicians of all specialties (one per 220 inhabitants, a very large proportion) and 522 000 nurses (one per 100 inhabitants). There are nearly 3000 hospitals with 450 000 beds (almost one bed per 100 inhabitants, in gradual decrease) and 7700 polyclinics.

A meeting convened by the Ministry of Health on 25-26 May 2005 in Kharkiv discussed the results of TB services in 2004 and recommendations to draft the 2006-2010 national TB control plan (See Annex IV). During the mid-term assessment mission, the new Minister of Health decided to constitute a TB management unit in the Ministry, and requested WHO support to prepare a medium term plan of action for TB control. These are also conditions to apply for GFATM support, which was considered for 2005 and postponed to 2006. Application to GDF to pilot fixed-dose combinations and patient boxes is under consideration. At present TB drugs are purchased in country and distributed by the central government. TB drugs produced in Ukraine are not fixed dose combinations, and the laboratories do not satisfy at the moment the international quality control requirements to compete with international products and to be included in the white list of the Global Drug Facility.

TB and General Health Care in Donetska Oblast and Kyiv City. The Donetska Oblast TB health care service structure comprises 45 rayon TB health facilities. They are responsible for TB case registration and management reporting procedures, treatment, rehabilitation, and TB prevention. Fifteen of these have inpatient departments, and the remaining 30 have only outpatient units (TB office in rayon central hospital or polyclinics). In total, the Donetska Oblast health care service has 3 000 TB beds, 500 of which are in the Oblast TB Hospital, for 4500 new cases reported annually which should receive 6 months treatment, mostly ambulatory. Oblast TB hospital beds are divided into categories of pulmonary TB, extra pulmonary TB, surgery, and children (about 150 beds for 40 new child cases per year in Kyiv) and adolescents.

¹⁵ Kucher T. et al., 2002.

DOTS Coverage Estimates in Project Sites

A DOTS implementation pilot project was established in Ukraine in 2001 in the Donetsk Oblast, supported by WHO with funds from USAID. A second DOTS pilot project was initiated in 2003 in Kyiv City implemented by the local government, funded by the European Union and with technical support from KNCV/KIT. In addition, based on the clear need to adopt a standardized system across all regions of Ukraine as soon as possible, the Ukrainian parliament ratified a loan agreement with the World Bank in November 2003 for \$60 million for TB and HIV/AIDS control in the country¹⁶. The World Bank loan project is planned to continue through June 2007 and includes three major components: TB control, HIV/AIDS prevention and control, and TB and HIV prevention and control in prisons. The TB component budget is \$28.7 million.¹⁷ These funds will be used to implement the MoH's "National TB Strategy Adapted to International Standards" and will strengthen the government's capacity both at the central level (MOH, ITP, and NRL), and in the country's 27 regions through support for training and education, improved diagnosis and treatment, public awareness, and monitoring and evaluation. The prison component is budgeted at \$12.7 million. It was designed as a separate component because of the institutional nature of the prison system, which is a self-contained and centrally managed system.

Prior to DOTS implementation in Donetsk Oblast, TB incidence and mortality rates in Donetsk were 81.9 and 28.5 per 100 000, respectively. The primary MDR rate was 9.7 percent. As of the end of 2003, all TB cases were registered under the DOTS system.

4. PATH project strategy and activities

USAID CSHGP approved a grant of \$1.5 million to PATH for 3 years (2003-2006) to support TB control activities in Ukraine. A detailed implementation plan (DIP) for the project was presented to CSHGP in March 2004 and approved in April 2004¹⁸. A report on PATH activities of the first year of the project is available¹⁹. The USAID Kyiv office has provided additional support of \$1 million to expand activities in 2005-06. The revised work-plan with additional activities and the achievements by mid term of the project are attached (Annex III).

The objectives of the PATH project are to:

- Improve the capacity for DOTS expansion by advocating for political support including appropriate legislation and assistance in developing pilot sites.
- Improve the quality of diagnostic services in selected oblasts
- Improve the use of monitoring and surveillance data for TB programme management
- Reduce diagnostic delay, increase case detection and improve treatment adherence
- Improve provider practices by improving capacity to diagnose and treat TB based on the DOTS strategy, and enhance knowledge and response to TB/HIV interaction.

¹⁶ Law № 1287–IV, *Ratification of WB loan agreement for TB and HIV/AIDS control in Ukraine*, November 182003.

¹⁷ Report No: 25062 UA, Project appraisal document of a proposed loan in the amount of US\$60 million to Ukraine for a TB and HIV/AIDS control project, November 22, 2002.

¹⁸ PATH support to Ukraine NTP. Detailed implementation plan 2003-2006, supported by CSHGP, USAID. April 30, 2004.

¹⁹ Support to Ukraine in implementing its national TB program, Cooperative Agreement GHS-A-00-03-00010-00. PATH Annual Report, October 30, 2004.

PATH's main strategy has been to support Oblast and City TB control programmes, as a method to show feasibility and appropriateness of the DOTS strategy, as well as supporting government adoption of effective control methods. PATH has continued and complemented support from other agencies (WHO, KNCV/KIT) and taken the leadership in collaboration with Oblast authorities. With additional resources, PATH is now starting support to three additional sites (Sevastopol, Dnipropetrovska and Kharkivska Oblasts).

The mission observed the progress achieved by PATH and mainly the impact on adoption and development of the DOTS strategy in Ukraine at national and at Oblast/City level (pilot areas). A summary of achievements by the time of the mission for each component is included in Annex III. A comprehensive report of PATH activities until July 2005, including multiple annexes, is attached in separate²⁰.

- Regarding **political commitment**, DOTS has been adopted by presidential decrees in 2001 backed by the Ministry of Health in September 2003. However many obsolete laws are still valid (mandatory mass screening with photo-fluoroscopy, mandatory hospitalization) so adoption of modern TB control methods is easily blocked. Although there is a general complain about insufficient resources for TB (specialists, equipment), available resources are used inefficiently and, in some cases, support barriers to patient diagnosis and successful treatment.
- In the **laboratory** component PATH has collaborated with WHO and the government to characterize the situation, train staff, and provide guidance at the central level and in Donetsk and Kyiv. PATH has also supported quality control of smears through panel testing. The governmental body that will oversee the national TB laboratory network is being debated and remains uncertain: the Institute so far has assumed this role with a person in charge; equipment and facilities are best in the central laboratory in Kyiv (overdeveloped for just routine TB program support at city/Oblast level); and the government is dedicating WB funds to construct another site as reference laboratory. A particular observation is the large emphasis on diagnostic cultures of all samples for diagnosis, while the specialists do not wait for the results to make a diagnosis and start treatment / hospitalization so laboratory staff time and cost is wasted. Reading of 300 fields for smear microscopy as regulated seems unnecessary and not followed in practice, is contrary to international guidelines and not cost-effective. Operational and cost-effectiveness research to justify or advise changes in procedures, functions of the central laboratory, are not yet sufficiently developed.
- There is intensive work in preparation of the **information system** (registration and reporting), and data is available from Donetsk for evaluation of treatment outcomes. **However**, the basic registration forms are still under discussion and in general contain much data of little value to the program or to clinical management of the patients. The adaptation of the models recommended internationally is slow due to requirements from specialists (mainly the National TB Institute and Kyiv) to include a large quantity of data, the absence of a national policy and guidelines for TB control giving priority to detection and cure of infectious cases, and the lack of national capacity to make a rapid and effective decision on the proposals. Some widely used indicators are not consistent with modern

²⁰ PATH Support to Ukraine in Implementing Its National TB Program. Report October 1, 2004 – July 31, 2005. Cooperative Agreement No. GHS-A-00-03-00010-00

international concepts (such as TB prevalence: cumulative cases known (active or cured) and not the active cases existing in the community).

A major achievement is having incidence data for all Oblasts and cohort outcome data for Donetsk. **However, the information now available is not used for action.**

For instance, the rapid deterioration of success rates and increasing default outcome of treatment in Donetsk (see Table 1), which is a demonstration Oblast, has not produced due alarm and no corrective action has been taken. Deterioration and poor results in treatment outcomes (the main indicator of quality of the TB programme) should lead to immediate analysis of the causes (operational research) followed by rapid testing of corrective actions. The high failure rate (12%) could be due to MDR, poor quality drugs or inadequate treatment regimen or a combination; high death rates during treatment could be due to severity at the time of diagnosis (deaths early on treatment), to HIV infection or to inadequate treatment regimens; default could be due to poor information to patients or to poor access to ambulatory care for directly observed treatment. Each of the causes should lead to different strategies to improve results.

It is of interest that smear conversion rates have improved and in Mariupol re-treatment outcomes improved while primary treatment outcomes have deteriorated (are the patient losses only in the continuation phase? Are the losses linked to particular institutions? Is the regimen selection incorrect?). These are key questions for operational study. In Kyiv there is yet no data available. Obtaining, analyzing and using data on smear conversion at 2-3 months from all newly implemented areas is essential for program monitoring, particularly during the implementation and expansion of the new strategy.

Table 1

Outcome of treatment in new smear positive TB cases, Donetsk *

Year / Quarter	SUCCESS %	FAILURE %	DEATHS %	DEFAULT %	TRANSFER %
2003 / 1	71.1	5.6	14.1	8.9	-
2003 / 2	64.0	10.3	15.4	10.3	-
2003 / 3	68.4	11.6	7.9	12.1	-
2003 / 4	65.6	9.4	10.4	12.5	2.1
2004 / 1	56.8	13.2	12.1	13.9	4.0
2004 / 2	65.0	10.9	12.6	16.2	2.4

* Definitions may not accurately reflect international recommendations.

- Behaviour change communication (BCC) has concentrated on conducting formative research and on developing informational materials for the community and TB patients. These aspects seem well developed, and in particular the decision-makers at Oblast level seem well briefed and committed. However general experience and the results of the analysis indicate that the major barriers for the population are in the provision of services. Diagnosis only by specialists (even in pulmonary smear positive cases confirmed by the laboratory), mandatory hospitalization for long periods, frequent surgery and dispensarization (i.e., control for life of cured patients) are all barriers to population confidence in the system. With modern ambulatory treatment TB can be cured in most cases without interference with patient life routines. Persons infected with TB, including treated patients, have a risk of developing TB disease (justifying chemo-prophylaxis) but

are not ill or active TB patients, so they should not be labeled as such. This is not the view of the medical profession (particularly of specialists), which this is the group most in need of BCC.

- **Improving provider practices** is a slow process, and it is linked to BCC, training and analysis of results. A major problem in the TB program at present is the almost complete absence of direct supervision and of clear, comprehensive guidelines. Multiple procedures were observed during the mission, for instance the use of different regimens (daily, intermittent in the second phase, intermittent from the start, and frequently modified regimens during treatment).

In Ukraine a major threat is TB/HIV co-infection. In general the practice is to offer VCT to all TB patients and to refer HIV positive to the HIV/AIDS services for care. Prophylaxis in HIV infected without active TB is indicated, but the procedures are unclear and not consistent with international guidelines (use of INH 3 months per year, use of INH plus pirazinamide or ethambutol). Detection of TB in HIV infected is done. Co-trimoxazol as prophylaxis of other HIV-related infections is not used. There is no systematic use of data from TB patients for HIV surveillance of trends. ARV use is just starting (the GFATM grant for HIV had implementation problems and the WB loan utilization is slow) and the information on ARV use in TB patients is scanty.

5. Achievements

PATH support has contributed to the improvement of TB control achieved by the government of Ukraine. Among the major advances observed are:

- Government commitment to the DOTS strategy in the Oblast/Cities already implemented and in those to be started. National commitment, which was limited until now to provision of funds for TB drugs and a focal point for TB and HIV; the new authorities are committed to the DOTS strategy and health reform and this is a key moment to obtain lasting changes in policy. Staff involvement in TB control in the specialized and general (policlinic) services. DOTS strategy implemented in the prison system.
- Agreement and signature of Memorandums of Understanding (MOU) with partners (ITP, Sevastopol City, Dnipropetrovska and Kharkivska Oblast health administration. Additional MOU with the Ministry of Health (as part of a general PATH MOU), the WB TB-HIV/AIDS control project and with WHO are in process.
- Establishment of a Policy and Advocacy Consulting Group (PACG) to advise the MoH on legislative and policy documents. PACG also met to discuss the TB plan 2006-2010.
- Assessment to select additional oblasts for DOTS expansion (November 2004-February 2005). The Dnipropetrovska and Kharkivska Oblasts and Sevastopol City were selected.
- Substantial progress in laboratory network evaluation, provision of supplies and equipment, training and information system. Quality control of TB laboratories through panels of smears. Detection of adults with cough (probable sources of infection) by physicians in general health facilities.
- Treatment under direct observation is accepted as the standard of care and in general use. Use of Red Cross staff and volunteers as extension of TB services to the community. Gradual reduction in hospitalisation in the continuation phase in all areas receiving partner (WHO, PATH) support for DOTS implementation. Beginning of consultation with the patients regarding optimum place for observed treatment.

- Sufficient first line drug supplies since 2002, financed by the national government (Regimens I-III), although there are local stock-outs.
- Development of an information system to monitor patients and the programme results (cohort analysis), in progress. Data on treatment outcomes for Donetsk. Information on TB situation and procedures in several oblasts, obtained during evaluation visits for expansion. Partial acceptance of international recommendations and definitions.
- Good collaboration with WHO and the Red Cross Society for joint activities in support of DOTS implementation.

6. Constraints and DOTS implementation problems observed

At national level:

- Absence of a TB unit/team to develop comprehensive guidelines, to plan and to coordinate all sources of funding and technical cooperation, and to monitor and supervise activities.
- Survival of obsolete laws, which block modern strategies (mass screening with X-rays, mandatory hospitalization).
- Resistance of the TB specialists to adopt more effective TB control strategies and simpler instruments to allow monitoring and evaluation: the present PACG is probably not fully appropriate to advise the Ministry of Health on DOTS implementation.
- Lack of comprehensive and patient-friendly TB control guidelines from the Ministry of Health, based on effectiveness and efficiency and overruling previous norms.
- Insufficient coordination of the technical partners (PATH, WHO, WB) to support the Ministry of Health organization and capacity of decision to implement the DOTS strategy; and to facilitate health sector reform (for instance, transformation of TB beds to other purposes and change in the financing system for hospitals).
- Separate drugs, no reserve stocks (several months stock out of pirazinamide were observed in a TB hospital during the mission), lack of clear national decision and guidelines for standard regimens (multiple alternatives observed during the mission). Use of second line drugs with irregular supply or private purchase, without national guidelines.
- Excessive number of TB beds and TB hospitals for the existing case-load (one TB specialist for 14 new TB patients per year, and more than one TB bed per TB patient).

At Oblast/City level:

- Insufficient staff knowledge of the efficacy of interventions in reducing TB transmission and mortality (different from individual patient diagnosis) and inclusion in “TB prevalence” of patients cured of TB and persons only infected with TB. This leads to excessive hospitalization, in particular labeling of healthy children and cured adults as TB patients.
- Inadequate use of the laboratory capacity: reading (in theory) 300 fields, cultures made for diagnosis in all three samples but not taken into account by the specialist to diagnose, lack of analysis of the proportion of outpatients examined and the positivity to evaluate detection of suspects (less than 0.5% positive observed in a policlinic).
- Insufficient use of available information on trends of smear conversion and treatment outcomes to monitor program effectiveness and to take corrective actions.
- Excessive hospitalization, very limited use of the policlinics and hospital outpatient services for ambulatory treatment.
- Lack of program supervisors at all levels to ensure compliance with national guidelines (also lacking) and quality of care, and to complement training.

7. Conclusions

- The PATH strategy has shown to be appropriate and the changes observed in the pilot areas for DOTS implementation are substantial in comparison with the status of the new areas selected for expansion. Kyiv and Donetsk Oblast have integrated case detection in general facilities, increased ambulatory treatment, improved TB laboratory and developed the information system for monitoring. The Red Cross provides a good model for expansion of outpatient care to the community, in particular for high-risk populations. Implementation of PATH planned activities until the mid-term assessment is included in Annex III.
- The progress achieved by the country in TB control in comparison with the previous situation (described in the joint evaluation in 1999²¹, in consultant reports²² and in PATH evaluation visits²³ and observed during the mission) is satisfactory. Areas for improvement in the pilot areas include quality control of smears through re-reading (particularly of smear negative), systematic supervision, quality of data recording, quality of medical diagnosis and use of hospital beds (hospitalization of children without TB and of TB smear negative adults, duration) and in particular analysis and use of indicators for action (the proportion of defaulters is increasing to unacceptable levels in Donetsk, a demonstration area).
- The impact to change national policies has been much more limited, due to the lack of a TB program counterpart in the Ministry of Health, and high specialist resistance to revise current practices, simplify procedures and implement monitoring. Although formal coordination groups have been established, the information exchange and participatory decision making is insufficient. Major factors are the absence of a TB management unit at the Ministry of Health –essential for program sustainability, to coordinate and monitor activities and to coordinate the cooperating institutions-, and the absorption of some of the roles of the Ministry by specialized institutions and experts. What is required is strong leadership from the Ministry of Health, which should make the decisions, with a full-time TB control team plus a technical advisory group of recognized specialists with hands-on experience in DOTS implementation in Ukraine, supported by the international partners.
- Coordination among the external partners to support TB control policy changes is essential, particularly now that the Ministry of Health has given priority to health reform. Major policy changes include the abolition of obsolete laws and regulations (such as screening of general population and mandatory hospitalization), changing the system of financing TB hospitals according to the number of beds and redefining the functions and name of existing hospitals, separating their role in TB patient management from other reasons for hospitalization. A comprehensive guide for TB control activities, including policy (DOTS), technical (such as standard treatment regimens) and operational components (recording, reporting, training, supervision and monitoring) is indispensable to avoid the current uncertainty of field staff regarding procedures.
- HIV/TB co-infection is the main challenge for the future and control programs should be closely coordinated. The TB program includes offer of HIV test (VCT) to all patients, this should be complemented with referral for ARV treatment when indicated and, possibly, co-trimoxazol prophylaxis. The HIV program should intensify early detection of TB cases (all

²¹ Joint Review of Tuberculosis in Ukraine. WHO/EURO, 6-15 December 1999.

²² TB surveillance assessment mission to Ukraine. WHO/EURO, 20-24 May 2002.

²³ A. Dadu, PATH. Travel reports to Kharkiv, Kirovograd, Semfiropol, Sevastopol and Zaporozhye, 2005.

forms) and provide INH prophylaxis (6 months of INH) to those without active TB as part of the package of care. New, confirmed TB patients should constitute a group for regular HIV infection surveillance.

- The level of financial support from USAID to PATH seems adequate. However the continuity of support is indispensable to achieve full implementation of DOTS and ensure sustainability and impact of the strategy.

8. Recommendations

To USAID.

- Maintain support to PATH for the current project and consider expansion of the project after 2006 to consolidate the progress achieved.
- Promote close coordination between external partners (USAID, WHO, PATH, WB) to obtain political commitment and support implementation of DOTS as a national policy, with priority to ownership of the program, establishment of a TB management unit in the Ministry of Health and abolishment of obsolete regulations.

To PATH

- Coordinate with WHO the support to the Ministry of Health to establish a TB management unit (first component of the DOTS strategy), to abolish obsolete laws and regulations (mass screening, mandatory hospitalization), and to prepare comprehensive TB programme guidelines (policy, technical and operational).
- Support a joint national TB program evaluation and the preparation of a new national medium-term TB plan of action.
- Support retraining and supervision in the pilot areas to ensure strict compliance with standard procedures and recording and to achieve model results, monitoring progress through the trends in smear conversion and treatment outcomes. In particular, analyze the reasons for deterioration of the outcomes in the Donetsk Oblast and test corrective actions, monitor the quality of medical diagnosis (proportion of cases diagnosed that were smear positive) and support quality control of smears through re-reading of a sample of slides.
- Support quality control of smear examination by re-reading of a sample of slides (particularly negative in polyclinics); obtain data on trends of number of patients examined for diagnosis and positivity rate for each oblast;
- Support operational research (cost effectiveness of reading 300 fields, of doing several cultures and on the real proportion of adults with cough over 3 weeks attending general health facilities for any reason, and of long-term hospitalization);
- Continue training and DOTS expansion. Data on the prevalence of MDR is important but must wait the development of capacity of one of the laboratories and the capacity of the national program to select a representative sample of patients.
- Maintain and expand support to DOTS in additional Oblasts, monitor outcomes through quarterly analysis of smear conversion and take rapid corrective actions.

2 ANNEX I

2.1.1 Areas and institutions visited and main persons interviewed

2.2 Central level

Ministry of Health

- Dr Tatiana Alexandrina, Head, Department of Control and Treatment Management of Socially Dangerous Diseases

Institute of Tuberculosis and Pulmonology Laboratory

- Prof. Olexandr Zhurylo, Head of the Microbiological Laboratory
- Dr Anna Barbova, Head, TB Reference Laboratory

Ministry of Health/World Bank TB/HIV-AIDS Control Project

- Dr Volodymir Romaniv, Manager of Project Implementation Unit, MoH/ World Bank TB/HIV-AIDS Control Project
- Dr Leonid Turckenko, TB Coordinator, MoH/ World Bank TB/HIV-AIDS Control Project

USAID, Mission for Ukraine, Belarus and Moldova

- Dr Nancy Godfrey, Director, Office of Health and Social Transition
- Dr Olena Radziyevska, Project Manager, Office of Health and Social Transition

WHO

- Dr Kestutis Miskinis, Medical Advisor for TB control, WHO Office in Ukraine

Ukrainian Red Cross Society

- Dr Alla Khabarova, Executive Director, National Committee, Ukrainian Red Cross Society
- Dr Valeriy Sergovskiy, Executive Director Deputy, National Committee, Ukrainian Red Cross Society

Kiev City

Kiev City Central TB Dispensary

- Dr Leonid Turchenko, Chief doctor, Kiev City Central TB Dispensary, Chief TB Specialist of the Kiev City Health Administration
- Dr Natalia Filonenko, Chief doctor Deputy, Kiev City Central TB Dispensary
- Dr Natalia Goncharenko, Head of the Microbiological Laboratory, Kiev City Central TB Dispensary

Kiev City Red Cross organization

- Vera Milenko, Head of Kiev City Red Cross organization
- Tatiana Mironova, Head of Darnitsa Rayon Red Cross Committee, Kiev City Red Cross organization

Donetska Oblast

Donetska Oblast Health Administration

- Dr Lidiya Blokitna, Acting Head, Donetska Oblast Health Administration
- Prof. Svitlana Lepshyna, Chief TB Specialist, Donetska Oblast Health Administration

Donetska Oblast TB Dispensary

- Dr Maiya Goroshko, Acting Chief doctor, Donetska Oblast TB Dispensary
- Dr Anna Kovalyova, Deputy of the Chief doctor, Donetska Oblast TB Dispensary
- Dr Dolores Chikilyova, Head, Statistic and Management Department, Donetska Oblast TB Dispensary
- Dr Olena Yann, Head of the Microbiological Laboratory, Donetska Oblast TB Dispensary

Donetska Oblast Red Cross Organization

- Lyudmila Avsiankina, Head, Donetska Oblast Red Cross Committee
- Olga Averkina, Head, Yenakiyevo City Red Cross Committee

Donetska Oblast Health Center

- Dr Volodymyr Udodov, Chief doctor, Donetska Oblast Health Center

Donetsk City TB Dispensary

- Dr Galina Kurapova, Deputy of the Chief doctor, Donetsk City TB Dispensary
- Dr Lidia Rud', Head of the TB Laboratory, Donetsk City TB Dispensary

Donetsk City Polyclinic #16

- Dr Victoria Logintseva, Chief doctor, Donetsk City Hospital #16

Mariupol City TB Dispensary

- Dr Svitlana Svitlychna, Chief doctor, Mariupol City TB Dispensary, Chief TB Specialist of the Mariupol City Health Administration
- Tatiana Gorodnichaya, Head of the Microbiological Laboratory, Mariupol City TB Dispensary

Mariupol City HIV/AIDS Center

- Dr Pavlo Dovgalevskyy, Chief doctor, Mariupol City HIV/AIDS Center

Mariupol City Polyclinic #1

- Dr Yevgenia Animitsa, Chief doctor, Mariupol City Polyclinic #1

Dnipropetrovska Oblast

Dnipropetrovska Oblast Health Administration

- Dr Victor Veselskiy, Head, Dnipropetrovska Oblast Health Administration
- Dr Alla Drobnaya, Deputy of the Dnipropetrovska Oblast Health Administration

Dnipropetrovska Oblast TB Dispensary

- Prof. Dmitriy Kryzhanovskiy, Chief doctor of Dnipropetrovska Oblast TB Dispensary, Chief TB Specialist of the Dnipropetrovska Oblast Health Administration
- Maria Fonaryova, Head of the Microbiological Laboratory, Dnipropetrovska Oblast TB Dispensary

Dnipropetrovsk City TB Dispensary

- Dr Nadiya Ivanova, Chief doctor of City TB Dispensary
- Dr Natalia Neskromna, Chief doctor of City TB Polyclinic for Children

Dnipropetrovsk City Hospital #7

- Dr Lubov Romanenko, Chief doctor of Polyclinic, Dnipropetrovsk City Hospital #7

Sevastopol City

Sevastopol City Health Authority

- Dr Victor Pologov, Head of the Sevastopol City Health Authority
- Dr Nataliya Vyshnevetska, Deputy Head of the Sevastopol City Health Authority

Sevastopol City TB Dispensary

- Dr Vasyl Sintsov, Chief doctor of the Sevastopol City TB Dispensary
- Dr Galina Dubrovina, Deputy Chief doctor of the Sevastopol City TB Dispensary
- Larisa Kurnikova, Chief doctor of the Sevastopol City TB Polyclinic
- Larisa Palkina, Head of the Microbiological Laboratory, Sevastopol City TB Dispensary

2.3 MAPS OF UKRAINE



**MoH Ukraine meeting to review the results of TB service in 2004
and
National symposium to discuss draft National TB Control Program for 2006-2010
(25-26 May 2005, Kharkiv)**

Report

An annual meeting of the Ministry of Health of Ukraine (MoH) to review the results of work of TB service was held according to the MoH Order dated 14th May 2005 #157-Adm "About holding a meeting to review results of work of TB service in 2004" followed by the National Symposium to discuss draft National TB Program for 2006-2010 (25-26 May 2005, Kharkiv). PATH provided organizational and financial support to both events.

Over 100 managers of health care and TB service from all over Ukraine took part in the meeting and symposium, including S.M. Hanenko, First Deputy Minister of Health; T.A. Aleksandrina, Head, MoH's Dept. for Organization of Treatment of Socially Dangerous Diseases; and her staff; O.P. Nedospasova, Leading Specialist, MoH's Center for Health Statistics; representatives of the F.G. Janovsky Institute of Pulmonology and Tuberculosis AMS Ukraine (IPT): Prof. V.M. Melnik, Deputy Director; Prof. O.I. Bilogortseva, MoH's Chief Children's Phthisiatrist; Prof. S.O. Cheren'ko; and B.O. Volos, Head, Health Department of Kharkiv Oblast State Administration; Chief doctors and heads of Organization and Methodic Departments of the Crimean Republican, oblasts, Sevastopol and Kyiv City TB dispensaries, MoH's Center for Health Statistics, Heads of health departments of the Ministry of the Interior, National Security Service, Ministry of Defense, State Penitentiary Service, Sea Fleet of Ukraine, Railways Service, Heads of TB Departments of Medical Institutes and Universities, WHO officers for TB control in Ukraine, PATH staff and consultants, as well as project partners. Also invited to take part were the representatives of the USAID Mission and Policy Office, though they were unable to attend.

Copies of draft Concept of the National TB Control Program for 2006-2010 and the Workplan of the National TB Control Program for 2006-2010 that had been prepared by the MoH Working Group were distributed by PATH staff to all participants of the symposium well in advance for review and discussion during symposium. Also distributed were materials regarding results of introduction of DOTS strategy in Ukraine and other countries, implementation of PATH project "Support to Ukraine in Implementing its National TB Program in 2002-2005", as well as PATH activities in Ukraine and other countries.

25th May 2005

The following reports were presented to the participants of the Annual meeting:

Results of work of TB service of Ukraine in 2004 were reviewed by Prof. V.M. Melnik, Deputy Director of IPT, who presented the main statistical indices of development of TB epidemic in Ukraine in 2004, status of TB service, and the existing shortcomings. The author failed to analyze in detail the causes of steady worsening of the epidemic situation in the country.

Prof. Melnik noted that according to the WHO criteria Ukraine belongs to countries with the

high morbidity rate (over 30 cases per 100,000 population). During 2004 there was further increase in the TB incidence (by 4.4%) and mortality (by 4.3%). In 2004 a total of 38,403 TB cases were detected, and 10,787 people died of TB. Currently 107,000 persons with active form of Tb undergo treatment, while the total number of patients registered with TB dispensaries is 597,000.

An average TB morbidity rate in Ukraine is 80.9 per 100,000 population vs. 77.5 in 2003. The highest TB morbidity rates were registered in Kherson Oblast (166.2 per 100,000 population), Mykolayiv Oblast (114.9), Lugansk Oblast (112.4), Donetsk Oblast (96.1), Kirovograd Oblast (95.6) and Kharkiv Oblast (94.0).

An average TB mortality rate in Ukraine is 22.6 per 100,000 population vs. 21.8 in 2003. The highest TB mortality rates were registered in Kherson Oblast (46.9 per 100,000 population), Odesa Oblast (33.5), Donetsk Oblast (33.1), Dnipropetrovsk Oblast (30.0) and Lugansk Oblast (28.7).

A significant number of destructive and fibro-cavernous forms of TB in newly diagnosed patients are a peculiar feature of the epidemic situation in Ukraine. In 2004 the morbidity rate of destructive forms was 26.7 per 100,000 population, and that of fibro-cavernous forms of TB – 1.5 per 100,000 population.

Owing to the centralized procurement of TB drugs by the MoH, they are in adequate supply. In 2004 the bacterioexcretion termination rate was 89.5%, or higher by 0.4% and by 2.8, than in 2003 and in 2002, respectively. However, the validity of this index does not correspond to international standards, since no cohort analysis has been introduced in Ukraine so far.

In 2004 there were 124 TB dispensaries (TBD) in Ukraine, out of which 102 have in-patient departments. In the in-patient departments of TBD of the MoH there are 5.3 beds per 100,000 population. In 2004 there were 3,249 TB doctors (or 0.7 per 100,000 population) and 7,941 nurses. A prestige of health workers working for TB service is very low, young doctors do not want to work at TBD. As a result, average age of TB doctors is 58.

The worsening of situation with TB is caused by health (spread of multidrug resistant TB, HIV, inadequate funding of TB facilities, and lack of skilled personnel) and social factors (low standard of living of significant part of population, significant number of prisoners, insufficient involvement of NGOs, local communities and volunteers).

Analysis of the implementation of activities to control TB in Ukraine, envisaged by the National TB Control Program for 2002-2005 (hereinafter – Program) showed that:

- The existing system of activities to control TB in the country is not perfect;
- There is no mechanism to coordinate, monitor and assess Program activities;
- Mechanisms of TB detection and control of treatment of patients are not well enough;
- Measures to prevent the spread of TB/HIV co-infection are being introduced too slowly;
- The system of training of health workers, volunteers and the system to raise public awareness in TB prevention and treatment needs improvement;
- The development of scientific research into modern methods of TB prevention, diagnosis and treatment and introduction of their results are quite slow;
- The community potential in organizing primary activities pertinent TB prevention and social support of TB patients has been used quite insufficiently;

- The approach to spending budget funds to control TB is quite irrational.

In the circumstances, there, there is a need to develop a new effective national program for TB control for 2006-2010.

2. Main indices of the activity of Ukraine's TB services related with rendering medical care to children and adolescents were presented by Prof. O.I. Bilogortseva, Chief Scientist, IPT, MoH's Chief Children's Phthisiatrist.

Against the background of the rise of TB incidence among adults, the epidemic indices among children remained stable during recent years; in 2004 this index equaled to 9.3 per 100,000 population aged 0-14 yrs and 31.3 per 100,000 population aged 15-17 yrs. The highest incidence rate was registered among children and adolescents, living in socially maladapted families, homeless, and Roman population and Crimean Tatars. The reasons that facilitate control of Tb spread among children and adolescents include BCG vaccinations and booster doses, as well as tuberculin diagnosis. Therefore, these activities need to be carried on in the future. Due to inadequate skills of nurses there are problems with observing proper methodology and interpreting results of vaccination. Nurses need more training and international organizations can help. During recent years there were reports of adverse effects following BCG vaccination with the lesion of bones and joints, which resulted in law cases against health workers.

3. Organization of medical care to patients with TB/HIV co-infection was dealt with by S.O. Cherenjko, Leading Scientist, IPT.

During recent years there was a tendency towards steady increase of TB incidence among HIV-positive subjects, and detection of HIV during testing TB patients, who are being treated at TBD. There are 2.4 cases of HIV-associated TB per 100,000 population, but the validity of this index is low due to lack of system for diagnosis. High mortality rate among such patients is due to late diagnosis of TB in HIV-positive persons resultant from problems with diagnosis, poor chemoprevention of TB (6-month prevention course with isoniazide is very difficult to complete), lack of rapid tests for TB diagnosis, as well as due to difficulties to diagnose and treat opportunistic infections.

In turn, the problems of TB diagnosis in HIV-positive persons are due to:

- Atypical clinical manifestations of the disease (frequent atypical localization of TB in lower lobes of the lungs;
- Prevalence of non-pulmonary forms of TB, particularly, TB of lymph nodes;
- Poor coordination of TB service and AIDS centers in the regions, and lack of test systems;
- Inadequate professional skills of health workers in pre- and post-testing counseling;
- Insufficient professional training of health workers in lymph node biopsy and their microbiological test for MTB.

4. About TB incidence status and problems in organizing TB treatment in penitentiary system told S.B. Zhivago, Head, Health Department, Ukraine's State Penitentiary Department.

Controlled treatment of TB patients was introduced in all health facilities of the State Penitentiary Department. Owing to MoH's centralized procurement there is no problem with TB drugs.

A problem of inadequate supply of laboratory equipment is going to be resolved through the World Bank loan within the framework of project "Control of TB and HIV/AIDS in Ukraine". In many health facilities there are many vacancies due to low salaries and heavy working conditions. The Government has to provide health workers with preferential housing and increase salaries.

5. Results of implementation of "Tuberculosis Control Component " of the WB and MoH project "Control of TB and HIV/AIDS in Ukraine" were presented by L.V. Turchenko, Project Coordinator, and Chief Doctor of Kyiv City Central TB Dispensary.

WB and MoH Project "Control of TB and HIV/AIDS in Ukraine" already started tenders to purchase laboratory equipment and consultation services in training health workers and health education. The project has been put on hold because the MoH failed to approve forms for recording and reporting.

In addition to the loan, the WB will provide a grant in the amount of \$1M for social support of TB patients, who undergo controlled supportive treatment.

6. Importance of risk groups in TB pediatrics was considered by Prof. I.O. Sirenko, Head, Dept. of Children's TB, Kharkiv Medical Academy of Post-Graduate Education.

Tuberculin diagnosis is an extremely important and valuable method for TB detection among children and adolescents. There is no alternative to tuberculin diagnosis. Doctors and nurses need to be regularly trained in the proper technique and interpretation of results obtained.

26th May 2005

The following reports were presented to the participants of the symposium to discuss draft National TB Control Program for 2006-2010:

1. Address by S.V. Hanenko, First Deputy Minister of Health. On behalf of M.E. Polishchuk, Minister of Health of Ukraine, he welcomed the participants and voiced a political decision, that the MoH has taken to introduce DOTS strategy in Ukraine. Holding the symposium to discuss National TB Program is very important since MoH is determined to step aside from traditional monopoly in taking decisions by MoH's Main TB Specialist, and to resolve strategic and key issues through wide discussions involving specialists from the field. The symposium participants should select 5 to 6 specialists from the regions to the MoH's Working Group for restructuring TB service of Ukraine. A center for information and methodic support of National TB Program will be set up within MoH.

The Government realizes that coping with TB epidemic can be through resolving health-related, social and political issues. In this context, Ukraine's President prepares a decree about responsibilities of regions' governors for TB epidemic control. Introduction of cost effective strategy to control TB epidemic and cost effective health system as a whole is MoH's priority #1. It is quite essential to learn how to use international aid to control TB in other health sectors. S.M. Hanenko demonstrated TB Drug Kit, which Health Minister brought from the WHO Headquarters in Geneva. The price of such kit, which includes combined TB drugs for

one TB patient for 6 months is much lower compared to TB drugs which are currently procured by MoH using state budget funds.

2. Analysis of implementation of the National TB Program for 2002-2005 was made by T.A. Aleksandrina, Head, MoH's Dept. for Organization of Treatment of Socially Dangerous Diseases.

The acting National TB Program for 2002-2005 had been adopted by the Decree of Ukraine's President dated 20th Aug'01, #643/2001. The Program's key activities had been implemented. The following problems interfered with an effective implementation of the Program:

- Lack of an effective mechanism to coordinate Program implementation;
- Lack of an effective system to monitor Program implementation;
- Imperfect system for TB detection and in-patient treatment;
- Imperfect system for controlled treatment of TB patients during out-patient/supportive phase;
- Spread of TB among HIV-positive patients;
- Shortcomings in the training and motivation of the staff of TB service;
- Imperfect system for informing community about how to prevent TB;
- Lack of initiative at the regional level and specific proposals to restructure TB service;
- Insufficient funding of TB Program activities by the local authorities in the majority of regions;
- Insufficient involvement of primary health facilities and staff in TB Program realization;
- Insufficient involvement of public organizations in TB Program realization.

3. Draft Concept of the National TB Program for 2006-2010 (Annex 1) and the **Workplan of the National TB Program for 2006-2010** (Annex 2) were presented by Prof. V.M. Melnik, IPT Deputy Director.

4. Cooperation between MoH Ukraine and PATH Project on "Support to Ukraine in Implementing its National Program for TB Control" during 2002-2005 was presented by A.V. Tsarenko, Project Manager, Ukraine Country Program. All participants were given handouts with the information about PATH activities in implementing a project "Assistance to Ukraine in Implementing National TB Program for 2002-2005" and other related projects in different parts of the world (Annex3).

5. Results of implementation of PATH project on "Support to Ukraine in Implementing its National Program for TB Control" in Donetsk Oblast during 2002-2005 were presented by O.E. Klochkov, Chief Doctor, Donetsk Oblast TB Dispensary, and S.G. Svitlychna, Chief Doctor, Mariupol City TB Dispensary (Donetsk Oblast).

6. Results of discussion of the Inter-Agency Working Group of the Main Health Department of Kyiv City State Administration to develop a draft Kyiv city program of TB control for 2006-2010 and experience of implementing city program during 1994-2005 were presented by L.V. Turchenko, Chief Doctor, Kyiv City TB Dispensary.

Draft National TB Program for 2006-2010 and draft model of the Regional TB Program for 2006-2010 were discussed by

1. I.M. Gorbatjuk, Chief Doctor, Vinnytsa Oblast TB Dispensary: In general, the proposed draft concept and draft workplan of the National TB Control Program are acceptable. However, the mechanism of introduction of controlled treatment of TB patients needs a more detailed description. In particular, introduction of the posts of visiting nurses of TB service, who would be in charge of the controlled treatment of TB patients in an out-patient phase. Also, it is essential that a mechanism be developed for a compulsory isolation in TBD or hospital of TB patients with elimination of bacilli till complete abacillation. To prevent the spread of epidemic of chemoresistant TB there is need to set up special wards for patients with chemoresistant TB and for patients with chronic TB. A proposal to set up a MoH's Working Group for restructuring TB service.
2. A.I. Ahtyrsky, Chief Doctor, Zaporizhzhya Oblast TBD: To introduce an effective controlled treatment of TB patients it is necessary to improve a mechanism for involving general health system staff in dispensing TB drugs. The experience of Zaporizhzhya Oblast showed that the general health system staff are not willing to do this due to a complicated reporting system.

TB service of Zaporizhzhya Oblast has an experience of setting up (in cooperation with NGOs and social welfare agencies) within TBD and hospitals of special Rooms for social and psychological support. Still urgent is an issue of hospitalizing patients with TB/HIV co-infection – should these be regular wards or special units? Should a decision is made to accommodate those patients in regular wards; will this violate the rights of other patients?

3. O.M. Burjatynsky, Chief Doctor, Kherson Oblast TBD: An issue of forced treatment of TB patients with elimination of bacilli, who systematically violate treatment regimen and have asocial conduct, is quite urgent. Usually, these patients suffer from alcoholism. Therefore, while in a TBD or hospital they go to the town, buy and consume alcohol and do some offense. During current year such patients have beaten a doctor on-duty; also there are cases of violence against other patients. Each month doctors of TB facilities have to prematurely discharge such patients, who pay no attention to admonitions and warnings, thus facilitating a spread of epidemic of chemoresistant TB.
4. V.V. Filjuk, Chief Doctor, Odesa Oblast TBD: All pros and contras of introduction of DOTS strategy should be assessed by MoH (with due account of the experience and peculiarities of Ukraine's TB service) before taking final decision. MoH should consult with regions and look for a compromise.
5. L.V. Turchenko, Chief Doctor, Kyiv City TBD: Supported Dr. Filjuk and noted that DOTS requirements should be properly interpreted, taking into consideration traditions, achievements and experience of Ukraine's TB service. Concern was expressed about the fact that DOTS may ruin an existing TB system. Kazakhstan was taken as an example. Dr. Turchenko visited this country recently within the framework of the KNCV/KIT project for TB control in Kyiv City. According to Dr. Turchenko, TB specialists in Almatu feel extremely sorry that on recommendation of international consultants (who "take no responsibility for the consequences of their recommendations", Dr Turchenko believes) "the Soviet system of TB service" was destroyed and nobody knows what to do next. TB epidemic spreads rapidly, while

local specialists remain helpless after international consultants left.

6. A.V. Tsarenko, PATH Project Manager, "Assistance to Ukraine in Implementing its National TB Program for 2002-2005" emphasized (on behalf of USAID and WHO) that adding in the NTP a clause providing for a forced treatment of TB patients may be considered as a violation of human rights and Ukraine's legislation about patient's voluntary consent to undergo treatment. It is essential to study a related experience of other countries and regulate this issue with the Ministry of Justice and human rights experts. Setting up special units for patients with TB/HIV co-infection would contradict Ukraine's legislation regarding confidentiality of patient's HIV-status.

Draft resolution of the MoH's meeting and the National symposium was approved as follows:

1. Support and approve of the draft concept and workplan of NTP activities as a whole.
2. Request that the working group (in cooperation with specialists of international organizations) completes draft concept and workplan of NTP activities with due account of the results of discussions, held during national symposium.
3. Development of concepts of the National TB Program for 2006-2010 should be based the following principles of DOTS strategy (as adapted to Ukraine's conditions) providing for:
 - Maintaining tuberculin diagnosis as a method for selecting children for revaccination, chemoprevention among HIV-positive and detection of MTB in children;
 - Chest X-ray of subjects belonging to risk groups by medico-social criteria, patients who requested medical aid and who have symptoms of TB for TB diagnosis and to detect other chest pathology.
4. Continue study and assure compliance with acting legislation and international standards of the mechanism for mandatory treatment of TB patients with elimination of bacilli, persons with asocial conduct and those who avoid treatment till elimination is terminated.
5. Develop and approve of by related regulatory acts the standards of diagnosis and treatment of TB patients, which comply with international requirements.
6. Introduce (with involvement of international and public organizations) changes in the TB curricula for medical and post-graduate students to introduce DOTS strategy.
7. Develop a system of motivation to raise the prestige of TB specialist in order to involve young specialists to TB service.
8. Restructure TB service to improve effectiveness of NTP providing for involvement of general health facilities and their staff in detection and controlled treatment of TB patients in supportive phase, as well as for an increase of the number of TB patients who receive treatment on the out-patient or day hospital basis.
9. Develop a system to prevent TB epidemic among HIV-positive and a system of treatment of patients with TB/HIV co-infection.

2.4 Conclusions

1. High officials at MoH realize the importance of introduction of DOTS strategy to increase efficacy of the National TB Control Program.
2. No comprehensive assessment and analysis of the results of implementation of the NTP in 2002-2005 have been made. Therefore, there is need to request MoH to arrange for an independent assessment with participation of international experts, with the results obtained to be taken into account during development of a new NTP.
3. The proposed draft concept and workplan of NTP activities do not fully conform to the requirements of DOTS strategy and the specialists of PATH, WHO and USAID could provide assistance to the MoH's working group or give proposals to MoH regarding the revision of the concept and workplan according to the requirements of DOTS strategy.
4. Some managers of TB Service in the regions and at the Institute of Pulmonology and Tuberculosis do not understand or have somewhat wrong understanding of some clauses of DOTS strategy. Therefore, international organizations need to explain the benefits of DOTS strategy more actively through trainings, conferences, symposia, study tours to countries of Europe, in which the strategy has been successfully introduced.
5. Specialists working for PATH projects in the pilot sites should be involved in sharing experience about implementation of DOTS strategy in Ukraine.

3 ANNEX IV

3.1 MAIN DOCUMENTS CONSULTED

- PATH. Support to Ukraine. Detailed Implementation Plan. April 30, 2004.
- PATH. Support to Ukraine in Implementing its National TB Programme. Annual Report, October 30, 2004.
- PATH. Support to Ukraine in Implementing its National TB Programme. Behaviour Change Strategy.
- PATH. Support to Ukraine in Implementing its National TB Programme. Technical proposal U/OP-03-002, December 2, 2002.
- PATH. The results of the implementation of External Quality Control (by the method of panel testing) of sputum smear microscopy stained by Ziehl-Neelsen.
- Guidelines for sputum microscopy (RU), Donetsk, 2004.
- WHO EURO. Report of a Joint Review of Tuberculosis in Ukraine. 6-15 December 1999. WHO EUR/00/5017620.
- WHO EURO. Tuberculosis Surveillance Assessment Mission to Ukraine, 20-24 May 2002.

Annex B: Action Plan/Revised Timeline for Year 3

Action Plan/Revised Timeline for Year 3

	1	2	3	4	5	6	7	8	9	10	11	12
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
General Management Activities												
Coordinate activities with project partners in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.												
Hold annual stakeholders' meeting.												
Support local TB experts and officials to attend regional and international technical conferences and meetings.												
Conduct final assessments and draft final report.												
Component 1: Improve capacity of DOTS expansion within Ukraine												
1.1. Monitor development of new legislation and recommend additions/revisions.												
1.1.1. Review legislative and policy documents, identify gaps or contradictions, and recommend additions or revisions to legislative base.												
1.1.2. Convene quarterly PACG meetings												
1.2. Convene technical symposia.												
1.2.1. Finalize topics and convene meetings.												
1.3. Increase access to up-to-date technical literature among TB decision-makers and specialists.												
1.3.1. Design website and listserv.												
1.3.2. Collect, organize, distribute, and discuss TB guidelines, articles, bulletins, and news through listserves.												
1.4. Facilitate development of new National TB Program strategy and detailed work plan.												
1.4.1. Participate in planning meetings with all stakeholders to review draft plan; provide written comments.												
1.4.2. Support participation of 1-2 experts in a national TB program assessment.												
1.4.3. Participate in revision of National TB Plan based on feedback and support MOH to launch program.												
Component 2: Improve the quality of TB diagnosis.												
2.1. Introduce direct smear microscopy QC systems in general health care and TB laboratories in Donetsk and in expansion oblasts.												
2.1.1. Conduct meetings with partners.												
2.1.2. Convene quarterly meetings of working groups.												
2.1.3. Conduct quarterly monitoring visits to laboratories of Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.												

	1	2	3	4	5	6	7	8	9	10	11	12
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
2.1.4. Support implementation of QC system in laboratories of Donetsk City and Oblast: by Feb 2006 in 20% of laboratories; by March 2006 in 50%; by September 2006 in 100% of laboratories.												
2.1.5. Support introduction of QC system in laboratories in pilot sites.												
2.1.6. Conduct trainings on QC of smear microscopy in pilot sites.												
2.1.7. Conduct national training of trainers for TB laboratory personnel.												
2.2. Develop guidelines and introduce QC for culture and identification tests for MTB.												
2.2.1. Prepare and publish methodological recommendations for QC of culture tests and tests for sensitivity to TB drugs.												
2.2.2. Develop training curriculum on QC for culture tests and tests for sensitivity to TB drugs.												
2.2.3. Conduct training on QC for culture tests and tests for sensitivity to TB drugs in Donetsk City (Mariupol'''' and Gorlovka)												
2.2.4. Conduct training on QC for culture and sensitivity tests to TB drugs in expansion oblasts.												
2.3. Strengthen DST and MDR monitoring.												
2.3.1. Develop training curriculum for operators on application software to record MDR TB in laboratories.												
2.3.2. Introduce EMIS for MDR TB in Donetsk Oblast TB Dispensary laboratory and level III laboratories in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.												
2.3.3. Train coordinators in use of software to record MDR TB in laboratories.												
2.3.4. Monitor application (field assessment visits, collection, and analysis of feedback information).												
2.3.5. Provide technical support for use of software to record MDR TB.												
2.4. Dissemination of results.												
2.4.1. Publish results in professional journals.												
2.4.2. Arrange meetings with partners on QC of laboratory TB diagnosis.												
2.4.3. Arrange for external independent assessment of QC system of laboratory TB diagnosis.												
Component 3: Improve use of TB monitoring and surveillance data.												
3.1. Evaluate and revise data recording and reporting forms.												

	1	2	3	4	5	6	7	8	9	10	11	12
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
3.1.1. Convene TB MIS Discussion Group to evaluate and revise recording and reporting forms in collaboration with stakeholders.												
3.1.2. Print Form TB-01 for pilot sites.												
3.1.3. Provide training on use of data reporting and recording for project partners in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Sevastopol City.												
3.2. Design and implement TB EMIS.												
3.2.1. Update and field test electronic application of TB MIS.												
3.2.2. Establish/help maintain email service and connect field electronic data collection points to Ukraine TB Network (for Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities).												
3.2.3. Design training on TB EMIS for operators and data analysts.												
3.2.4. Train data entry staff from Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Sevastopol Cities.												
3.2.5. Participate in WHO training on TB surveillance.												
3.2.6. Monitor TB MIS implementation.												
3.3. Develop tools for routine monitoring of diagnostic efficiency.												
3.3.1. Conduct small study to assess screening efficiency of x-ray.												
3.4. Support institutionalization of TB MIS to assess drug susceptibility.												
3.4.1. Ongoing monitoring of progress towards institutionalization.												
3.5. Develop and introduce model approaches for information system integration between TB and HIV programs.												
3.5.1. Convene meetings with HIV and TB authorities to develop plan of action.												
3.5.2. Assess status of HIV data management and mechanisms for linking to TB.												
3.6. Integrate pharmaceutical management into the TB management information system.												
3.6.1. Monitor effectiveness of integration and use of data for program planning.												
3.7. Dissemination of results.												
3.7.1 Write journal article on MIS project results and submit for publication.												

Component 4: Reduce diagnostic delay, increase case detection, and improve adherence to TB treatment.											
4.1. Increase awareness and understanding of TB transmission, symptoms, treatment, and cure among the general public and specific at-risk populations.											
4.1.1. Print and reprint public awareness IEC materials.											
4.1.2. Collaborate with partners to disseminate IEC materials (display posters, distribute brochures).											
4.1.3. Develop TV and radio spots.											
4.1.4. Re-launch media campaign in Donetsk.											
4.1.5. Initiate media campaign in Kyiv.											
4.1.5. Initiate media campaign in Kharkiv, Dnipropetrovsk Oblasts, and Sevastopol Cities.											
4.1.6. Organize public awareness events for World TB Day.											
4.1.7. Monitor BCC indicators.											
4.1.8. Conduct final formative research (KAP survey and focus groups).											
4.1.9. Analyze final formative research results, draft reports.											
4.2. Improve health-seeking behavior and treatment adherence among people diagnosed with TB.											
4.2.1. Collaborate with partners to disseminate materials.											
4.2.2. Collect data of study to assess factors affecting patient adherence to treatment in Donetsk Oblast.											
4.2.3. Data analysis and interpretation stage.											
4.2.4. Conduct final TB patient exit survey in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.											
Component 5: Improve provider practices.											
5.1. Train TB providers in IPC/C and VCT in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.											
5.2. Work with KMAPGE, Donetsk, and other selected medical universities to incorporate IPC/C and VCT curriculum into training curricula for TB doctors.											
5.3. Evaluate IPC/C and VCT training activities.											
5.4. Conduct DOTS/clinical training for all relevant TB personnel in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.											
5.5. Conduct DOTS/clinical training for general health providers on detection and follow-up in Donetsk, Kharkiv, Dnipropetrovsk Oblasts, and Kyiv and Sevastopol Cities.											
5.6. Evaluate DOTS/clinical training activities.											

Annex C: Progress Report by Intervention Area

Component 1: Improve capacity for DOTS expansion within Ukraine.			
Objectives	Major Planned Activities	Status	Comments
1.3. Increase access to up-to-date technical literature among TB decision-makers and specialists.	<ul style="list-style-type: none"> Distribute key literature via print, email, web, or meetings. 	Done, ongoing	PATH provided translated abstracts and articles to TB specialists with the MOH and ITP, medical universities, and TB health care providers in all oblast TB dispensaries. PATH continues to expand its email listserve (the UA TB Listserve) and has supported access to the internet in its pilot sites. PATH provided the Donetsk, Dnipropetrovsk, and Kharkiv Oblast TB hospitals and dispensaries and the Sevastopol and Mariupol' City TB dispensaries with computers and internet access. In addition, PATH helped to establish email service and a local area network connection in the hospitals and dispensaries, enabling them to have access to the listserve.
	<ul style="list-style-type: none"> Support key local TB experts and officials to attend regional or international technical conferences and meetings. 	Done	<p>PATH supported six officials, representing Dnipropetrovsk, Donetsk, and Kharkiv Oblasts and Kyiv and Sevastopol Cities, to attend the summation conference on the KNCV/KIT/Kyiv City Health Administration Project on TB Control in Kyiv in April 2005.</p> <p>A. Bishop, K. Gamazina and A. Tsarenko participated in the 35th International Union Against Tuberculosis and Lung Disease World Conference held from 28 October to 1 November, 2004, in Paris, France.</p>

Component 2: Improve the quality of diagnostic services in selected oblasts.			
Objectives	Major Planned Activities	Status	Comments
2.1. Introduce direct-smear microscopy QC systems into general health care and TB labs in Donetsk.	<ul style="list-style-type: none"> Conduct facility assessments and site visits. 	Done	Assessment was conducted in the new Oblasts of Dnipropetrovsk and Kharkiv and in the city of Sevastopol.
	<ul style="list-style-type: none"> Conduct meetings with partners. 	Done	PATH lab specialist participated in working group meetings and roundtable discussions to develop new forms and legal documents.
	<ul style="list-style-type: none"> Create TB lab working group to introduce QC system in Donetsk City and Oblast. 	Done	

Component 2: Improve the quality of diagnostic services in selected oblasts.			
Objectives	Major Planned Activities	Status	Comments
	<ul style="list-style-type: none"> • Convene quarterly meetings of working group in Donetsk City and Oblast. • Conduct quarterly monitoring visits to laboratories. • Support introduction of QC system into laboratories in Donetsk City and Oblast: by February 2006, 20 percent of laboratories; by March 2006, 50 percent; by September 2006, 100 percent of laboratories. • Prepare and publish methodological recommendations for QC of smear microscopy. • Test and refine proposed QC system in collaboration with partners. • Develop training curriculum on QC introduction. • Conduct trainings on QC of smear microscopy in Donetsk City. 	<p>Done</p> <p>Done</p> <p>Done, ongoing</p> <p>Done</p> <p>In progress</p> <p>Done</p> <p>Done</p>	<p>Four meetings were convened.</p> <p>Four monitoring visits to laboratories were conducted; 10 laboratories were visited.</p> <p>Panel testing was introduced into laboratories in Donetsk Oblast; 70 laboratories participated; 78 technicians were evaluated.</p> <p>Prepared together with the ITP lab recommendations; 500 copies were printed for the labs in general health care settings of Donetsk Oblast.</p> <p>Trained personnel include 85 lab specialists from Donetsk; 3 lab specialists from Kyiv; laboratory chiefs from Dnipropetrovsk (plus 1 specialist), Kharkiv, and Sevastopol. In addition, 51 specialists participated in postgraduate training conducted by the chair of lab diagnostics of KAMPO; a total of 175 were trained.</p>
2.2. Develop guidelines and introduce QC for culture and identification tests for MTB.	<ul style="list-style-type: none"> • Prepare and publish methodological recommendations for QC of culture tests and tests for sensitivity to TB drugs. 	In progress	Drafting of QC for culture recommendations has been initiated jointly with the head of the reference lab and chief of the laboratory of microbiology. DST has begun.

Component 2: Improve the quality of diagnostic services in selected oblasts.			
Objectives	Major Planned Activities	Status	Comments
	<ul style="list-style-type: none"> • Develop training curriculum on QC for culture tests and tests for sensitivity to TB drugs. 	Done	Training curriculum on QC for culture tests and tests for sensitivity to TB drugs (content, schedule, participants) was developed and used for specialists in the new oblasts: Dnipropetrovsk, Kharkiv, Donetsk, and in Sevastopol and Kyiv with leading specialists of ITP (May 2005).
2.3. Strengthen DST plus MDR monitoring.	<ul style="list-style-type: none"> • Develop training curriculum for operators on application software to record MDR TB in laboratories. • Introduce EMIS for MDR TB in Donetsk Oblast TB dispensary lab. • Train coordinators in use of software to record MDR TB in laboratories. • Monitor application (field assessment visits, collection and analysis of feedback information). • Provide technical support for use of software to record MDR TB. 	<p>In progress</p> <p>Not yet done</p> <p>Not yet done</p> <p>Not yet done</p> <p>Not yet done</p>	Software under development.
2.4. Evaluation of new TB tests.	<ul style="list-style-type: none"> • Investigate possible linkages with FIND and other international TB diagnostic development groups. • If possible, identify test(s) with potential applicability in Ukraine. 	<p>In progress</p> <p>In progress</p>	<p>No diagnostics ready for field evaluation at this time. Contact with FIND continues.</p> <p>See above.</p>
2.5. Dissemination of results.	<ul style="list-style-type: none"> • Publish results in professional journals. • Arrange meetings with partners on QC of laboratory TB diagnosis. • Arrange for external independent assessment of QC system of laboratory TB diagnosis. 	<p>Not yet done</p> <p>Done</p> <p>Done</p>	Implementation results thus far were presented on three occasions during joint meetings with partners.

COMPONENT 3. Improve use of monitoring and surveillance data for TB program management			
Objectives	Major Planned Activities	Status	Comments
3.1 Evaluate and revise current DRRS forms and introduce analytic methods to assess patient progress and treatment outcome, overall program performance, and rapid managerial assessment protocols.	<ul style="list-style-type: none"> Analyze oblast situation regarding TB MIS: identify needs, priorities, available resources, behavior/ motivation issues, obstacles to desired performance, and actions necessary to solve problems. 	Done	Assessment completed; report issued and being used for discussion with partners (WHO, World Bank, and ITP) regarding development of MIS for NTP.
	<ul style="list-style-type: none"> Develop recommendations and action plan. 	Done	MIS implementation and monitoring protocol developed for Donetsk, Kharkiv, and Dnipropetrovsk Oblasts and Sevastopol City.
	<ul style="list-style-type: none"> Form discussion group on TB MIS. 	Done	Completed (MIS conception, DRRS elaborated and presented).
	<ul style="list-style-type: none"> Expand introduction of DRRS. 	In progress	Population coverage by DRS: Donetsk Oblast: 100 percent; Kharkiv Oblast: 10 percent; Sevastopol City: 100 percent; Dnipropetrovsk Oblast: initiated.
	<ul style="list-style-type: none"> Convene interagency technical working group on TB MIS (in collaboration with HLWG activities). 	In progress	In cooperation with World Bank, WHO, TBI, and TB dispensaries in project sites, elaboration of MIS for NTP is on track. Participated in new NTP development application to GFATM.
	<ul style="list-style-type: none"> Conduct national TOT in recording and reporting. 	Done	Specialists from ITP participated in a TOT on MIS.
	<ul style="list-style-type: none"> Disseminate results through symposia, seminars, and/or a national meeting. 	In progress	Analysis of TB situation globally, regionally, and nationally presented to partners and trainees at various forums.

Component 3. Improve use of monitoring and surveillance data for TB program management			
Objectives	Major Planned Activities	Status	Comments
3.2 Design and implement a TB EMIS for surveillance and case management of registered TB cases.	<ul style="list-style-type: none"> • Design and implement a TB EMIS. • Create a Ukrainian TB internet forum, listserv, electronic library. 	Ongoing Ongoing	Population coverage by DRRS: Donetsk Oblast: 70 percent of Kharkiv: 10 percent Sevastopol City: 100 percent of Dnipropetrovsk: on track. Electronic TB library created. Forty members included in UA TB Info Network and weekly TB news dissemination.
3.3 Develop tools and indicators for routine monitoring of diagnostic efficiency and effectiveness of existing and new TB screening methods and strategies.	<ul style="list-style-type: none"> • Develop/adapt key tools and methods on analytic methods for health providers, laboratory workers, etc. • Conduct workshops and on-the-job training in new analytic procedures and on using information for management. 	Done In progress	List of indicators for program outcomes with sources, formulas and interpretation developed and included in MIS training curriculum. Included in MIS training curriculum.
3.4 Support institutionalization of TB MIS to assess drug susceptibility.	<ul style="list-style-type: none"> • Monitor and evaluate implementation; provide technical assistance as needed. 	In progress	MIS capable of including DST and drug resistance information.
3.5 Develop and introduce model approaches for information system coordination and integration between TB and HIV programs to improve linkages and referral systems among facilities.	<ul style="list-style-type: none"> • Monitor and evaluate implementation; provide technical assistance as needed. 	In progress	MIS ensures confidentiality about HIV status. MIS will provide TB/HIV co-infection data. A draft work plan for TB-HIV collaborative activities has been developed.
3.6 Integrate pharmaceutical management into the TB MIS with data about drug consumption.	<ul style="list-style-type: none"> • Provide technical assistance as needed. 	In progress	MIS ensures collection of first-line drug expenditures. MOH has requested that PATH develop a more comprehensive drug MIS.

Component 4: Reduce diagnostic delay, increase case detection, and improve treatment adherence.			
Objectives	Major Planned Activities	Status	Comments
4.1. Increase awareness and understanding of TB transmission, symptoms, treatment and cure among the general public and specific at-risk populations.	<ul style="list-style-type: none"> Develop baseline research protocol and questionnaires; obtain IRB approval and conduct research. 	Done	
	<ul style="list-style-type: none"> Analyze formative research results and develop BCC strategy. 	Done	
	<ul style="list-style-type: none"> Conduct IEC materials development training workshops. 	Done	18 participants received training in October 2004.
	<ul style="list-style-type: none"> Revise existing IEC materials; develop and pretest new versions. 	Done	The following materials were developed: 2 posters in Ukrainian, booklet in Ukrainian and Russian, and 2 brochures for general population and patients and their families in Ukrainian and Russian.
	<ul style="list-style-type: none"> Collaborate with partners to disseminate IEC materials (display posters, distribute brochures, etc.). 	In progress	Prepared detailed distribution plan.
	<ul style="list-style-type: none"> Develop TV and radio spots. 	In progress	To be completed by October 2005.
	<ul style="list-style-type: none"> Re-launch media campaign in Donetsk. 	In progress	Printing and contracting with publishing house was delayed due to Orange Revolution (prices were unstable); IEC campaign now slated to begin in October 2005 in collaboration with the World Bank project.
	<ul style="list-style-type: none"> Initiate media campaign in Kyiv and expansion oblasts. 	Not done	Printing and contracting with publishing house was delayed due to Orange Revolution (prices were unstable); IEC campaign now slated to begin in October 2005 in collaboration with the World Bank project.
	<ul style="list-style-type: none"> Evaluate IEC materials and media campaign. 	Not done	To be conducted after IEC materials dissemination and media campaign.
<ul style="list-style-type: none"> Organize public awareness events for World TB Day. 	Done, planned again for 2006	Roundtables convened with NGOs and stakeholders in Kyiv and Donetsk; presentation for journalists.	

Component 4: Reduce diagnostic delay, increase case detection, and improve treatment adherence.			
Objectives	Major Planned Activities	Status	Comments
4.2. Improve health-seeking behavior and treatment adherence among people diagnosed with TB.	<ul style="list-style-type: none"> Conduct TB patient baseline exit survey in Donetsk, Kyiv, and expansion oblasts. 	Done	
	<ul style="list-style-type: none"> Revise existing IEC materials for patients and families; develop and pretest new versions. 	Done	
	<ul style="list-style-type: none"> Print/reprint TB patient and family education materials. 	Not done	Printing and contracting with publishing house was delayed due to Orange Revolution (prices were unstable); IEC campaign now slated to begin in October 2005 in collaboration with the World Bank project.
	<ul style="list-style-type: none"> Collaborate with partners to disseminate materials. 	Not done	
	<ul style="list-style-type: none"> Design study to assess factors affecting patient adherence to treatment in Donetsk Oblast. 	In progress	
	<ul style="list-style-type: none"> Create telephone hotline in Donetsk. 	Not done	Telephone hotline was to be created within the Oblast TB Dispensary. Activity was put off due to death of chief doctor. Replacement chief was just appointed in September.
	<ul style="list-style-type: none"> Develop and pilot peer education and outreach approaches. 	In progress	Working in close collaboration with the Ukrainian Red Cross
	<ul style="list-style-type: none"> Provide training to visiting nurses. 	Done	2 TOTs were conducted for the URCS chapters in Kyiv City and Donetsk oblast. Subsequently, the National URCS requested that PATH provide TOT for 20 coordinators from other oblasts.
<ul style="list-style-type: none"> Identify strategies for reducing refusal of care. 	In progress	First evaluation took place in August 2005, followed by strategy meetings with stakeholders on how to improve treatment adherence.	

Component 5. Improve provider practices by strengthening provider capacity to diagnose and treat TB based on DOTS.			
Objectives	Major Planned Activities	Status	Comments
5.1. Strengthen TB provider skills in interpersonal communication and counseling (IPC/C).	<ul style="list-style-type: none"> • Finalize training curriculum on IPC/C. • Train TB providers in IPC/C and VCT. • Evaluate training activities. • Work with Donetsk and other selected medical universities to incorporate IPC/C curriculum into training curricula for TB doctors. 	<p>Done</p> <p>In progress</p> <p>In progress</p> <p>In progress in Donetsk</p>	<p>Five trainings held in Donetsk Oblast, with 64 participants.</p> <p>Pre- and post-test and evaluation data collected.</p>
5.2. Improve provider skills in TB case management and follow-up.	<ul style="list-style-type: none"> • Review and adapt the TB clinical training curriculum developed by WHO and implemented in Donetsk. 	Done	<p>Clinical/training component consultant hired in April 2005.</p> <p>DOTS training curriculum based on WHO materials was developed and implemented in Donetsk. Curriculum was reviewed by K. Miskinis, head of the WHO office for TB Control in Ukraine.</p> <p>DOTS implementation: manuals/ training modules were printed in May 2005.</p>

Component 5. Improve provider practices by strengthening provider capacity to diagnose and treat TB based on DOTS.			
Objectives	Major Planned Activities	Status	Comments
	<ul style="list-style-type: none"> • Conduct TOT and facilitate roll-out training for primary health care providers on TB diagnosis and ambulatory treatment follow-up to ensure system readiness for proper referral of patients. • Conduct training workshops for TB providers at all levels, as necessary, on TB diagnosis, treatment, and follow-up in selected oblasts. • Collaborate with pre- and post-graduate health education institutions to introduce training curricula on TB treatment using DOTS and conduct TOT with professors of post-graduate training facilities. 	<p>Done, in progress</p> <p>In progress</p> <p>Done, in progress</p>	<p>Clinical/Training Component Implementation Plan was developed and discussed at the roundtable meeting with the project partners from the pilot sites, WHO, USAID, World Bank, and ITP.</p> <p>For TOT, participants were selected based on questionnaire responses from TB specialists in pilot sites in April 2005.</p> <p>First TOT was held in Donetsk May 30–June 2, 2005, by the DOTS Training Team from Donetsk trained by WHO and PATH..</p> <p>DOTS Implementation trainings were held in Kharkiv, June 29–July 01, 2005; in Sevastopol, July 11– 3, 2005; and in Dnipropetrovsk, August 3–5, 2005.</p> <p>PATH collaborated with Kyiv and Kharkiv Medical Postgraduate Academies, and Donetsk, Dnipropetrovsk, and Crimea Medical Universities. PATH involved professors from these institutes in DOTS TOTs.</p>

Annex D: Monitoring and Evaluation Matrix

PATH's Work Plan Matrix with Add-On Activities: Support to Ukraine in Implementing Its National TB Program

OBJECTIVES (Lead Staff)	INDICATORS	MEASUREMENT METHODS	MAJOR PLANNED ACTIVITIES	TIMING/ STATUS
<p>1. Improve capacity for DOTS expansion within Ukraine (A. Tsarenko).</p> <p>1.1. Monitor development of new legislation and recommend additions/revisions.</p> <p>1.2. Convene technical symposia.</p> <p>1.3. Increase access to up-to-date technical literature among TB decision-makers and specialists.</p>	<ul style="list-style-type: none"> Percentage of national and oblast authorities supporting DOTS. Number of new pieces of legislation in support of DOTS (TB control approaches recommended by WHO). Selection of "expansion oblasts" made or not. Number of project partners, key local TB experts, and officials attending regional or international technical conferences and meetings and participating in annual national TB symposia. 	<ul style="list-style-type: none"> Baseline and follow-up survey of policymakers. Legislative records. Site visits. 	<ul style="list-style-type: none"> Assess current level of national and oblast support. Set up Policy and Consulting Group to assist the MOH in developing and implementing appropriate orders (in collaboration with HLWG activities). Convene quarterly Policy and Advocacy Consulting Group meetings. Convene regional and national symposia on various topics related to improved TB control. Participate in key national meetings and committees related to TB control in Ukraine. Distribute key literature via print, e-mail, web, or meetings. Support key local TB experts and officials to attend regional or international technical conferences and meetings. 	<p>Years 1 and 3 Year 1</p> <p>Quarterly</p> <p>1 in 2005; 2 in 2006</p> <p>Years 1-3</p> <p>Years 1-3</p> <p>As possible</p>
<p>2. Improve the quality of TB diagnostic services in at least two oblasts (T. Ivanenko).</p> <p>2.1. Introduce direct smear microscopy QC systems in general health care and TB labs in Donetsk and add-on regions.</p> <p>2.2. Develop guidelines and introduce QC for culture and identification tests for MTB.</p>	<ul style="list-style-type: none"> Percentage of pilot facilities proficient in smear microscopy. Percentage of smears that are readable, of adequate quality. Smear conversion rate at 6 months. Proportion of positive smears among all smears analyzed at Level I and II labs. Accuracy of recordkeeping of specimens received, processed 	<ul style="list-style-type: none"> ITP, oblast, and laboratory reports on smear microscopy proficiency. ITP and oblast reports on MTB identification. ITP and oblast reports on TB drug sensitivity test. Monthly site visits. Evaluation of laboratory and TB control registries at TB dispensaries. 	<ul style="list-style-type: none"> Assess existing capacity to implement, document, and sustain QC for smear microscopy and culture methods in project sites. Convene inter-regional, interagency technical working group on laboratory QA/QC (in collaboration with HLWG activities). Identify and train oblast teams to implement QA procedures in project sites. Conduct ongoing monitoring of implemented QA procedures. Assess alternative diagnostic methods to serve as 	<p>Year 1</p> <p>Years 1-3</p> <p>Year 1-2</p> <p>Years 2-3</p>

OBJECTIVES (Lead Staff)	INDICATORS	MEASUREMENT METHODS	MAJOR PLANNED ACTIVITIES	TIMING/ STATUS
2.3. Strengthen DST + MDR monitoring. 2.4. Evaluate new TB tests. 2.5. Disseminate results.	and laboratory results. <ul style="list-style-type: none"> • Percentage of laboratories capable of identifying MTB. • Percentage of laboratories performing TB drug sensitivity test. • Number of training workshops. • Number of laboratories strengthened by region. • Number of specialists trained by region. • Documented evidence that smear microscopy results were used to make treatment decisions. • Evaluation data available on new diagnostic tools in selected sites. 	<ul style="list-style-type: none"> • Review of medical records; interviews with providers. • Feedback analysis from stakeholders, decision-makers, providers, patients. 	adjuncts or replacements to smear microscopy. <ul style="list-style-type: none"> • TOT training on smear microscopy QA/QC. • National TOT on smear microscopy and culture QA/QC. 	Years 1-3 Year 2 Year 3
3. Improve use of monitoring and surveillance data for TB program management (A. Dadu) 3.1. Evaluate and revise current DRRS forms and introduce analytic methods to assess patient progress and treatment outcome, overall program performance, and rapid managerial assessment protocols. 3.2. Design and implement a TB EMIS for surveillance and case management of registered TB cases. Develop tools and indicators for routine monitoring of diagnostic efficiency and effectiveness of existing and new TB screening methods and strategies. 3.3. Support institutionalization of TB MIS to assess drug susceptibility. 3.4. Develop and introduce model	To measure maturity of TB MIS structure and elements: <ul style="list-style-type: none"> • Proportion of population under surveillance system. • Number of major WHO-recommended TB cohort indicators that can be accurately measured and monitored at the national, regional and local levels (e.g., cure rate, completion rate, failure and fault rates, incidence, prevalence, and mortality rates, case detection and treatment success rates + HIV-attributable TB morbidity and mortality; primary and acquired MDR rates; diagnostic yield of existing and new TB screening methods and strategies; TB drug consumption rates). To measure quality and flow of TB surveillance/program information:	<ul style="list-style-type: none"> • Review of surveillance data from all rayons. • Evaluation of documentation at facilities, TB dispensaries, and SES (electronic database, registers, record-books, workbooks, admin .reports, analytical tables/graphs) as well as reports/results of special TB epidemiologic studies. 	<ul style="list-style-type: none"> • Form Discussion Group on TB MIS. • Convene inter-agency technical working group on TB MIS (in collaboration with HLWG activities). • Analyze oblast situation regarding TB MIS: identification of needs, priorities, available resources, behavior/motivation issues, obstacles to desired performance, and actions necessary to solve problems. • Develop recommendations and action plans. • Design and implement a TB EMIS. • Develop/adapt key tools and methods on analytic methods for health providers, laboratory workers, etc. • Conduct workshops and on-the-job training in new analytic procedures and on using information for management. • Monitor and evaluate implementation, provision of technical assistance as needed. • Assist with further modification and revision of the system based on feedback from the pilot regions. • Conduct comprehensive review of the reform results in the pilot regions and formulate recommendations for future directions. • Create a Ukrainian TB Internet Forum, listserv, electronic TB library. 	Year 1 Year 2-3 Year 1 Year 1 Year 1-3 Years 1, 2 Years 1-3 Years 1-3 Years 1-3 Years 2-3 Year 1

OBJECTIVES (Lead Staff)	INDICATORS	MEASUREMENT METHODS	MAJOR PLANNED ACTIVITIES	TIMING/ STATUS
<p>approaches for information system coordination and integration between TB and HIV programs to improve linkages and referral systems among facilities.</p> <p>3.5. Integrate pharmaceutical management into the TB MIS with data providing about drug consumption.</p>	<ul style="list-style-type: none"> Proportion of routine monthly TB surveillance reports that meet established criteria. <p>To measure strengthened analytical and information based management capacity of health workers:</p> <ul style="list-style-type: none"> Documented use of TB information system for preparedness and enhanced TB control/response at all levels of health system (e.g., for priority setting, advanced planning, resource mobilization and allocation, TB drug supply monitoring, case detection, lab QA, case management, treatment compliance, and monitoring MDR.). 	<ul style="list-style-type: none"> Evaluation of reports, registers, record-books, forms, and workbooks. Review of reports, protocols, orders, and interviews of health managers and practitioners. 	<ul style="list-style-type: none"> Disseminate results through symposia, seminars, and/or a national meeting. Provide technical assistance to adopt reforms in other regions. Conduct national TOT in recording and reporting. 	<p>Years 1-3</p> <p>Year 2-3</p> <p>Year 3</p>
<p>4. Reduce diagnostic delay, increase case detection, and improve adherence to TB treatment (N. Zaika, K. Gamazina).</p> <p>4.1. Increase awareness and understanding of TB transmission, symptoms, treatment, and cure among the general public and at-risk populations.</p> <p>4.2. Improve health-seeking behavior and treatment adherence among people diagnosed with TB.</p>	<ul style="list-style-type: none"> Change in public awareness of TB transmission, symptoms, need for early diagnosis and treatment. Proportion of population aware of at least two symptoms of TB. Proportion of population who know that TB is curable. Number of articles, radio shows, and TV spots that accurately cover TB. Percentage of TB cases being detected early. Percentage of patients using DOTS. Percentage of patients completing full treatment. 	<ul style="list-style-type: none"> Baseline and follow-up surveys and focus groups in target oblasts. Monthly review of key local news media. Medical records; provider survey. SES and TB Dispensary treatment data. SES and TB Dispensary treatment data. 	<ul style="list-style-type: none"> Validate formative research for development of messages, strategies, and appropriate media for behavior change interventions. Develop/expand mass media (TV, radio, video) to educate groups about the importance of prompt diagnosis and proper treatment of TB. Expand distribution of print materials for specific at-risk audiences. Convene media workshops for journalists. Create telephone hotline in Donetsk. Assess existing community networks for various patient groups. Develop and test model strategies for various target groups. Develop materials and support mechanisms for families, including materials with appropriate treatment and care information. Develop supportive materials for providers and patients. Implement research on factors affecting treatment adherence. 	<p>Year 1</p> <p>Year 1-2</p> <p>Year 1-2</p> <p>Year 1-3</p> <p>Year 1</p> <p>Year 1</p> <p>Year 2-3</p> <p>Year 1-2</p> <p>Year 1-2</p> <p>Year 2</p>

OBJECTIVES (Lead Staff)	INDICATORS	MEASUREMENT METHODS	MAJOR PLANNED ACTIVITIES	TIMING/ STATUS
<p>5. Improve provider practices by strengthening provider capacity to diagnose and treat TB based on DOTS (O. Klochkov, N. Zaika, K. Gamazina).</p> <p>5.1. Finalize training curriculum on interpersonal communication and counseling.</p> <p>5.2. Train TB providers in IPC/C and VCT.</p> <p>5.3. Work with Donetsk Medical University to incorporate IPC/C curriculum into training curricula for TB doctors.</p> <p>5.4. Improve provider skills in TB case management and follow-up.</p>	<ul style="list-style-type: none"> • Change in demand for TB counseling and testing. • Change in patient satisfaction among patients regarding provider counseling and information dissemination. • Number/percentage of cross-referral for TB+/ HIV+ patients. • Percentage of TB cases being detected early. • Percentage of patients using DOTS. • Change in provider knowledge of TB/HIV management. • Treatment success rate. • Case detection rate. • Cure rate. • Completion rate. • Failure rate. • Default rate. • Transfer-out rate. 	<ul style="list-style-type: none"> • Medical records, provider survey. • Patient survey or exit interview. • Medical records, provider survey. • SES and TB Dispensary case detection data. • SES and TB Dispensary treatment data. • SES and TB Dispensary treatment data. • Interviews and/or surveys with providers; training pre-/post test questionnaires. 	<ul style="list-style-type: none"> • Assess provider knowledge. • Prepare information materials. • Expand training on interpersonal communication and counseling, with focus on emerging risk groups. • Adapt existing PATH curricula on VCT for use with TB providers. • Implement training to improve HIV/TB co-infection knowledge and strengthen counseling skills and referral for HIV testing. • Review and adapt the TB clinical training curriculum developed by WHO and implemented in Donetsk. • Adapt for the Ukraine setting, the CORE TB Working Group TB training modules currently being developed for USAID-supported PVOs. • Conduct training workshops for TB providers at all levels, as necessary, on TB diagnosis, treatment, and follow-up in selected oblasts. • Conduct TOT and facilitate roll-out training for primary health care providers on TB diagnosis and ambulatory treatment follow-up to ensure system readiness for proper referral of patients. • Collaborate with pre- and post-graduate health education institutions to introduce training curricula on TB treatment using DOTS and conduct TOT with professors of post-graduate training facilities. 	<p>Year 1</p> <p>Year 1–2</p> <p>Year 1–3</p> <p>Year 1–2</p> <p>Year 1–3</p> <p>Year 1–2</p> <p>Year 2–3</p> <p>Years 2–3</p> <p>Years 2–3</p> <p>Years 2–3</p>

Annex E: Project Data Sheet

Project Data Sheet

Child Survival and Health Grants Program Project Summary

Annual Report Submission: October 31, 2005

PATH

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Project Web Site: No project specific site; see general website at www.path.org

A. Summary

1. Brief description of the program and its objectives.

Project Information:

Project Description:	"Support to Ukraine in Implementing Its National Tuberculosis Program." This project aims to improve the capacity for DOTS-strategy expansion by advocating for political support; strengthening tuberculosis (TB) diagnostic capacity and quality control procedures for smear microscopy, culture, and drug sensitivity testing; strengthening TB surveillance capacity; improving provider capacity; and increasing public awareness and patient support.
Partners:	Ministry of Health (MOH) of Ukraine; F.G Yanovsky Institute of TB and Pulmonology of Academy of Medical Sciences of Ukraine (ITP), Kyiv and Sevastopol City Health Administrations; Kyiv and Sevastopol City TB Dispensaries; Donetsk, Dnipropetrovsk and Kharkivsk Oblast Health Administrations, Donetsk, Dnipropetrovsk, and Kharkivsk Oblast TB Dispensaries; Kyiv and Sevastopol City Centers of Health and Sanitary Epidemiological Stations; Donetsk, Dnipropetrovsk, Kharkiv Oblast Health Centers and Sanitary Epidemiological Stations; World Health Organization (WHO) Office for TB Control in Ukraine; Royal Netherlands Tuberculosis Association (KNCV)/Royal Tropical Institute of Netherlands (KIT); World Bank (WB) TB/HIV/AIDS Control Project; Ukrainian Red Cross Society; Ukrainian National Council for Advocacy and Safety of Patients; Nongovernmental Organization (NGO) Medical Information and Analytic Center "Vector" (Kyiv); NGO Center "Health of Region" (Donetsk Oblast).
Project Location:	Donetsk, Dnipropetrovsk and Kharkiv Oblasts, Kyiv and Sevastopol Cities.

Grant Funding Information:

USAID Funding:(US\$)	\$2,500,000 (includes \$1 million add-on from the USAID regional mission in Kyiv, Ukraine)	PVO match:(US \$)	\$410,000
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Target Beneficiaries:

Type	Number
New TB patients (and their families members) in project sites	Approximately 11,660 new TB patients per year (about 30% of total TB patients in the country)

Beneficiary Residence:

Urban/Periurban %	Rural%
Approximately 80%	Approximately 20%

Capacity-Building Targets Planned:

PVO	Nongovt. Partners	Other Private Sector	Govt.	Community
	Ukrainian Red Cross Society		National and regional MOH health facility staff	

Interventions:

Policy/Advocacy Reform:

- Convene Policy and Advocacy Consultative Group to advise governmental partners on legislative reform.
- Monitor legislative development related to TB control.
- Distribute and facilitate access to key technical literature on TB control.
- Convene at least two national technical symposia for TB authorities and specialists.
- Conduct follow-up policymaker survey.

Laboratory Strengthening:

- Convene working group on TB laboratory quality assurance (QA) and quality control (QC) in Donetsk and expansion oblasts.
- Design QA and QC systems that will support all laboratory levels.
- Develop training curricula and methodological recommendations regarding QA and QC of smear microscopy for TB diagnosis.
- Introduce QC of direct smear microscopy in level I laboratories of the general health care system in Donetsk Oblast starting in project Year 1, and in Dnipropetrovsk and Kharkiv Oblasts, Kyiv and Sevastopol Cities, in Years 2 and 3.
- Introduce interlaboratory QC of smear microscopy in level I and II laboratories in Donetsk Oblast during project Years 1, 2, and 3, and in Dnipropetrovsk and Kharkiv Oblasts, Kyiv

and Sevastopol Cities, in Years 2 and 3.

- Introduce QA and QC of culture tests for *Mycobacterium tuberculosis* (MTB) starting in project Year 2.
- MOH to introduce an electronic system of surveillance of multi-drug resistant forms of TB in the context of the pilot project being implemented in Donetsk Oblast and Kyiv City.
- In cooperation with the Center for Microbiological Diagnosis of TB and the Chief of the National Reference Laboratory for Microbiological Diagnosis of TB, develop methodological recommendations regarding QC and QA of culture and drug sensitivity testing in laboratories at the oblast level.

TB Surveillance Strengthening:

- Revise, test, introduce, and monitor use of recording and reporting forms and guidelines in collaboration with all stakeholders.
- Conduct training on use of new recording and reporting forms in up to five regions.
- Design, test, introduce, and monitor use of electronic version of the TB Electronic Management Information System (EMIS).
- Conduct training on the use of data for problem identification, program monitoring, and strategic planning.

Behavior Change:

- Conduct training in IEC materials development.
- Revise existing and develop additional print materials on TB for patients, families, populations at risk, and the general public in Donetsk, Dnipropetrovsk, and Kharkiv Oblasts, and Kyiv and Sevastopol Cities.
- Revise and re-broadcast TV and radio spots aimed at the general public in Donetsk, Dnipropetrovsk, and Kharkiv Oblasts, and Kyiv and Sevastopol Cities.
- Expand existing curriculum and implement training for TB providers to improve counseling and communication skills and incorporate HIV voluntary counseling and testing (VCT).
- Investigate and document factors affecting patient health-seeking behavior and adherence to treatment.
- Undertake baseline and follow-up knowledge, attitudes, and practices (KAP) surveys.
- Collaborate with URCS to improve treatment adherence among vulnerable populations.

Health Care Providers Skills Strengthening:

- Improve provider practices by strengthening provider capacity to diagnose and treat TB based on DOTS.
- Improve systems to support appropriate referral of TB cases.
- Enhance knowledge of and response to HIV/TB interaction, with emphasis on appropriate counseling and client-provider interaction with emerging populations at risk.

Annex F: Supplemental Information for Midterm Evaluation Report

Supplemental Information for Midterm Evaluation Report

1. Baseline information from the DIP: Key Changes

A. Additional Funding from USAID Regional Mission in Kyiv, Ukraine.

USAID's contribution of an additional \$1 million over two years through the CSHGP is being used to solidify current efforts in Donetsk Oblast; expand PATH's activities in Donetsk, Dnipropetrovsk, and Kharkivsk Oblasts, and Sevastopol City; and collaborate with WHO to increase political commitment to DOTS at national and regional levels. PATH is now providing training in TB clinical management in the expansion oblasts. For fiscal year 2006, the USAID regional mission is providing an additional \$1 million through TB TASC. These funds will enable PATH to further expand its geographic coverage and accelerate implementation. Because these funds are being provided separately (rather than through CSHPG), PATH will not report on outcomes in the additional oblasts (Zaporozhe, Kherson, and Crimea) to CSHGP, but rather, it will report directly to the USAID Mission.

B. Delays in Implementation Due to Political Changes

Between November 2004 and January 2006, Ukraine's "Orange Revolution" dominated the country, and therefore, very little progress could be made on project implementation. Components particularly affected included the IEC and public awareness work, selection of and launch of activities in the new project sites, and legislative reform. Since January, PATH and its partners have been able to regain momentum, especially since the new government demonstrated stronger support and willingness to incorporate new strategies in TB control than the previous one. This progress, however, may be in jeopardy due to the recent dismissal of the government and replacement of key leadership within the MOH.

2. Evaluation Team Members

Dr. Fabio Luelmo	External Evaluation Consultant, TB Control Expert
Dr. Katya Gamazina	Deputy Country Director, Ukraine
Dr. Anatoliy Tsarenko	TB Project Director
Dr. Tamara Ivanenko	Program Officer, Laboratory Component
Dr. Andrew Dadu	Program Officer, MIS Component
Dr. Natalia Zaika	Program Officer, BCC Component

3. Evaluation Assessment Methodology

- Interviews and discussions with the PATH TB project team.
- Interviews with TB project partners.
- Meetings with national and oblast-level health authorities.
- Meetings with health providers.
- Government TB document review.
- PATH TB project document review.