

Evaluation of USAID Support to Tuberculosis Control in the Russian Federation

PATH

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Acknowledgments

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Abbreviations

ACSM	Advocacy, communication, and social mobilization
AIDS	Acquired immune deficiency syndrome
AIHA	American International Health Alliance
ART	Antiretroviral therapy
CDC	US Centers for Disease Control and Prevention
CDR	Case detection rate
CPT	Cotrimoxazole preventive therapy
CTRI	Central Tuberculosis Research Institute
DOT	Directly observed treatment
DOTS	WHO-recommended TB-Control Strategy
DR	Drug resistance
DST	Drug susceptibility testing
DTBE	CDC's Division of Tuberculosis Elimination
EQA	External quality assurance
FLD	First line drugs
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
HCI	USAID Health Care Improvement project
HIV	Human immunodeficiency virus
HLWG	High Level Working Group on tuberculosis in the Russian Federation
HRD	Human resource development
IFRC	International Federation of Red Cross and Red Crescent Societies
IPT	Isoniazid preventive therapy
ISTC	International Standards for Tuberculosis Care
MDR	Multi-drug resistance
MDR-TB	Multi-drug-resistant tuberculosis
MMR	Mass miniature radiography; photofluorography in the general population
NGO	Nongovernmental organization
MoHSD	Ministry of Health and Social Development
NTP	National Tuberculosis Control Program
OPD	Outpatient department (ward)
PEPFAR	US President's Emergency Plan for AIDS Relief
PHC	Primary health care
PLHA	Persons living with HIV/AIDS
PPD	Purified tuberculin
PTB	Pulmonary tuberculosis
RAMS	Russian Academy of Medical Sciences
RF	Russian Federation
RHCF	Russian Health Care Foundation
RIPP	Research Institute of Phthisiopulmonology of the Sechenov, Moscow Medical Academy
RRC	Russian Red Cross
SLD	Second-line drugs
SOP	Standard operating procedures
TA	Technical assistance
TB	Tuberculosis
TB/HIV	Patients co-infected with HIV and TB
URC	University Research Corporation
USAID	United States Agency for International Development
VCT	Voluntary counseling and testing for HIV
WB	World Bank
WHO	World Health Organization
XDR	Extensively Resistant Tuberculosis

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Executive Summary

In 2009, the United States Agency for International Development (USAID) commissioned PATH to carry out an independent evaluation of USAID-supported TB control activities. These activities are carried out through USAID's implementing partners the World Health Organization (WHO), the International Federation of the Red Cross and Red Crescent Societies (IFRC) and the U.S. Centers for Disease Control and prevention (CDC). Associated HIV and TB/HIV activities are implemented by the same partners and the American International Alliance (AIHA) and University Research Corporation (URC). The U.S. Pharmacopeia (USP) is involved in TB drug management. The team did not have sufficient information to evaluate USP's activities.

The team assigned by PATH to carry out the evaluation included Dr. Fabio Luelmo, Dr. Mayra Arias Pinel, and Dr. Olena Radziyevska. The main objectives of the evaluation were to identify the aspects of the USAID-supported TB project that have been most successful, the components that should be considered by USAID to scale-up, and the gaps that USAID might consider addressing in the future, as well as to make recommendations to USAID based on the findings.

The evaluation was conducted over a period of two weeks, from October 19–30, 2009. It included interviews with representatives of the institutions of the Ministry of Health and Social Development (MoHSD) working in TB control at the central level and in the Republic of Chuvasia and the Vladimir and Belgorod Oblasts; interviews with staff of the key non-governmental organizations (NGOs) supporting TB control in the Russian Federation; review of reports to USAID from implementing partners (WHO, CDC, IFRC, AIHA) and review of national TB statistics. The team observed the TB program activities in three sites and obtained data from the partners and government reports to compare the results of supported projects with data from the Russian Federation. The main components reviewed were: political commitment; coordination; human resource development; TB case detection; diagnostic practices; laboratory practices; treatment practices; drug management; multi-drug-resistant TB (MDR-TB); TB/HIV co-infection; infection control; and advocacy, communication, and social mobilization (ACSM). In addition, available data were used to evaluate the effect of project strategies supported by USAID on the quality of interventions and the possible impact on the burden of TB disease, death, and prevention of multi-drug resistance (MDR).

The evaluation determined that the regions supported by USAID for TB control have shown the feasibility of:

- Obtaining oblast/Republic government support to finance program activities, revise policies for TB control, and maintain regular supplies of first-line drugs.
- Integrating TB services into the general health care system including detection of TB suspects; performing laboratory testing of TB by quality-assured microscopy and directly observed treatment and patient support and follow up.
- Establishing a laboratory network for TB and maintaining a system of quality assurance of microscopy at intermediate (regional) level.
- Improving the quality of TB diagnosis by increasing the proportion of diagnosed patients that were confirmed by sputum smear microscopy or culture; improving the

results of treatment and reducing default, thereby lowering risk of creating drug resistance.

- Rationalizing the use of resources, with less cost and better access to patients; reducing the number of sanatoria, TB beds, and duration of hospitalization.
- Reducing TB prevalence in the community and reducing TB mortality, particularly in the prison system.

However, these sites represent less than 8 percent of the population and of the TB cases in the country, so the direct impact of the USAID-supported projects on the burden of TB disease in the Russian Federation is small. The sites are more important as pilot and demonstration areas, but the use of this national resource by other regions and expansion of the lessons learned has been very slow.

To utilize the sites as demonstration areas and expand the experience countrywide, some improvements are required. The most important are:

- Updating the knowledge of managerial federal and local staff regarding TB transmission and relative risk of TB infection by treated and untreated smear-positive and smear-negative patients, as the basis for infection control and treatment of patients at home.
- Improving the diagnostic criteria used by TB specialists, so that the large majority of the pulmonary cases is diagnosed through bacteriological confirmation.
- Develop and have widely available standard operating procedures (for case management; laboratory procedures (diagnostic methodologies, quality control); referral systems (TB and HIV services; prison-civilian sectors)), work plans, and training materials at oblast and district levels.
- Improve practices and refresh knowledge of internationally recommended standards
- Operational research to address program issues. Examples are the real proportion of suspects among adults attending general health facilities; the number and proportion of smear-positive pulmonary tuberculosis (PTB) detected by mass miniature radiography (MMR); and the proportion of failures due to change of treatment because of MMR and other reasons.

With these improvements, some of the sites (such as Chuvashia for quality of clinical diagnosis, Belgorod and Chuvashia for integration of TB care in general health facilities and Vladimir for rationalization of the use of resources) could rapidly become demonstration areas for application of the experience to other oblasts.

At national level, USAID support has facilitated the implementation of the WHO TB-Control Recommended Strategy (DOTS) by the prison system (Ministry of Justice), with significant epidemiological impact on TB incidence and mortality and effective coordination with the civilian system (Ministry of Health and Social Development); the development and adoption of a recording and reporting system compatible with international standards and with Russian information requirements; the creation and functioning of the High Level Working Group (HLWG); and the revision of technical and operational guidelines (Ministry of Health Order #109).

The main obstacles to full implementation of the DOTS strategy in the country are:

- The lack of a national TB control program (NTP unit) in the Ministry of Health and Social Development (MoHSD) that can oversee the program and maintain a focus

on public health. Functions of particular importance are ensuring regular supplies of first-line drugs to prevent MDR-TB, monitoring program activities and impact, and promoting the rational use of financial resources.

- The current technical and operational procedures still do not follow international recommendations (for example, with MMR, hospitalization, repeated Bacillus Calmette-Guérin [BCG] vaccination plus mass tuberculin screening of children, and mass photofluorography) and there is insufficient knowledge of international evidence regarding TB transmission, cost-effective control measures, and impact at all levels. In addition, even though there have been efforts to establish collaborative activities to address TB and HIV coinfection and guidelines for management of HIV and TB coinfection, these guidelines are still not consistent with current international standards and practices vary among oblasts and facilities.

The mission has the following recommendations for future USAID activities for improved TB control in the Russian Federation:

1. Continue support to existing sites through the partners, with emphasis on correcting the problems detected, and develop selected sites as demonstration centers. This includes preparing written plans of action, standard operating procedures (SOP), and training materials; creating human resource development (HRD) plans that include job descriptions, competencies of staff, continued education and performance-based evaluation; preparing SOP for infection control measures appropriate to different levels (specialized and general); and developing the organization to receive and train staff from other oblasts and to carry out post-training supervision visits.
2. Promote political commitment of other oblasts to implement similar TB programs, including oblast funding of observation visits to the selected demonstration sites, and collaboration to support training visits. The key criteria for the selection of new oblasts for expansion of the experience should be the effective political commitment of the local authority to fund training and implement changes. Other criteria would be the number of inhabitants and population density (Annex VI), the number of TB cases reported, high HIV prevalence, and close distance to existing funded sites (Annex I and VII). Expansion should be rapid and require minimum external resources—the aim is dissemination of the experience, not replication of pilot projects. The Research Institutes in Russia should be involved during the planning and implementation phases of expansion, whilst in parallel, their capacity to provide technical assistance in DOTS and DOTS-Plus implementation and TB/HIV (per international standards) to the regions should be promoted. The Institutes would work closely with the NTP Central Unit to achieve a concerted response to TB in current and future USAID-supported sites.
3. Advocate and provide technical assistance (TA) for the creation of a TB unit in the MoHSD, with public health functions. Advocacy may include direct discussion with MoHSD authorities to offer USAID collaboration (on the basis of the recent presidential agreement of April 2009); providing information to the health committees within the Duma and the Council of the Federation; and engaging the political authorities/administrations of the USAID-supported sites to back the recommendations of the HLWG. Key reasons are the need to prevent further expansion of MDR by ensuring first-line drug supplies, and better utilization of the large resources that the Federation dedicates to TB control (over 1 billion dollars

per year), a substantial part of which goes to costs of hospitalization and other low-impact strategies. An effective mechanism would be to appoint a TB coordinator in the MoHSD and assign selected professionals from the National Institutes to staff the TB unit, after appropriate retraining for their new functions.

4. Advocate and provide TA to support the revision of the national guidelines for TB control (Ministry of Health Order #109) to adopt current international recommendations, and from the new version to develop standard operating procedures appropriate for practice and training. The revised order should be complemented by written standard operational procedures. The national norms should consider the new treatment guidelines to be published in 2010 by WHO and other Stop TB partners (including management of MDR-TB) and should aim to improve the rational use of resources and simplify procedures for TB detection and case management.
5. Promote TB/HIV collaboration, specifically support rapid expansion of the TB/HIV integrated care model, which includes counseling and testing (CT) for HIV for TB patients and TB screening for persons living with HIV/AIDS (PLHA) based on symptoms and bacteriology, in addition to purified tuberculin (PPD) tests and chest X-rays. Also, support the development, dissemination and adoption of TB/HIV screening and treatment protocols that are consistent with international recommendations, under a national policy framework.
6. Through the implementing partners, promote the delivery of TB and TB/HIV training in a cohesive and complementary manner. Attention should be given to avoiding duplication of efforts among USAID implementing partners. Curricula developed by an implementing partner can be adopted by others (i.e. AIHA's TB/HIV curricula). Training should be evaluated through sound methodologies (pre- and post-training tests, patient chart audits, patient satisfactory surveys, changes in TB indicators). Moreover, curricula developed by implementing partners can be integrated in under- and postgraduate medical education, which is currently focused primarily on clinical aspects of TB treatment and reflect outdated practices.
7. Strengthen USAID support to ACSM efforts in a coherent manner with the aim of increasing case detection through bacteriology testing and treatment outcomes (reducing default and transfer-out). These are priorities that require advocacy and communication interventions to further promote the revision of current policies and practices, promote cost-effective budget allocation, and consistent involvement of social networks to providing support to TB patients. Intensive ACSM activities are especially needed to improve TB control outcomes among socially marginalized populations, including coinfecting TB/HIV patients, many of whom experience stigmatizing attitudes. Thus, the capacities to plan, implement, and evaluate ACSM activities at the federal and regional levels should be improved.
8. Promote and support operational research at national, oblast and, facility levels to solve problems and provide information for program decisions. Of particular interest are the real prevalence of TB suspects (cough of long duration) and smear-positive persons among policlinic outpatients at facility level; the reasons for high rates of failure and death during treatment; and the number of infectious sources detected through MMR compared to screening of persons with symptoms.

Potential areas for USAID's support to TB control in the Russian Federation in the following years are:

1. **On the role of NGOs in TB control** –Russia has a well-developed network of the community-based Red Cross units which are contributing to TB control in sites visited. This model can be strengthened and replicated in other sites where USAID will expand activities. Sustainability can be achieved by promoting improved coordination between local Red Cross chapters and local administrations to work towards common goals and fund-raising. The role of the Red Cross chapters in advocacy to bolster political commitment is vital. The Red Cross local chapters could be used as a platform from which to garner community engagement in TB-control related activities. The team does not consider that newly created/supported local NGOs could represent a major element for TB control in Russia. However, the strengthening and streamlining of ACSM for TB and TB/HIV would require linking with NGOs working in HIV prevention and care. ACSM activities should be carried out under the framework of a National and regionally-adapted ACSM strategy with corresponding workplans. USAID may consider supporting this strategy.
2. **On SLD** – The team is not able to provide in-depth information and recommendations on procurement, management and use of second line drugs practices. The Green Light Committee is collaborating with the country for that specific purpose. USAID may consider supporting technical assistance to guide and build in-country capacity for the WHO prequalification processes regarding SLD for TB. Additional technical assistance may be required to develop and establish policies and protocols for pharmaceuticals quality assurance and rational use of pharmaceutical.
3. **On rapid testing and molecular diagnostics** –Support for technical assistance for the effective introduction and adoption of new methods to optimize smear microscopy (LED-based fluorescent microscopy, front-loaded smears) and molecular line probe assays may be considered by USAID. Rapid liquid culture methods (i.e. MGIT) are already in use at sites visited. Rapid liquid culture method should be made available throughout the country at the regional level. This should be expanded in a phased manner, and emphasizing sustained quality assurance, in-line with international recommendations. USAID may opt to support this process through the provision of technical assistance to oblast laboratories. Moreover, USAID may consider coordination and collaborating with organizations working in research and development of new diagnostics. Eventually it may explore role of the private sector in the Russian Federation and the provision of technical assistance to these entities for the manufacturing of evaluated and recommended rapid TB diagnostic tools.

1. Introduction, objectives, and methods

In 2009, the United States Agency for International Development (USAID) commissioned PATH to carry out an independent evaluation of USAID-supported TB control activities. These activities are carried out through USAID's implementing partners - the World Health Organization (WHO), the International Federation of the Red Cross and Red Crescent Societies (IFRC) and the U.S. Centers for Disease Control and prevention (CDC). Associated HIV and TB/HIV activities are carried out by the same partners and the American International Alliance (AIHA) and University Research Corporation (URC). The U.S. Pharmacopeia (USP) is involved in TB drug management. The team did not have sufficient information to evaluate USP's activities.

The team assigned by PATH to carry out the evaluation of the project included:

- Dr. Fabio Luelmo, TB consultant (team leader)
- Dr. Mayra Arias Pinel, PATH Washington, DC
- Dr. Olena Radziyevska, PATH Ukraine

The team was accompanied in some of the field visits by Ms. Carolyn Mohan, TB advisor, Office of Global Health, USAID/Washington, DC.

The main objectives of the evaluation were to:

1) Identify:

- Aspects of the USAID-supported TB project that have been most successful and why.
- Components that should be considered by USAID to scale up.
- Gaps that USAID might consider addressing in future years (which would be appropriate for USAID support and would yield positive results).

2) Make recommendations to USAID based on the findings.

The evaluation was conducted over a period of two weeks, from October 19–30, 2009. It included interviews with staff of the key organizations supporting TB control in the Russian Federation (RF), including visits to institutions in Moscow, Belgorod, Chuvashia, and Vladimir (Annex III); review of reports to USAID from implementing partners WHO, CDC, IFRC and AIHA and representatives from Ministry of Health and Social Development of the Republic of Chuvashia and the Vladimir and Belgorod Oblasts; and review of national TB statistics. The list of key persons interviewed and institutions visited is included as Annex IV.

USAID TB Control Program description

Beginning in 1991,¹ Russia experienced a massive, nationwide epidemic of TB, especially drug-resistant (DR) TB. From 1999 to the present, USAID has funded the CDC Division of Tuberculosis Elimination (DTBE), the WHO country office, the IFRC, and other local partners to assist the RF to curb its TB epidemic. Considerable input was also provided by

¹ World Health Organization (WHO). *Global Tuberculosis Control—Epidemiology, Strategy, Financing*. WHO/HTM/TB/2009.411. Geneva: WHO; 2009.

implementing partners focused on HIV and TB/HIV management – AIHA and URC. USAID country mission priorities have included:

- Setting up Directly Observed Treatment Strategy (DOTS) demonstration projects in four territories.
- Setting up DOTS-Plus pilot projects in two territories.
- Working with Russian federal partners to build capacity, update TB control policies, and incorporate international recommendations for TB control.
- Addressing TB prevention and control in HIV-infected persons.
- Addressing HIV among TB patients.
- Assisting WHO and Russian partners in the transition from USAID to GFATM support.

Collaboration with IFRC and Russian Red Cross (RRC) on TB/HIV began in 2001. In 2005 the Russian Federation received over \$100 million from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) for Rounds 3 and 4; WHO support for GFATM-related activities also began in 2005. The specific objectives of the USAID project to support TB control have been to develop sustainable capacity for:

- Accurate, rapid, laboratory-based diagnosis of TB, including drug-resistant TB and TB in HIV-infected persons.
- Effective treatment for all forms of TB in light of the high prevalence of drug resistance and increasing prevalence of HIV-associated TB.
- Valid, timely recording and reporting of morbidity, mortality, and bacteriological data.
- Primary prevention of TB transmission in health care facilities, including prisons.
- Secondary prevention of TB in HIV-infected persons and other high-risk groups.
- Program management to eliminate drug shortages and train health care workers.
- Informing/influencing the regulatory environment for TB control at the federal level.

2. Background

2.1 Epidemiology of TB in the Russian Federation

Russia is a federation divided in 49 oblasts, 21 republics, 10 autonomous okrugs, 6 kays, 2 federal cities, and 1 autonomous oblast. The capital is Moscow. The population is estimated at 142.5 million (2007²).

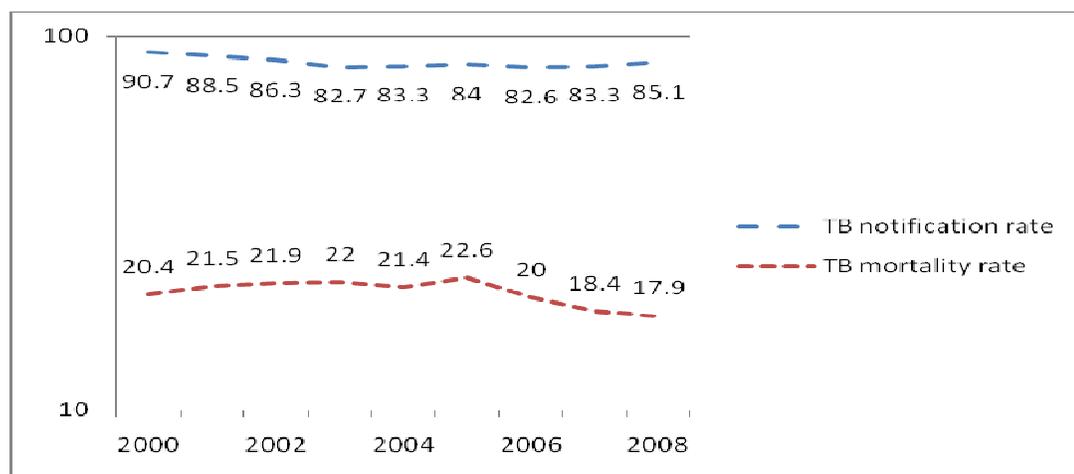
Russia is one of 22 high-TB-burden countries in the world. The estimated TB incidence (all forms) in 2007 was 110 per 100,000 (157,000 cases) and the new sputum smear-positive rate was 48 per 100,000. The TB mortality in 2007 was 18 per 100,000 (25,000

² World Health Organization (WHO). *Global Tuberculosis Control—Epidemiology, Strategy, Financing*. WHO/HTM/TB/2009.411. Geneva: WHO; 2009.

TB deaths per year). A high proportion of the incidence and mortality are due to co-infection with HIV: 26,000 new cases and over 5,000 deaths were in HIV-infected persons. Overall TB mortality is down from 20.4 per 100,000 in 2000, but the proportion of TB deaths in HIV-infected persons increased from 10 percent to over 20 percent. Resistance to TB drugs is a major problem. According to the WHO Global Tuberculosis Report that presents data for 2007, 13 percent of new TB cases and 49 percent of previously treated TB cases had multi-drug-resistant TB (MDR-TB).³

Reported incidence declined gradually from 70 per 100,000 in 1970 to 48 in 1980 and 34 in 1990, probably reflecting a gradual decrease in the TB burden. The breakdown of the former Soviet Union resulted in deterioration of the social conditions including an increase in poverty and homelessness and internal migration, with an increase of TB. A shrinking health budget resulted in an erratic supply of anti-TB drugs, inadequate treatment, and drug resistance. Reported TB incidence almost tripled from 50,641 cases in 1990 to 140,677 in 2000. Since then there was a gradual decrease in cases reported until 2006 (124,689) (Figure 1). Contributing factors were a decrease in population, a significant (over 60 percent) reduction of TB in prisons (Figure 2), and gradual improvement of health services and social conditions.

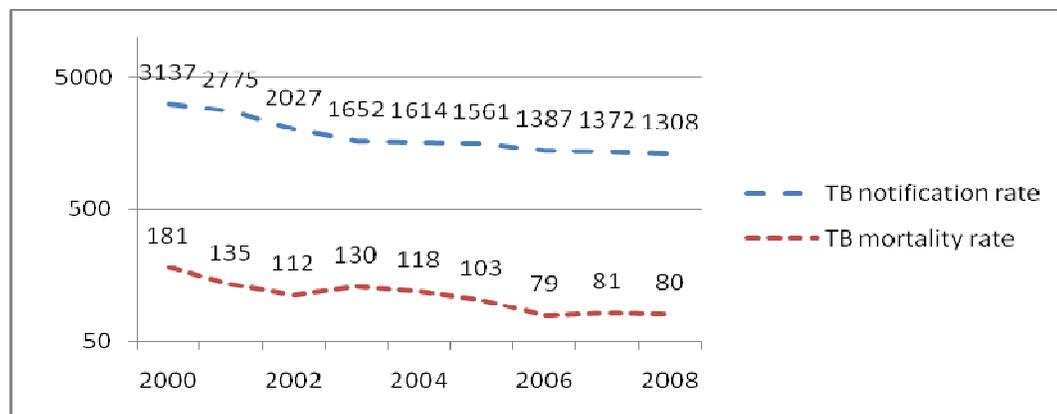
Figure 1. TB notification and TB mortality in the Russian Federation, 2000–2008. Rates per 100,000 inhabitants.



Source: WHO Moscow office, TB presentation, October 19, 2009

Figure 2. TB notification and TB mortality in the prison services in the Russian Federation, 2000–2008. Rates per 100,000 inhabitants.

³ World Health Organization (WHO). *Global Tuberculosis Control—Epidemiology, Strategy, Financing*. WHO/HTM/TB/2009.411. Geneva: WHO; 2009.



Source: WHO Moscow office, TB presentation, October 19, 2009

In 2007 the country reported 127,000 new and relapse TB cases (89 per 100,000), of which 33,000 were new pulmonary smear-positive (23 per 100,000). The case detection rate (CDR) for smear-positive cases was 49 percent. The CDR for all forms was 89 percent. Most detected TB cases (81.3 percent) were registered in Ministry of Health and Social Development (MoHSD) facilities; cases detected in medical facilities under other jurisdictions (Ministry of Internal Affairs, Ministry of Defense, Ministry of Justice, etc.) accounted for 13.1 percent. The notification rate for smear-positive cases increased, due mainly to expansion of laboratory capacity and changes in diagnostic practices (more emphasis on laboratory confirmation). In 2008 the TB notification rate was 85.1 per 100,000 (an increase over previous years and stable compared with 2002) and the reported new smear-positive rate was 23.9, similar to 2007.

The TB notification rate in prisons decreased from 3,137 cases per 100,000 in 2000 and 2,027 cases per 100,000 population in 2002 to 1,308 in 2008. The TB mortality rate in prisons decreased from 181 deaths per 100,000 population in 2000 and 112 per 100,000 in 2002 to 80.1 in 2008. In 2008 TB in prisons represented about 10 percent of the total cases, a substantial reduction in eight years.

2.2 TB control in the Russian Federation

At the regional level, all TB services are provided by special facilities called tuberculosis dispensaries. Each of the Russian regions has one or more of these dispensaries. In large and populous regions where more than one dispensary is present, one of them is appointed to co-ordinate activities in that region. A 1995 MoHSD decree specifies the functions of the dispensaries. In addition, a network of five Tuberculosis Research Institutes provides specific technical and methodological assistance to the regional tuberculosis services.⁴ The leading role belongs to the Russian Institute of Phthisiopulmonology (RIPP) in Moscow.

The Russian Federation has adopted the DOTS strategy and achieved 100 percent coverage in 2007, although two major components of the DOTS strategy are not fully implemented. The strong managerial unit (with focus on public health) in the Ministry of Health required as one of the criteria for government commitment⁵ is not in place; and first-line drug supply is still irregular, resulting even in interruption of drugs to patients, as

⁴ Moscow, St Petersburg, Yekaterinburg, Novosibirsk, and Yakutsk.

⁵ WHO. *An Expanded DOTS Framework for Effective Tuberculosis Control*. WHO/CDS/TB/2002.297. Geneva: WHO; 2002.

noted during the meeting of the High Level Working Group (HLWG). The current process of health reform, which includes decentralization of drug purchase to the regions without a central unit to support it, may complicate the situation regarding cost and quality of drugs.

In 2007, cohort analysis showed treatment success of 57.8 percent in new smear-positive patients in the civilian sector, 45.8 percent in relapses, and 31 percent in other re-treatment cases. The low success rates are strongly influenced by high mortality during treatment (12.7 percent in new cases in 2007) and by high proportion of failures (15.5 percent in new cases in 2007). Failures include changes of treatment, mainly due to confirmation of multi-drug resistance (MDR); the reasons for the high mortality compared with other countries are not clear and merit operational studies. Better indicators of the capacity of the control program to maintain patients on treatment are the default rate or the default plus transfer out rates. In 2007, the default rate for new TB cases in the Russian Federation was 10 percent and the transfer out rate was 4 percent. The default rate in relapses was 13.7 percent and in other retreatment was 19.5 percent. A consequence of high default and lost transfer cases, as of irregular drug supply, is the development and transmission of drug-resistant TB, which has very high levels and is still growing.

The country is gradually modifying its traditional strategies to comply with internationally recommended methods of TB control. Major steps were Order #109 of the Ministry of Health (March 2003) and its annexes, and the Statute of the High Level Working Group on TB in the Russian Federation (HLWG), November 2005. However, many old practices that are currently not recommended internationally⁶ are still maintained. These include repeated BCG vaccination, case detection through mass screening of children with tuberculin tests and of the general population with mass miniature radiography (MMR), a large number of specialized TB sanatoria and TB beds with mandatory hospitalization (for an average of four months), restriction of the diagnosis and treatment indication to TB specialists even in cases confirmed by the laboratory, and active follow-up of cured patients. They contribute to the high costs of the national TB program (over US\$8 per capita, or over one billion dollars per year) and limit access of the community to TB care. Integration of TB care in general health facilities and health staff is developing at a very slow pace, even in the pilot projects. Major factors to slow progress are the low priority given to interrupt transmission versus clinical diagnosis and the restrictions to change imposed by current national documents (prikazes). The prevalence of inappropriate practices is evidenced in diagnosis by the high proportion of patients treated without bacteriological confirmation (only 50,000 of 110,000 new cases were confirmed by smear or culture and only 33,000 by smear in 2007)⁷; very few patients receive ambulatory treatment from the start even if they are sputum smear-negative; and the results of over 80 million miniature X-rays in the general population are evaluated by the cases diagnosed and not by the sources of infection detected.

2.3 USAID assistance and financial mechanisms

USAID has assisted the development of internationally recognized TB control interventions in the RF since 1998. The USAID funding was granted through and implemented by the WHO, IFRC, and CDC. Currently, USAID supports nine territories in

⁶ Tuberculosis Coalition for Technical Assistance (TBCTA). *International Standards for Tuberculosis Care (ISTC)*. The Hague: TBCTA; 2006.

⁷ World Health Organization (WHO). *Global Tuberculosis Control—Epidemiology, Strategy, Financing*. WHO/HTM/TB/2009.411. Geneva: WHO; 2009.

the country (Khakasia, Pskov, Belgorod, Chuvahsia, Vladimir, Adygea, Jewish Autonomous Region, Orel and Khabarovsk). The tenth area - Buryatia was recently included to the USAID TB program. Primarily USAID works on expanding DOTS; preventing MDR-TB; and improving TB and MDR TB case management, infection control, and TB/HIV management. USAID's funding for TB control amounted to US\$7.1 million in fiscal year 2008. Despite this figure representing a relatively small portion of the entire country's TB control budget, it has significantly complemented the government's and other partners' efforts. USAID's assistance thus far has resulted in the revision of TB control policies and reporting forms of the MoHSD; training of close to 3,000 professionals, including lab personnel; technical assistance (TA) in the preparation of GFATM R4 application; TA for regions to prepare Green Light Committee (GLC) applications to access second-line drugs (SLDs); starting of treatment for more than 4,000 MDR-TB patients in GLC-approved projects; and increased HIV screening for TB patients and TB screening among persons living with HIV. Throughout, USAID has supported ongoing training, supervision, and evaluation of TB activities and indicators, areas that represented gaps in the system. Perhaps USAID's greatest contributions to TB control in the RF were facilitating a foundation and environment for obtaining and implementing the World Bank loan project and the GFATM TB grant, and garnering commitment for TB control from the RF government.

3. Findings regarding the USAID supported program

3.1 By implementing agency

International Federation of Red Cross and Red Crescent Societies (IFRC)

USAID has funded the IFRC since 2001 with the aim of implementing DOTS and DOTS-Plus; improving access to vulnerable populations (psychosocial support and incentive systems); strengthening collaboration between the civilian and prison sectors; raising awareness and education in the community; and creating a cadre of community nurses supporting TB control activities. This project will end in September 2010. Activities are implemented through the IFRC's agreement and collaboration with the Russian Red Cross (RRC). The IFRC has provided financial and technical support to the RRC to carry out activities since 2001 in Pskov, Belgorod, and Khakasia, as well as in Khabarovsk (2005), Adygea (2006), and the Jewish Autonomous Oblast (2007). The RRC has a network of 89 regional and 1,210 local chapters.

The collaboration of USAID through IFRC and RRC has resulted in improved treatment success, and particularly in lower default and transfer-out rates in Belgorod, Khakasia, and Pskov compared to the RF; this has yet to happen in Khabarovsk, Adygea, and the Jewish Autonomous Oblast, which were incorporated into the project at a later time. The IFRC has provided close technical guidance to the oblast TB program authorities and the RRC, both of which have a presence in the community. Together they have guided and strengthened the transition of TB services to primary health care (PHC) settings, focusing strongly on improving treatment adherence through a cadre of trained nurses and staff that deliver social and psychological support within a patient-centered approach. Other contributions of the IFRC are participating in high-level groups that shape TB policies; developing tools that help replicate the model to other oblasts; and advocating and fund-raising for TB control activities at the regional and local levels.

The RRC conducts comprehensive educational and communication activities targeting patients, penitentiary system, and the community. Although these activities are essential to a TB control program, it is unclear how or if they have impacted TB control in the regions. These activities require understanding of the target populations' beliefs and attitudes so that tailored messages can be delivered adequately—to patients to improve adherence; to communities to mobilize to promptly seek care, lower stigma, and advocate for TB programs; and to oblast and local health authorities to prioritize TB.

World Health Organization (WHO)

WHO currently receives funding from USAID under the Advanced Development of the Tuberculosis (TB) Control Project in the Russian Federation (RF). The project's duration is from August 1999 to October 2010. Funding started under grant No. 118-G-00-99-00112 in 1999 in three pilot regions: Ivanovo, Orel, and Vladimir. Activities have expanded to the Republic of Chuvashia and to work with the Central TB Research Institute of the Russian Academy of Medical Sciences (CTRI RAMS) and the Research Institute of Phthisiopulmonology of the Sechenov Moscow Medical Academy (RIPP MMA). The WHO TB Control Program operates in the Russian Federation on the basis of the 2008/2009 Biennial Collaborative Agreement between the Ministry of Health and Social Development (MoHSD) of the Russian Federation and the Regional Office for Europe of WHO, signed on March 26, 2008.

This alliance has been crucial to the enhancement of TB control in Russia. WHO in Russia provides technical assistance to the Russian government, the Russian Health Care Foundation (RHCF) and federal TB research institutes, as well as to World Bank (WB) and GFATM-supported projects. These activities focus on technical support to develop training materials and guidelines; DOTS and DOTS-Plus expansion (including applications to GLC and training on management of MDR-TB); training activities targeted at TB laboratory diagnosis, supervision, monitoring and evaluation; and research for recommending evidence-based policies. Moreover, WHO has been instrumental in promoting and developing revised TB control policies in Russia that are more in line with international standards; coordinating between partners; and introducing new diagnostic and infection-control tools to detect and manage MDR-TB in a country with one of the highest rates in the world. The DOTS and DOTS-Plus projects piloted by WHO with USAID funds (in Orel and Vladimir Oblasts and the Republic of Chuvashia) guided and facilitated the expansion of revised TB-control strategies in the country.

US Centers for Disease Control and Prevention (CDC)

The CDC has been funded by USAID to support TB control in Russia since 1999. Specifically, CDC provides technical assistance to the oblasts, WHO, and IFRC in several areas, including MDR-TB, laboratory strengthening, infection control, and TB/HIV. Under CDC's guidance a Center of Excellence has been established in Vladimir for Infection Control; this center has become a training venue for infection control for staff in multiple oblasts and even other countries, and has potential to grow into a Regional Training Center for the Eastern European and Central Asia regions. Importantly, CDC is working to improve TB screening among HIV-positive individuals and to provide HIV voluntary counseling and testing (VCT) for TB patients, an issue that requires attention as HIV rates increase in the country. Through its collaboration with CITRI, the CDC has contributed to modernizing TB labs and is advancing research for understanding and preventing the development of acquired MDR-TB.

University Research Corporation (URC)

In 2004, with USAID funding, URC began implementation of the USAID Health Care Improvement project (HCI) to develop and scale up an Improvement Collaborative Model to enhance TB/HIV integrated care in the cities of St. Petersburg, Orenburg, Engels, and Togliatti. Currently, URC is expanding this work to other locations in the St. Petersburg and Orenburg oblasts. TB/HIV care is coordinated among the TB dispensaries and AIDS centers, and implemented in polyclinics and PHC facilities. The achievement of this project include increased TB screening among persons living with HIV/AIDS (PLHA) from 0 at baseline (2005) to close to 700 by the 3rd quarter of 2007. This project has led the way to the formation of district inter-institutional teams (local health departments, TB dispensaries, AIDS centers, PLHA nongovernmental organizations, narcologic dispensaries, polyclinics, infectious disease clinics, etc.) that oversee implementation of activities and outcomes. This has facilitated the institutionalization of the model; increased access to VCT for TB patients; and improved recording, reporting, and information sharing. This project has permitted co-infected patients receive optimal and continued care.

American International Health Alliance (AIHA)

AIHA started work in Russia in 2005 under US President's Emergency Plan for AIDS Relief (PEPFAR) funding, focusing on HIV training. AIHA assists in building partnerships between the medical community in the US and health programs in Eastern

Europe for the advancement of HIV clinical and palliative care in Russia. Currently, AIHA is working in St. Petersburg, Saratov, Orenburg, Samara, Sakhalin, and Moscow. Thus far, it has developed a series of training courses on HIV, including a course on TB/HIV co-infection. Some of AIHA's courses were incorporated into the MoHSD training curriculum. Trainees include infectious disease specialists, general practitioners, and nurses. Training has been provided to staff of charitable organizations, URC, and RRC. AIHA also partners with the private sector, including Glaxo Smith-Kline (for HIV) and Eli-Lilly (for TB), to build expertise among Russian specialists. The capacity of AIHA for developing and implementing online courses (distance learning) has ample potential for TB training and should be further explored. The extent to which AIHA's partnership with Eli-Lilly to build up the capacity of TB experts is linked to current USAID and WHO projects needs to be determined; it is important that training content is consistent and especially that it is not duplicative.

3.2 By program component

3.2.1 Political commitment

There has been significant improvement in political commitment at national level since 2002, as shown by the official adoption and the expansion of the DOTS strategy, the World Bank loan for TB control and the implementation of GFATM support, provision of national financial resources, and the approval of revised technical and managerial guidelines. Major achievements were the creation and regular meetings of the HLWG to coordinate activities and provide the regions with a forum for discussion, the revision of the national guidelines (Order #109 of the MoHSD), and the development and implementation of a recording and reporting system compatible with international recommendations and with the requirements of the national clinical TB specialists.

A major weakness is the lack of a key element of the DOTS strategy—a strong managerial team and focal point at central level (MoHSD).⁸ Some of the functions of this team are carried out by the Research Institutes with WHO cooperation, but the public health approach and integration of TB activities in the general health system should not be the responsibility of specialized facilities and staff. The HLWG is therefore without an executive arm, and there is no fully dedicated counterpart for TB technical assistance in the MoHSD. It should be noted that this focal unit is not only part of the DOTS strategy but also a normal requirement for consideration of GFATM grants. The creation of this unit was recommended by the HLWG meeting.

3.2.2 Coordination

Coordination between USAID and its partner organizations and between the partners and the recipients of technical assistance (oblast and Republic authorities) seems excellent. Coordination of partners with other agencies such as the Health Care Foundation (executor of the GFATM Round 4 grant), the prison system authorities, and the National Institutes seems good. The influence of the partners in national policy has been limited, however, in large part due to the absence of a public-health-oriented unit in the MoHSD. The impact of technical recommendations has been much faster in the Ministry of Justice (prison system). At intermediate (oblast, Republic) level, the coordination observed between

⁸ WHO. *An Expanded Framework for Tuberculosis Control*. WHO/CDS/TB/2002.297. Geneva: WHO; 2002.

civilian and prison authorities in the sites observed was excellent, and resulted in good collaboration to maintain patients on treatment after their release from prison.

3.2.3 Human resource development

Although there have been major changes in the last decade, the health system in most of Russia is still structured as it was in the former Soviet system, with the focus on highly specialized staff and inpatient care. In general there is a lack of a holistic, family-based approach in medical care. This and the lack of incentives leads to high concentration of physicians in the cities and more scarce resources in rural areas. The largest budget component of TB control in the RF is dedicated to staff (36 percent), followed by running costs of hospitalization (28 percent).⁹ Nonetheless, the greatest funding gap in the budget is also related to dedicated staff. WHO in Russia has identified the insufficient number of qualified and motivated staff, due to poor wages and recognition, as an important problem. An important factor is that TB control is a vertical system based on specialists and does not use the human resources of the general health facilities for ambulatory care of TB cases, as happens in most other countries. Doctors working in TB control at central and oblast levels have to distribute their time between clinical and administrative duties. This limits their capacity to implement a robust public health program that addresses barriers to case finding, treatment outcomes, and prevention of drug resistance in an effective and efficient manner.

It is unclear if and to what extent the WHO Strategy and the Prikazes 109 and 50 are disseminated during pre-service training in medical schools in Russia. In the Republic of Chuvashia (site visited during the mission), the TB dispensary has established coordination with medical schools in the region to raise awareness on TB control and provide some training.

Under the scope of USAID-, PEPFAR-, WB-, and GFATM-funded projects, major training efforts have occurred in the form of post-graduate courses nationally and internationally, visiting tours, in-service training, and supervision visits. Joint efforts have also resulted in the creation of a cadre of trainers for training on monitoring activities, as well as the development of training modules, guides, and other educational materials on TB control, including TB/HIV and DR. TB experts from the five Research Institutes are assuming more active roles in training, supervising, and monitoring activities at their corresponding regions. Through WHO's coordination, Russian TB experts in pilot areas have attended the meeting/workshop on Human Resource Development (HRD) organized by TBCAP/KNCV. However, it is doubtful that HRD plans have been developed or implemented at central and oblast levels.

Staff at the oblast and rayon TB dispensaries, polyclinics, and primary health care facilities (in feldshers) visited generally base their practices on the Prikazes 109 and 50. Generally there is an overreliance on mass fluorography for case finding. Additionally, photofluorography in the general population (regardless of symptoms) covers about half the population of the country each year as a mandatory TB case-detection method. Staff collect and report TB data, but do not always interpret or use this information to plan and intervene accordingly to improve performance, case detection, and treatment outcomes.

⁹ World Health Organization (WHO). *Global Tuberculosis Control—Epidemiology, Strategy, Financing*. WHO/HTM/TB/2009.411. Geneva: WHO; 2009.

This highlights a gap in supervision and monitoring (from central to oblast level, and from oblast to rayon and local levels) of TB control activities. Nonetheless, the facilities visited in Belgorod, Chuvahsia, and Vladimir are well staffed, and the providers are motivated and committed.

3.2.4 Case detection

The case detection rate (CDR) is difficult to calculate for regions, as the denominator is only estimated for whole countries; even for these, it is only a best guess based on available information. However, trends in notification are useful if the methods for detection and the definitions do not change in time. Russia had a fairly stable notification rate in the last eight years. WHO estimates for 2007 a CDR of 75 percent for all cases (down from 81 percent in 2000) and 49 percent in new smear-positive cases (up from 37 percent in 2000). WHO estimates that TB incidence increased 2.1 percent from 2006 to 2007. Reported smear-positive cases have increased, possibly due to increase in coverage of the DOTS strategy and the use of microscopy in the general facilities, but is still very low at 23.9 per 100,000 compared with the total new cases reported in 2008 (85.1 per 100,000). Smear-positive TB cases are the main sources of infection in the community, but the Russian program still concentrates mainly on X-ray detection of any form of pulmonary TB, and over half of the diagnosed pulmonary cases have neither smear nor culture confirmation.

In some of the sites with external support there is a rapid reduction in the reported TB incidence and smear-positive incidence (Orel supported by USAID, Ivanovo), which can be attributed to program activities (Figures 3 and 4). It is difficult, however, to separate the epidemiological impact (reduction in the community) from the operational impact (better diagnosis with reduction of non-confirmed and increase of smear-positive cases). In fact, improved detection of smear-positive cases can hide a reduction in sources in the community. A good indicator of prevalence of sources of infection in the community is the positivity of microscopy in the general health care facilities. This proportion seems quite low in comparison with other countries, and the indicator could be followed easily as the information is available at regional level.

Examination of adults with respiratory symptoms (cough of long duration) in general facilities with sputum microscopy examination is the method recommended by WHO since 1974¹⁰ for detection of the most infectious TB cases. In the sites visited, the polyclinics examine outpatient suspects by microscopy, but only if the treating physician identifies them as suspects. Some patients attending for other than respiratory reasons may not be identified during their consultation. A simple operational study at facility or oblast level could easily determine the real prevalence of suspects among outpatients along with the prevalence of smear-positive cases among them; this information can be compared with the proportion of outpatients routinely examined by microscopy in those facilities.

However, in the USAID-supported areas, as in entire the Russian Federation, important resources are spent in screening the general population because it is mandated by national regulations. More than 60 million MMR and 20 million tuberculin tests are done in the

¹⁰ WHO. *WHO Expert Committee on Tuberculosis Ninth Report*. WHO Technical Report Series 552, 1974.

country each year, a costly and ineffective policy discouraged by international consensus. MMR produces 0.9 TB diagnoses per 1,000 examined—with a large proportion of the diagnoses not confirmed by the laboratory; while 1 million persons examined by sputum microscopy (70 percent in general facilities) yield 2.2 infectious TB sources per 1,000. Currently, 56 percent of TB cases are diagnosed by screening, 42 percent in persons attending facilities with symptoms, and 2.5 percent post-mortem. The proportion of the cases diagnosed by MMR screening that are smear-positive or bacteriologically confirmed, and the proportion of children diagnosed as having TB infection whose tuberculin reaction may be to BCG are important areas for operational research that have not been sufficiently addressed.

Figure 3. Reported tuberculosis incidence of new pulmonary cases in Russia and selected regions, 2008.

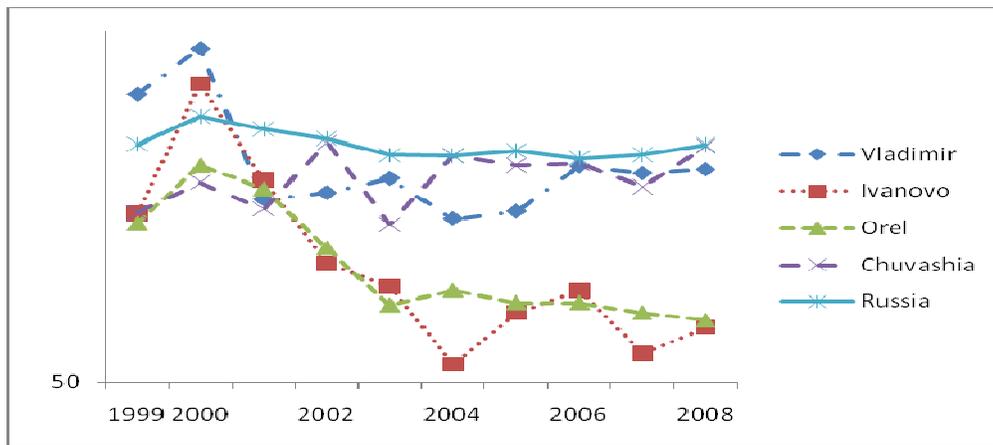
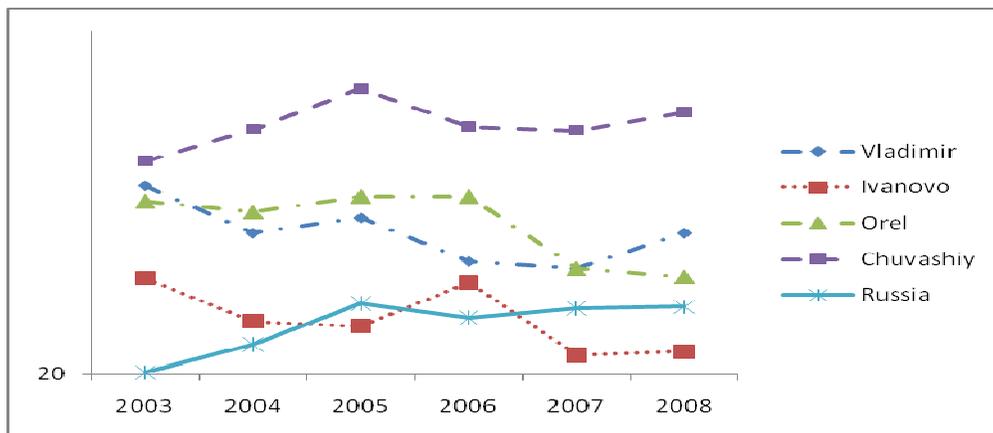


Figure 4. Reported tuberculosis incidence of new pulmonary smear-positive TB cases in Russia and selected regions, 2008.



3.2.5 Diagnostic practices

The proportion of cases confirmed by smear microscopy out of all pulmonary cases in the Russian Federation increased from 21 percent in non-DOTS areas in 2001 to 31 percent

countrywide in 2007; and the proportion of new pulmonary cases confirmed by the laboratory in 2007 was 47 percent. In 2008 the proportion of new pulmonary cases confirmed by smear was 33 percent and by culture 40.9 percent; this leaves more than half of the pulmonary cases diagnosed by clinical and X-ray criteria without bacteriological confirmation. The proportion of confirmed cases is still quite low compared with expectations (about three-quarters of the cases should be confirmed) indicating very high confidence in radiological diagnosis; it strongly suggests overdiagnosis of inactive forms or other pathologies. The problem is more evident in retreatments, for which international recommendations indicate that the diagnosis should be made without laboratory confirmation only by exception: the proportion of smear-positive in new cases plus relapses was only 26 percent in 2007.

Reviewed data plus observation in the three areas visited shows that diagnostic criteria and practices in the supported areas are in general better than the national average (Annex V, Table 6). The proportion of new pulmonary cases confirmed by culture varied between 80.7 percent in Orel and 37.2 percent in Khabarovsk. The proportion of diagnoses not confirmed by bacteriology varied from 25 percent in Chuvashia to 60 percent in the Jewish Autonomous Oblast in 2008. The proportion of pulmonary cases confirmed by smear is in general higher in the supported projects than in Russia, as shown by the reported incidence of total and smear-positive cases (Figures 3 and 4 above, and Tables 1 and 2 in Annex V). However, the quality of diagnosis is still inadequate, even in most supported areas, compared with that observed in other countries: The US reported in 2007 over 80 percent of pulmonary cases confirmed by the laboratory, and France reported 51 percent smear-positive and over 60 percent confirmed by the laboratory. The Russian site which could be used as a model for training and demonstration is Chuvashia, followed by Pskov and Orel.

A major contributor to the number of cases without bacteriological confirmation treated as TB is the regular screening with MMR, which is a mandatory policy in the country. Data is available on the number of cases diagnosed and the proportion of the total TB cases; and it is used for justification of the procedure. Data on the number of infectious sources (smear-positive) detected and treated, or on the proportion of smear- or culture-positive cases diagnosed in that group, is not readily available. Even in the supported areas, the focus is still on preventing “destructive” pulmonary disease and not on reduction of transmission by the most cost-effective methods. The prevalent medical belief that MMR reduces the development of more severe pulmonary TB is not backed by international evidence^{11,12} or by the fact that in spite of many years of MMR, the cases diagnosed in TB dispensaries continue to be severe and have high mortality during treatment.

Improvement of diagnostic criteria and practices in the supported areas seems a high priority to avoid unnecessary (and inappropriate) treatment and to rationalize the use of resources.

3.2.6 Laboratory

¹¹ Rieder H. What is the role of case detection by periodic mass radiographic examination in tuberculosis control? In: *Toman's Tuberculosis*, 2nd edition, WHO, 2004.

¹² Krivinka R et al. Epidemiological and clinical study of tuberculosis in the district of Kolin, Czechoslovakia. Second report (1965–1972). *Bull. WHO* 1974, 51:59–69.

At the national level, the head of the specialized TB laboratory network is the Research Institute of Phthisiopulmonology (RIPP)—it provides training, acts as a reference for culture and drug-susceptibility testing (DST), and provides proficiency testing on demand. It does not oversee the full TB laboratory network, however. The head for microscopy is in the national Central Laboratory in Moscow, which covers multiple diseases.

At the intermediate level, the supported projects have laboratory networks that include microscopy in the specialized services and polyclinics, with planning and quality control of slides by re-reading (a very good system, probably more appropriate than the most recent international recommendation). In the sites visited the system functions well. In general there is one microscopy unit per fewer than 50,000 inhabitants, workload within acceptable limits (15–25 slides per day per microscopist), and low positivity (around 1 percent in polyclinics). In one site the number of microscopes was reduced from 200 to 22, while maintaining the same number of examinations, a good example of more rational use of resources. One site is testing the UV attachment to convert the light microscope into fluorescence, a practical development for places with a large number of smears.

The proportion of false positive/false negative is still relatively high; although international publications indicate less than 5 percent as acceptable, good programs such as Peru's have reached national levels of less than 1 percent. The issue is less important in Russia because of the repetition of smears (by the polyclinic and specialized facility laboratories) and the systematic use of culture; but a false positivity of 1 percent would result in a very poor predictive value when the real positivity is low, as in Russia.

Recently there was a large investment in rapid methods for DST using liquid media (Bactec). Staff in the sites visited noted that reagents are imported and quite expensive, and that if there are insufficient resources for TB drugs the purchase of reagents would need to be curtailed.

3.2.7 Treatment practices

The provision of technical input by USAID and its implementing partners at the national level resulted in the development of the RF Ministry of Health Order #109 of March 23, 2003, which officially endorsed modified DOTS-based approaches to TB control countrywide. There is an overall recognition that this document was a significant step toward adoption of internationally recommended policies for TB case management. It allowed institutionalization of treatment practices that had been introduced in USAID-supported pilot sites in previous years. However, the document requires further revision to be in accordance with up-to-date international TB treatment guidelines, such as elimination of treatment regimen category IIB, which is likely to cause a growing number of MDR-TB cases; more detailed description of treatment regimens for poly- and multi-drug-resistant TB cases; and removal of rifabutin from the list of second-line drugs.

According to the MoHSD regulations, treatment of all TB cases is initiated as inpatient care (in a TB hospital) in all visited areas. Sputum smear-negative TB cases could be treated in a day-care ward of the TB hospital. Although all TB specialists have been trained in TB case diagnosis and treatment in postgraduate advanced medical courses and by USAID implementing partners, TB diagnosis in the sites must still be confirmed and the treatment regimen established by the central doctor/expert consultative committee (CVKK). This seems an unnecessary centralization that could be replaced by regular case reviews.

Treatment regimens and TB drug dosage for the majority of patients with regular TB in all visited USAID-supported sites follow the requirements of Order #109, which are in accordance with WHO treatment guidelines. Nevertheless, some TB cases—“severe ones”—are treated inappropriately, not following even Order #109 ; deviation from treatment regimens includes, for example, replacement of streptomycin by kanamycin in regimen IIA, as well as expanded use of regimen IIB, which may cause development of additional resistance to TB drugs.

Direct observation of treatment (DOT) is a part of inpatient TB case management in all visited hospitals. The length of inpatient care has been reduced in the sites visited, but it is still longer than necessary. Extended hospital time is based frequently on X-ray results rather than on sputum conversion, an inadequate practice. For patients who live in areas where ambulatory DOT does not exist, social conditions is a reason for maintaining hospitalization, a policy that fits international recommendations.

USAID technical assistance and training laid a solid basis for implementing GLC-approved MDR-TB case management programs in visited sites. MDR-TB treatment is provided in accordance with WHO recommendations and established treatment regimens and dosage in each site. Compliance with international GLC-supported approaches is regularly monitored during supervisory visits by USAID implementing partners and GLC missions. However, the personnel tend to divide daily doses and give the required TB drugs three or sometimes even four times a day. This practice, against international guidelines, was justified by medical staff as reducing possible intolerance of TB drugs. Side effects are registered. Despite the availability of required testing and examinations to evaluate adverse effects and the availability of auxiliary drugs to mitigate them, the above indicated practices may be caused by inadequate knowledge of and lack of experience in counteracting side effects. Additional training and technical assistance is needed to strengthen management of side effects. Adequate supply of auxiliary drugs to overcome side effects should be ensured for the entire course of treatment, including the outpatient phase of treatment. Some MDR-TB patients who previously received second-line drugs have developed resistance to them. Observers noted a lack of knowledge on general approaches to modifying treatment regimens required in these cases. Additional refresher training, technical assistance and the availability of moxifloxacin as well as anti-TB drugs of the 5th group for MDR-TB patients resistant to second-line drugs will help to overcome this deficiency and make the updated knowledge an operational tool.

Over the last 3–5 years, USAID investments helped to improve significantly TB control program management at the regional level. In addition to continuous work with TB control administrators, active involvement of the regional governments and general health administrations in TB control management allowed establishing outpatient treatment and follow-up with direct observation of drug intake by TB patients; it also offered social support and incentive programs to encourage TB patients’ adherence to treatment. Financing of social support/incentive programs is being taken over by local governments.

Various options of ensuring DOT at the ambulatory stage have been observed in the visited territories:

- **At DOT sites at the Russian Red Cross units.** With USAID/IFRC support, the RRC has developed a comprehensive patient-centered TB treatment and support program to improve adherence to treatment (for example, in Belgorod). A cadre of

RC nurses has been trained to provide services to TB patients residing at close distance to RRC units or to specifically established DOT spots. The TB dispensary refers patients for follow-on treatment to the local RRC unit, transfers drugs to the unit, and oversees case-management practices. If patients cannot come to a DOT point, a volunteer goes to their homes. The RRC staff also provide social support, food incentives, and psychological support (professional psychologists are involved). Specific psychosocial interventions may help to address marginalized populations, alcoholics (the TB program in Tomsk has relevant experience and good results). The increasing number of MDR-TB patients will be referred to the RRC units for ambulatory treatment in the continuation phase. So far, the TB dispensary requires that MDR-TB patients with any signs of side effects are referred back to the dispensary. With increased experience, additional training, and established clear algorithms for mitigating side effects, the current practices could be revisited with regard to slight-to moderate side effects.

- **At day-care wards of TB hospitals and TB offices of outpatient departments within central district general hospitals.** At the completion of an intensive phase of treatment in a TB hospital, a patient is referred to a district TB specialist/coordinator providing services in the territory where the patient resides. A district TB coordinator is supposed to explain and provide advice on the possible options regarding where to continue DOT. The majority of TB patients in urban settings prefer these two options. The possibility exists to organize follow-on treatment in any district outpatient clinic (policlinic) upon patient request. Home-care teams also provide DOT in order to avoid interruption of treatment.
- **Integration of TB services, in particular ambulatory follow-on treatment, at the primary health care level in rural settings.** DOT in rural areas is provided at offices of family practice doctors and feldsher-akusher points (FAPs). Transportation is available to ensure DOT at TB patients' homes.

A comprehensive package of activities/approaches was used to ensure solid ambulatory DOT and to decrease the proportion of patients who interrupt treatment (default rate) and can potentially become drug-resistant TB cases. In summary, this package included:

- Advocacy and communication with central and regional administrations.
- Provision of DOT close to patients' homes.
- DOT spots of the RRC.
- DOT at the primary health care level in rural settings.
- Patient education.
- Patient-oriented psychological programs.
- Day-care wards.
- Home-care services.
- Trained DOT personnel.
- Specific trainings to improve communication and counseling skills of the medical staff and social workers (including the RRC and the prison system).
- Involvement of a social network.

The USAID and implementing partners' efforts contributed to improved treatment outcomes, including significantly higher success rates in Belgorod, Vladimir and Chuvahsia as compared to the Russian Federation overall, as well as lower default and transfer-out rates in these territories compared to the RF (Figures 5 and 6). This has yet to happen in Khabarovsk, Adygea, and the Jewish Autonomous Oblast, which joined the

USAID-supported program later and have still default and transfer-out rates higher than the average of the RF. Special attention to these regions is required to prevent the development of additional MDR TB cases. As these regions expand treatment of MDR TB cases, they should ensure that treatment is not interrupted.

Figure 5. Treatment success rates of new pulmonary smear-positive patients in selected WHO/USAID-supported oblasts. Civilian sector, cohort of 2006.

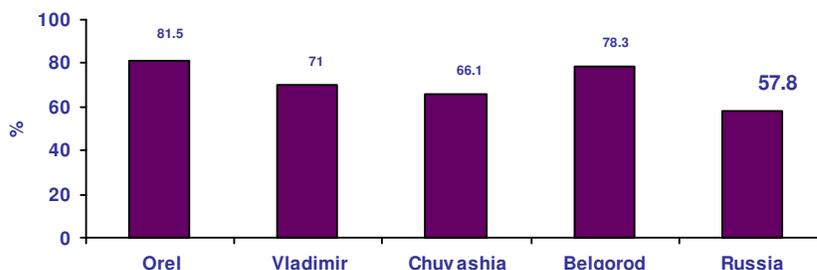
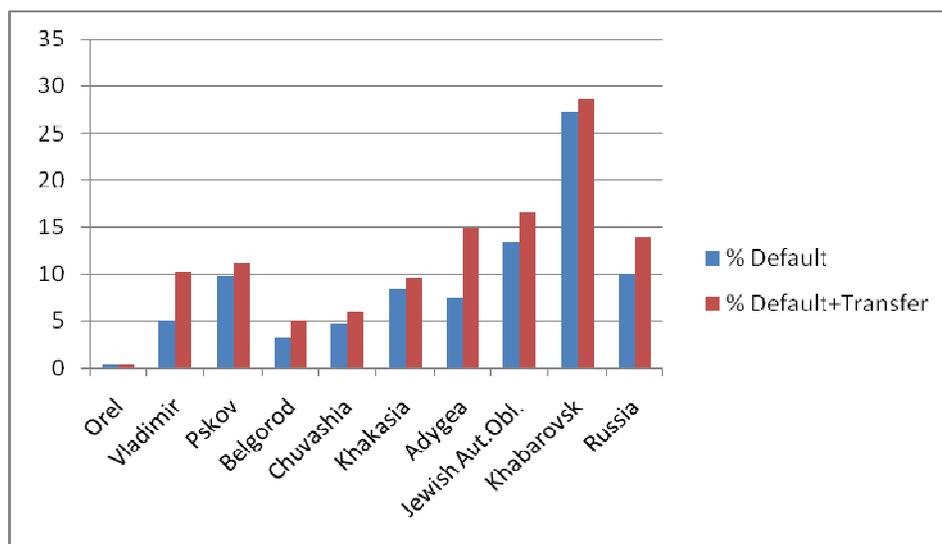


Figure 6. Treatment default and default plus transfer-out rates of new pulmonary smear-positive patients in WHO/USAID-supported oblasts. Civilian sector, cohort of 2007.



3.2.8 Drug management

The three sites visited had regular supplies of drugs and appropriate drug management. Drugs were obtained by the regional governments with various financial resources, including the local budget. There were no cases of treatment interruption due to drug supplies. That is not the case in the country in general: during the HLWG meeting, several regions indicated poor drug stocks, interruption of supplies to patients, and problems in resupply. The health reform policy of decentralization of funds without protecting programs of national importance, such as tuberculosis, is an added risk. National policy mandates purchase of drugs produced in the country, if available, and quality assurance is left to the regions.

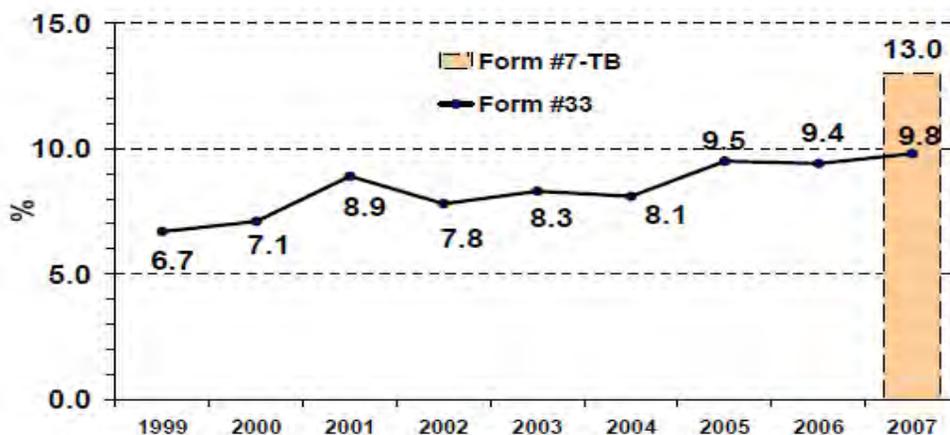
Second-line drugs (SLDs) have been used for years and purchased with funds available from GFATM grants; purchase at lower cost was facilitated by the Russian Health Care Foundation and the Green Light Committee (US\$1,200 instead of \$6,000 per case). The

loan and grant funds are exhausted, however, so continuation of drug supplies for MDR-TB patients will depend on national and regional resources, and the mechanism of drug purchase of imported drugs by the regions is not clear.

3.2.9 Multi-drug-resistant TB

In its 2009 Global Surveillance Report, WHO estimates that 13 percent of new and 49 percent of previously treated TB cases are MDR-TB. Moreover, in 2007 among new TB cases only 28.5%¹³ percent of the estimated MDR-TB cases were diagnosed and notified by TB control programs. This underscores the need to expedite expansion of demonstrated high-quality DOT-Plus projects in Russia, particularly when the MDR-TB trend has been upward in recent years. Of special concern is the high accumulation of chronic cases. Four of the nine projects supported by USAID are among the oblasts with the highest rates of TB in Russia (Khakasia, Pskov, Belgorod, and Chuvahsia).

Figure 7. Reported prevalence of MDR TB in the Russian Federation¹⁴



In the USAID-supported sites visited (Belgorod, Chuvahsia, and Vladimir), as in Russia in general (Figure 7), the proportion of MDR-TB among new smear-positive cases is increasing. Similarly, among previously treated TB cases, MDR increased from 2007 to 2008, with the exception of Chuvahsia. In 2008, the proportion of MDR-TB for new and previously treated cases in those sites was higher than in the RF (Table 1).

¹³ Total new cases in 2007: 106,668; estimated prevalence of MDR in new cases - 13%. Expected MDR-TB cases among new cases in 2007 = 13,867; notified MDR-TB cases among new cases in 2007 = 3,959 (28.5%)

¹⁴ Tuberculosis in the Russian Federation, 2007. An analytical review of the main tuberculosis statistical indicators used in the Russian Federation. Edited by M.I. Perelman and Y.V. Mikhailov

Table 1. Prevalence of MDR-TB in new smear-positive and previously treated pulmonary TB cases in USAID supported projects and the Russian Federation, 2006-2008

Prevalence of MDR-TB (%)							
	New smear-positive TB cases (%)				Previously treated smear-positive TB cases (only relapse)		
	2006		2007	2008	2006 (WHO data)	2007	2008
	National data	WHO data					
Belgorod	6.7		11.3	19.2	-	32.2	51.6
Chuvahsia	12.7	-	14.6	14.2	-	52.6	45.7
Vladimir	7.4	10.3	9.4	14.0	31.8	29.5	32.7
Russian Federation	9.4	-	12.9	13.6	-	24.8	28.8

TB dispensaries in all oblasts have the capacity to do drug-susceptibility testing (DST). Rapid liquid methods for DST have been introduced in most of the oblasts although they were not endorsed in Prikaz #109. In addition, conventional culture and DST methods (solid media) are done. DST is carried out for both first- and second-line drugs. A problem faced at regional labs is the irregular availability of supplies and reagents. Purchase of these materials is decentralized to the oblast level. There have been stock-outs of reagents and materials for rapid culture and DST (BACTEC MGIT systems) that delay diagnosis of DR.

The five Research Institutes do training and supervision of oblast (regional) labs. The Research Institutes supervise and provide TA to oblast reference labs two or three times per year. External funding (USAID, WB) has sustained these activities and there is concern that the MoHSD will not be as supportive once the external funding ends. External quality assurance (EQA) for oblast laboratories is carried out by the Federal Service for External Quality Control (FSEQC). However, this is done only for first-line drugs (FLDs). Staff in the TB dispensary in Chuvashia reported not getting any feedback from the FSEQC for their DST performance on liquid media; thus they report the results based on the conventional DST method, which takes longer.

Despite the lack of a national MDR/XDR-TB control strategy or response plan, there are 28 GLC-approved DOTS-Plus projects in the country (29 with Tomsk), thanks to the financial and technical support of external partners (WHO, IFRC, USAID, RHCF, GFATM). These 28 projects have approval to treat a total of 9,003 MDR-TB patients, which may represent more than 28 percent of the cases estimated¹⁵. Nine regions supported by USAID are included in these 28 sites. The Round 9 application to GFATM, which was not approved, proposed increasing enrollment of an additional 10,000 patients. In addition there are MDR TB patients treated with drugs procured by local governments or other sources.

The responsibility for budgeting and purchasing SLDs is currently within the MoHSD, through a centralized process. In 2009, however, 100 percent of SLDs were purchased under the scope of the GFATM project since the MoHSD did not budget for them in 2008.

¹⁵ WHO latest estimate is 31,397 MDR-TB cases in 2007.

Important delays in acquiring SLDs have prevented patients from commencing treatment in a timely fashion. In the Republic of Chuvashia, approval from GLC was granted in 2005, yet the drugs arrived only in 2008. Similar accounts have been reported in Adygea, Khabarovsk, and the Jewish Autonomous Oblast. As of November 2009 only 4,344 MDR-cases had started treatment (48 percent of the total approved by GLC since 2005) (Table 2). WHO, with funding from USAID, has provided ongoing TA to the RHCF on procurement, supply, and management of SLDs, including organizing a mission to assess existing barriers. While managing the GFATM and WB projects, the RHCF has acquired experience in the processes of drug procurement and management, and is willing to continue this activity; nonetheless, there is resistance from the MoHSD. There are concerns regarding the capacity of the oblasts to ensure smooth enrollment of more patients with MDR-TB beyond September 2010. In the sites visited (Belgorod, Chuvashia, Vladimir), SLD are financed from various sources that include the GFATM, federal budget, and regional budgets. Some oblasts (Belgorod) have an emergency budget to avert stock-outs; this allows them to purchase drugs without tendering.

Table 2. Number of patients approved for treatment by the Green Light Committee (GLC) in DOTS-Plus projects and number that have started multi-drug-resistant TB treatment

	Number approved for treatment	Number of patients who have started treatment
Orel	200	104 (52%)
Vladimir	350	256 (73%)
Pskov	250	151 (60%)
Belgorod	250	245 (98%)
Chuvashia	210	195 (93%)
Khakasia	324	211 (65%)
Adygea	50	25 (50%)
Jewish Autonomous Oblast	40	0
Khabarovsk Kray	300	22 (7.3%)
TOTAL RUSSIA	9,003	4,344 (48%)

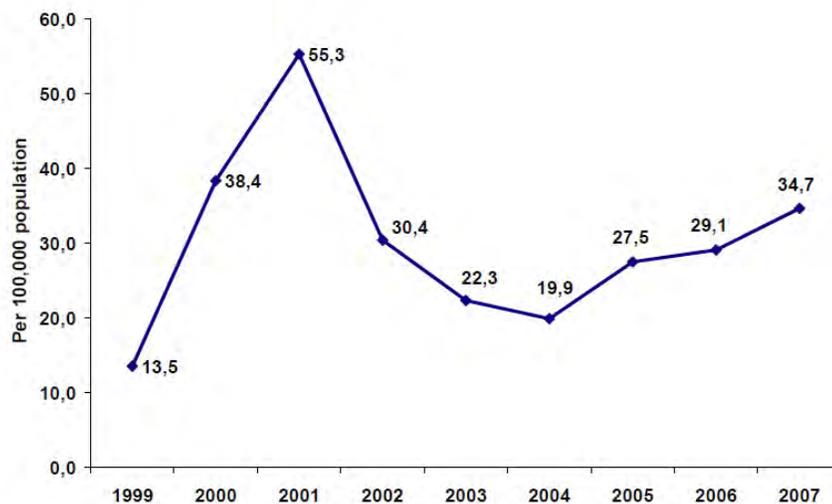
WHO has provided and facilitated national and international MDR-TB training for TB specialists working in DOTS-Plus projects, based on international guidelines. Still, there are no national approved standards for case and program management; therefore, practices may vary by region. Similarly, there is no national surveillance system for MDR-TB. In projects implemented by IFRC there are plans to develop an MDR-TB recording and reporting system.

3.2.10 TB/HIV co-infection

Since 2004 and up to 2007 (last year of data available) the annual number of new HIV infections has increased in the RF (Figure 8). The incidence rate of persons infected with

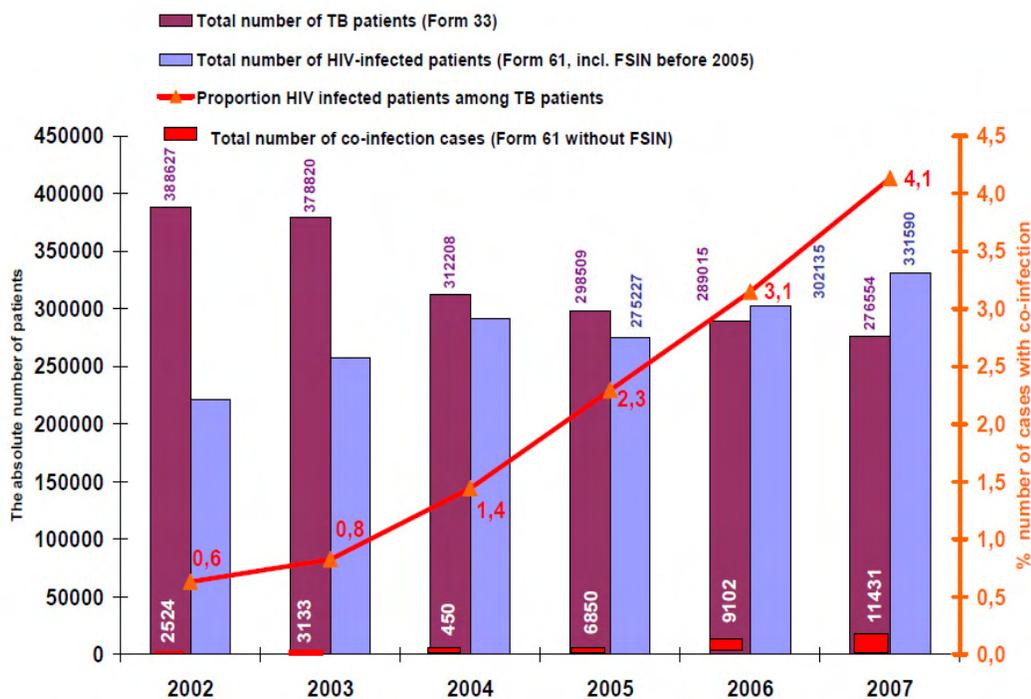
HIV in 2007 was 34.7 per 100,000 compared to 19.9 per 100,000 in 2004, and 13.5 per 100,000 five years earlier (1999).

Figure 8. Reported incidence of HIV infections in the Russian Federation. Rates per 100,000.



Source: Perelman MI, Mikhailova YV, eds. *Tuberculosis in the Russian Federation 2007. An analytical review of the main statistical indicators used in the Russian Federation*. Moscow, 2008.

Figure 9. Reported number of TB patients (prevalence), HIV-infected patients and TB-HIV co-infection in the Russian federation, 2002–2007.



Source: Perelman MI, Mikhailova YV, eds. *Tuberculosis in the Russian Federation 2007. An analytical review of the main statistical indicators used in the Russian Federation*. Moscow, 2008.

Consequently, the number of TB patients who are co-infected with HIV has increased. The percent of TB patients co-infected with HIV increased two-fold from 2004 to 2007 (0.6 percent to 4.1 percent) (Figure 9). According to national statistics, in 2007 90.9 percent of new TB cases were tested for HIV antibodies; a steady increase from 89.9 percent in 2006 and 88.5 percent in 2005. The percent of HIV-infected individuals screened for TB has increased in the same time period from 37.8 percent in 2005 to 54.6 percent in 2007.

Upon detection of HIV infection in different health care facilities, an HIV patient register card is issued, with duplicates sent to regional AIDS centers, and from there data is reported to the national level. Each person found seropositive for HIV in a PHC or hospital is referred to an infectious disease specialist and for TB screening in a designated clinic within a TB dispensary. In other cases, as in Belgorod, TB screening occurs at AIDS centers where a TB specialist screens persons with HIV/AIDS for TB and manages co-infected patients. Screening for TB among HIV-positive cases is done only with purified tuberculin (PPD) and radiography. As per policies of the National AIDS Center, cotrimoxazole preventive therapy (CPT) and isoniazid preventive therapy (IPT) are provided only when the patient's CD4+ lymphocyte count is less than 200mm³. In practice, IPT and other procedures vary widely from provider to provider as there are no clear TB/HIV case and program management guidelines, including for IPT, in Russia.

Since 2005 PEPFAR and USAID have supported curricula development and training activities for HIV/AIDS case management through the AIHA. This includes a course on TB/HIV. Even though the MoHSD has incorporated some of the courses developed by AIHA, it is not clear if the TB/HIV module is one of them. This course is currently not

part of the training imparted by the Research Institutes. Still, over the years AIHA has trained a substantial number of infectious disease and general practitioners in St. Petersburg, Sarotov, Orenberg, Samara, Sakhalin, and Moscow. The AIHA has collaborated with the URC in training URC staff on TB/HIV. Through the work of the URC, integration of HIV/AIDS and TB services is being implemented in St. Petersburg, Orenburg, Engels, and Togliatti/Samara. This integration includes clinical and program collaborative activities.

A positive aspect of the management of TB/HIV co-infection is the presence of a focal TB/HIV person in the oblast TB dispensaries that were visited. This person is responsible for coordinating management of co-infected cases and recording and reporting information. TB/HIV data is recorded and reported through a unified system from oblast TB dispensaries to the National Center for TB Care to HIV Patients in the MoHSD. This has improved the completeness and quality of information, and includes the penal system. In URC/USAID supported sites there is an inter-institutional team at the oblast level that coordinates and oversees TB/HIV integrated activities.

The areas visited still have a low prevalence of HIV infection in TB patients, so TB/HIV management has had a relatively low priority. This will change as HIV infection continues to increase.

3.2.11 Infection control (IC) knowledge and practices

Numerous trainings in up-to-date TB infection control (IC) approaches have been carried out by USAID implementing partners. Internationally recommended IC approaches are known, well understood, and accepted by TB program managers and specialists in all visited facilities. IC plans were developed in USAID-supported sites. However, a strategic IC plan at the federal level including the revised roles and responsibilities of the sanitary system is yet to be developed. So far, Annex 13 of Order #109 indicates required anti-epidemic measures in tuberculosis niduses (sources), including disinfection, which are largely outdated.

Modernization of infection control measures in TB facilities is much appreciated and supported by regional general and health administrations. Personal protection and working habits have significantly improved in all visited sites. Respirators for personnel are available and used as appropriate in TB facilities. Respirator “fit testing” for staff is in place. Proper monitoring and documentation of the hospital-acquired infection should be in place.

The visited sputum collection units at general outpatient clinics were equipped with ventilation systems and UV, although its cost-effectiveness was doubtful due to the type of equipment and place of installation. There is a protocol for sputum collection, which is commonly followed. In Belgorod, the ventilation system was well functioning in the MDR-TB department, with positive pressure in clean zones and negative pressure in dirty ones.

The Vladimir Oblast TB Dispensary is seen as a model center of expertise and a demonstration site in infection control. Improvements (ventilation, UV lights) were completed and other key elements of infection control were effectively implemented. However, full administrative measures such as isolation/separation of patients with sputum smear positive regular and MDR-TB were not observed during the visit. Dining for both

regular TB and MDR TB patients is provided in the same room; although there is a schedule to first serve patients with regular TB and then, after UV, MDR-TB patients, the appropriate patient flow was not followed during the visit. There is a plan to construct a new MDR-TB department with funding provided by the local government. However, it is doubtful that this center of excellence should be used as a demonstration site for expansion to other oblasts. The measures taken are good for specialized hospitals, but represent a substantial investment in engineering that would not be justified for general health facilities, where most persons with cough attend before diagnosis, or for patients already under treatment and bacteriologically negative. As the international recommendations (and the DOTS strategy) promote integration of activities, IC measures should be appropriate for that environment. For instance, collection of sputa in primary health care facilities can be done in the open air outside the buildings, a more practical approach. The selected demonstration sites should be able to demonstrate effective IC measures for both specialized and general facilities for the most common circumstances.

3.2.12 Advocacy, communication, and social mobilization (ACSM)

USAID and the implementing partners advocated effectively for international approaches in TB control at the federal and regional levels. Active participation in HLWG proceedings resulted in increased government commitment to TB control and the development of regulations on TB case management. Advocacy and communication efforts raised public awareness and strengthened links between the civil and penitentiary systems. Intensified efforts are required to further bring federal policies and standards closer to international recommendations for cost-effective TB case management.

The comprehensive educational and communication activities conducted by the IFRC/RRC targeted local communities. Although these activities are essential to a TB control program, it is necessary to focus them better, targeting the improvement of patients' adherence to TB treatment. Specific awareness and social mobilization programs should be developed for at-risk populations including migrants, homeless people, and other marginalized populations, which are commonly not covered by health insurance and have limited access to conventional TB services at the local level. These activities require understanding of the target populations' beliefs and attitudes, so that tailored messages can be delivered adequately to patients to improve adherence and to communities and local authorities to trigger seeking of care. Specific interventions should be developed for fundraising.

4. Conclusions

4.1 What worked in the supported sites

The sites supported by USAID for tuberculosis (TB) control in the Russian Federation have shown the feasibility of:

- Obtaining oblast/Republic government support to finance program activities and to revise policies for TB control.
- Integrating detection of respiratory-symptomatic individuals (TB suspects) and performing quality-assured microscopy in general health facilities.
- Establishing a laboratory network for TB and maintaining a system of quality assurance of microscopy.

- Improving the quality of diagnosis by increasing the proportion of diagnosed patients that were confirmed by sputum smear microscopy or culture.
- Maintaining regular supplies of first-line drugs.
- Integrating directly observed treatment (DOT) and patient support and follow-up in general health facilities.
- Improving the results of treatment and reducing default, with a lower risk of creating multi-drug resistant (MDR) TB.
- Implementing infection control (IC) measures.
- Treating MDR-TB patients.
- Rationalizing the use of resources, with less cost and better access to patients; reducing the number of sanatoria, TB beds, and duration of hospitalization.
- Reducing TB prevalence in the community (smear-positive notification in Orel, Vladimir, and Ivanovo has diminished in spite of maintaining the level of detection activities).
- Reducing TB mortality, mainly in prisons.

However, the sites represent less than 8 percent of the population and of the TB cases in the country, so the direct impact of the USAID-supported projects on the burden of TB disease in the Russian Federation (RF) is small. The sites are more important as pilot and demonstration areas, but the use of this national resource and experience by other regions and expansion of the lessons learned has been very slow.

4.2 What needs improvement in the supported sites

To utilize the USAID-supported sites as demonstration areas and expand the experience countrywide, some improvements are required:

- Updating the knowledge of managerial staff regarding TB transmission and relative risk of TB infection by treated and untreated smear-positive and smear-negative patients, as the basis for infection control and treatment of patients at home.
- Improving the diagnostic criteria used by TB specialists for clinical decisions, so that the large majority of the pulmonary cases is diagnosed through bacteriological confirmation.
- Develop and have widely available written standard operating procedures, work plans, and training materials at oblast, rayon, and facility levels.
- Increase the analysis of outcomes of activities by facility and rayon staff, and the display of trends at all levels for staff motivation and training.
- Improve the administrative measures of infection control and development of facility-based infection control plans.
- Strengthen and coordinate current ASCM efforts through the development of the regional ASCM workplans.
- Rapidly expand MDR-TB treatment.
- Increase managerial capacity. There is insufficient managerial capacity at the oblast levels; Chiefs of TB Dispensaries have to carry out clinical tasks in addition to

overseeing the TB program. This limits their time to carry out activities inherent to public health and managing all aspects of a TB control program.

- Conduct operational research to address program issues. Examples are the real proportion of suspects among adults attending general health facilities; the number and proportion of smear-positive pulmonary TB detected by mass miniature radiography (MMR); the proportion of failures due to change of treatment because of MMR and other reasons; and the underlying causes of death during treatment (much higher than in other countries, even with HIV co-infection).

With a few rapid improvements, some of the sites could become demonstration areas for application of the experience to other oblasts. In particular, Chuvashia could be a model for the quality of clinical diagnosis, Belgorod and Chuvashia for the integration of activities in general facilities, and Vladimir for the rational use of resources (reduction of beds, duration of hospitalization, reduction of microscopy units, and outpatient treatment from start).

4.3 National level strengths

At the national level, USAID support has facilitated:

- Implementation of the DOTS strategy by the prison system (Ministry of Justice), with very good epidemiological impact on TB incidence and mortality and good coordination with the civilian system (Ministry of Health).
- Development and adoption of a recording and recording system compatible with international standards and with Russian information requirements.
- Creation and functioning of the High Level Working Group on TB.
- Revision of the technical and operational guidelines (Ministry of Health Order #109) and a reduction of discrepancies between national and current international recommendations.

4.4 National level challenges

The key challenges at national level are:

- There is no national TB control program (NTP unit) in the Ministry of Health (part of the DOTS strategy and recommended by the HLWG) responsible for program oversight and support to oblasts. Some of the activities corresponding to this unit have been carried out by the National Institutes and by WHO, neither of which is part of the Ministry of Health. Absence of an NTP unit can contribute to the existing irregular supply of first-line drugs, leading to MDR. Moreover, ensuring regular supplies is a condition of DOTS and should be a responsibility of the NTP unit in the Ministry of Health. A unit at the federal level would also facilitate and expedite the availability of second-line drugs within Green Light Committee (GLC)–approved projects, which was identified as a problem during the site visits. The following program weaknesses are in large part consequences of the lack of an NTP unit at the MoHSD.
- The technical and operational procedures still do not follow international recommendations (for example, with MMR, hospitalization, repeated Bacillus Calmette-Guérin [BCG] plus mass tuberculin screening of children, and mass photofluorography). There is insufficient knowledge of international evidence regarding TB transmission, cost-effective control measures, and impact at all levels.

The national policy is geared toward management of TB as a clinical issue and not toward prevention of transmission (and MDR) as a public health responsibility of the government.

- Even after the RF participation in the MDR/XDR Control Meeting in Beijing in spring of 2009, there is no MDR/XDR-TB strategy/response plan at the national level. Moreover, there are no national MDR/XDR-TB case-management guidelines for clinicians and program managers, with clear definitions, monitoring of treatment, cohort analysis procedures, and recording and reporting.
- Despite assessments and training on drug procurement and management of second-line drugs, delays in their introduction and availability to patients persist. These delays increase the risk of transmission to others. It is noteworthy that in most USAID-supported sites, as in the RF in general, the proportion of MDR-TB among new smear-positive cases is increasing, a reflection of recent infection with MDR strains circulating in the community.
- There are no national practical guidelines for integrated management of TB/HIV co-infection. Practices vary among oblasts and facilities. Isoniazid Preventive Therapy (IPT) and Clotrimoxazole Preventive Therapy (CPT) are not carried out in general due to poor knowledge and capacity among staff.
- There is no guidance from the national level to the oblasts on human resource development (HRD), particularly the development of HRD plans. Such plans should include job descriptions, competencies of staff, continued education and training, incentive plans, and performance-based evaluation.

5. Recommendations

Based on its October 2009 independent evaluation of the USAID TB control program in the Russian Federation the PATH team makes the following recommendations:

1. Continue support to existing sites through the partners, with emphasis on correcting the problems detected, and develop selected sites as demonstration centers. This includes preparing written plans of action, standard operating procedures (SOP), and training materials; creating human resource development (HRD) plans that include job descriptions, competencies of staff, continued education and performance-based evaluation; preparing SOP for infection control measures appropriate to different levels (specialized and general); and developing the organization to receive and train staff from other oblasts and to carry out post-training supervision visits.
2. Promote political commitment of other oblasts to implement similar TB programs, including oblast funding for observation visits to the selected demonstration sites, and collaboration to support training visits. The key criteria for the selection of new oblasts for expansion of the experience should be the effective political commitment of the local authority to fund training and implement changes. Other criteria would be the number of inhabitants and population density (Annex VI), the number of TB cases reported, high HIV prevalence, and close distance to existing funded sites (Annex I and VII). Expansion should be rapid and require minimum external resources—the aim is dissemination of the experience, not replication of pilot projects. The Research Institutes in Russia should be involved during the planning and implementation phases of expansion, whilst in parallel, their capacity to provide technical assistance in DOTS and DOTS-Plus implementation and TB/HIV (per international standards) to the regions should be promoted. The Institutes would work closely with the NTP Central Unit to achieve a concerted response to TB in current and future USAID-supported sites.
3. Advocate and provide technical assistance for the creation of a TB unit in the Ministry of Health, with public health functions. Advocacy may include direct discussion with MoHSD authorities to offer USAID collaboration (on the basis of the recent presidential agreement of April 2009); advocating to the health committees within the Duma and the Council of the Federation; and engaging the political authorities/administrations of the USAID-supported sites to back the recommendation of the High Level Working Group on TB. Key reasons are the need to prevent further expansion of multi-drug-resistant (MDR) TB by ensuring first-line drug supplies, and better utilization of the large resources that the Federation dedicates to TB control (over 1 billion dollars per year), a substantial part of which goes to costs of hospitalization and other low-impact strategies. An effective mechanism would be to appoint a TB coordinator in the MoHSD and assign selected professionals from the National Institutes to staff the TB unit, after appropriate retraining for their new functions.
4. Advocate for and support the revision of the national guidelines for TB control (Ministry of Health Order #109) to adopt current international recommendations; from the new version, develop standard operating procedures appropriate for practice and training. The national norms should consider the the guidelines to be published in 2010 by WHO and other Stop TB partners (including management of

- MDR-TB) and should aim to improve the rational use of resources and simplify procedures for TB detection and case management.
5. Support rapid expansion of the TB/HIV integrated care model, which includes voluntary counselling and testing for TB patients and TB screening for people living with HIV/AIDS based on symptoms and bacteriology, in addition to purified tuberculin (PPD) tests and chest X-rays. Also, support the development and adoption of TB/HIV screening and treatment protocols under a national policy framework.
 6. Through the implementing partners, promote the delivery of TB and TB/HIV training in a cohesive and complementary manner. Attention should be given to avoiding duplication of efforts among USAID implementing partners. Curricula developed by an implementing partner can be adopted by others (i.e. AIHA's TB/HIV curricula). Training should be evaluated through sound methodologies (pre- and post-tests, patient chart audits, patient satisfactory surveys, changes in TB indicators). Moreover, curricula developed by implementing partners can be integrated in under- and postgraduate medical education, which is currently focused primarily on clinical aspects of TB treatment and reflect outdated practices.
 7. Strengthen USAID support to ACSM efforts in a coherent manner with the aim of increasing case detection through bacteriology testing and treatment outcomes (reducing default and transfer-out). These are priorities that require advocacy and communication interventions to further promote the revision of current policies and practices, promote cost-effective budget allocation, and consistent involvement of social networks to providing support to TB patients. Intensive ACSM activities are especially needed to improve TB control outcomes among socially marginalized populations, including coinfecting TB/HIV patients, many of whom experience stigmatizing attitudes. Thus, the capacities to plan, implement, and evaluate ACSM activities at the federal and regional levels should be improved.
 8. Promote and support operational research at national, oblast and, facility levels to solve problems and provide information for program decisions. Of particular interest are the real prevalence of TB suspects (cough of long duration) and smear-positive persons among polyclinic outpatients at facility level; the reasons for high rates of failure and death during treatment; and the number of infectious sources detected through MMR compared to screening of persons with symptoms.

Potential areas for USAID's support to TB control in the Russian Federation in the following years are:

1. **On the role of NGOs in TB control** –Russia has a well-developed network of the community-based Red Cross units which are contributing to TB control in sites visited. This model can be strengthened and replicated in other sites where USAID will expand activities. Sustainability can be achieved by promoting improved coordination between local Red Cross chapters and local administrations to work towards common goals and fund-raising. The role of the Red Cross chapters in advocacy to bolster political commitment is vital. The Red Cross local chapters could be used as a platform for from which to garner community engagement in TB-control related activities. The team does not consider that newly created/supported local NGOs could represent a major

element for TB control in Russia. However, the strengthening and streamlining of ACSM for TB and TB/HIV. This would require linking with NGOs working in HIV prevention and care. ACSM activities should be carried out under the framework of a National and regionally-adapted ACSM strategy with corresponding workplans. USAID may consider supporting this strategy.

- 2 On SLD** – The team is not able to provide in-depth information and recommendations on procurement, management and use of second line drugs practices. The Green Light Committee is collaborating with the country for that specific purpose. USAID may consider supporting technical assistance to guide and build in-country capacity for the WHO prequalification processes regarding SLD for TB. Additional technical assistance may be required to develop and establish policies and protocols for pharmaceuticals quality assurance and rational use of pharmaceutical.

- 3. On rapid testing and molecular diagnostics** –Support for technical assistance for the effective introduction and adoption of new methods to optimize smear microscopy (LED-based fluorescent microscopy, front-loaded smears) and molecular line probe assays may be considered by USAID. Rapid liquid culture methods (i.e. MGIT) are already in use at sites visited. Rapid liquid culture method should be made available throughout the country at the regional level. This should be expanded in a phased manner, and emphasizing sustained quality assurance, in-line with international recommendations. USAID may opt to support this process through the provision of technical assistance to oblast laboratories. Eventually it may explore role of the private sector in the Russian Federation and the provision of technical assistance to these entities for the manufacturing of evaluated and recommended rapid TB diagnostic tools.

ANNEXES

- I. Map
- II. Scope of work
- III. Itinerary of field visits
- IV. Key persons interviewed and institutions visited.
- V. Reported incidence and treatment outcomes
- VI. Russian Federation oblasts with population >800 000 and density >25 000 per km²
- VII. Map of USAID-supported sites by implementing partner and coverage of the Research Institute's technical assistance to regions
- VIII. References

Annex I. USAID supported TB control sites in the Russian Federation



10 highest TB notification rate regions

Annex II. Scope of work

Evaluation of USAID Russia TB Control program

PATH - TASC2 TB, Task Order 02 - GHS I-02-03-00034-00

Country:	Russia
Project title:	USAID/Russia TB Control Project Evaluation
Period:	October 18, 2008 – October 31, 2009
Main PATH contact:	D’Arcy Richardson
Estimated budget:	\$95,000 (CSH FY08) Field support activity

Background

Although the Government of Russia (GOR) has regulations in place to implement the internationally recognized DOTS strategy nationwide and the GOR TB budget has significantly increased reaching more than \$700 million per year (consolidated), many challenges remain such as low patient adherence to TB treatment, poor infection control, the irrational use of drugs and other resources, and insufficient involvement of civil society in TB control. As a result, Russia treatment success rate of 58% is significantly below the WHO-recommended 85% level. Russia still ranks 12 among 22 TB high burden countries in the world and the only high burden country located in the European region. With the alarming growing rate of MDR TB in Russia, registered at 10.7 % of all new TB cases and potentially 5-6% of all new cases of MDR deemed to be extensively drug resistant (XDR), Russia ranks the third among countries with the biggest registered cohorts of MDR TB cases worldwide.

USAID/Russia Tuberculosis (TB) Control program has been implemented since 1998. The objectives of the USAID TB Control program are to reduce TB mortality, morbidity and disease transmission and to prevent development of drug resistance through adaptation and incorporation in routine TB control practice internationally recognized and cost-effective WHO-recommended approaches to TB diagnostics and treatment. The program is implemented in nine regions of Russia both in civilian and penitentiary sectors, and on the federal level. The program sites and components are managed by the World Health Organization (WHO) and the International Federation of Red Cross and Red Crescent Societies (IFRC). The main areas of the USAID Russia TB control program are policy reforms and further DOTS expansion and enhancement, diagnosis and treatment of MDR TB, strengthening of the civil society involvement in TB control, improving management of TB/HIV, professional and general public education and information. CDC provide technical assistance to the program in such areas as prevention and treatment of multi-drug resistant tuberculosis (MDR TB), improvement of infection control at TB facilities, development of treatment protocols and conduct of operational research related to various aspects of TB control, training of Russian TB professionals and capacity building of Russian TB institutions, strengthening performance of TB diagnostic laboratories.

The latest program evaluation was performed in 2002, and recommendations were incorporated in the USAID-supported program implementation. An external review of the international TB programs in Russia was also conducted in 2006. Both documents are available for review.

PATH Activities

USAID Russia has requested technical support to conduct an intermediate evaluation of USAID-supported TB control activities. The purpose of the evaluation is to:

- Assess the strengths and weaknesses of USAID's TB program and determine the progress made towards achieving USAID/Russia TB program goals and objectives, and
- Make recommendations for improvements and priorities for USAID to consider in the future.

Recommendations should include feasible adjustments to strengthen the sustainability of effective programs and/or new or innovate suggestions for addressing gaps or priorities within the Russian context. USAID/Russia anticipates consistent or slightly increased levels of funding for the next few years. The evaluation team should seek to address the key issues raised in the set of questions provided in this SOW.

The main areas of USAID Russia support for the TB control program are policy reforms; further DOTS expansion and enhancement; diagnosis and treatment of MDR-TB; strengthening civil society involvement in TB control; improving management of TB/HIV; and professional and general public education and information. The evaluation will focus on these areas, and will encompass the following topics as requested by the USAID Russia Mission:

- General observations:
 - What are the most effective aspects of the USAID-supported TB program in terms of contributions to the overall TB control efforts in Russia?
 - In what areas should USAID-supported programs be scaled up? How?
 - Are there new areas or gaps that USAID might consider given the potential for slightly more funds in the near future?
- Political commitment:
 - What developments occurred in national TB program since the previous evaluation in 2002 in terms of policies, funding level and systemic changes? What was USAID TB control program impact to those changes?
 - To what extent does the federal and local government support DOTS implementation; both nationwide and in USAID TB control program sites?
 - Are federal and local governments committed to enhance the role of NGOs and the community in TB control efforts?
 - What opportunities exist to strengthen GOR's support for international TB control efforts in Russia, including USAID TB program?
- Coordination between national authorities, international technical agencies and donors, NGOs and other stakeholders, and Global Fund to Fight AIDS, Tuberculosis, and Malaria program:
 - What mechanisms of coordination currently exist in Russia? Are they effective?
 - What is the role of USAID in the coordinating mechanisms?
 - To what extent is there cooperation between USAID-supported programs and GFATM? How it could be improved?

- Are coordination mechanisms between various agencies in USAID TB Control program sites well-established and effective? What improvements are needed?
- Is coordination between civilian and penitentiary TB services effective?
- Skills and knowledge of health personnel related to TB control:
 - Are health personnel in USAID program sites aware of the internationally recognized and WHO-recommended methods of TB control?
 - Is the international approach supported by health professionals?
 - To what extent and how well international recommendation are used? What kinds of improvements or corrections are needed? What would be the optimal way to introduce them in USAID program sites and beyond?
 - How can USAID TB programs help to facilitate the higher level of adoption of the international standards by health professionals countrywide?
 - To what extent is staff at primary care clinics addressing TB? What could be done to increase TB vigilance among staff members of PHC?
 - What operational research is needed to identify deficiencies and/or new priorities?
- Impact of training, peer monitoring and education of health professionals:
 - What are the main deficiencies in skills and knowledge of health professionals related to TB and TB/HIV? What topics and types of trainings are most needed?
 - What are some of the issues with drug management? What is the capacity for drug forecasting? What has been made by USAID TB Control program in this area and what additional actions could be planned?
 - What has been the impact of the WHO-supported monitoring site visits?
- Treatment practices, including DOT:
 - What was the role of USAID TB control program in adaptation of internationally recognized approaches to TB diagnosis/treatment?
 - What positive aspects of the USAID effort should be expanded?
 - How have USAID-supported activities contributed to treatment success rate in the program sites? What are the current trends in TB notification and mortality rates in the sites? What actions may be undertaken to accomplish better results?
 - What MDR treatment regimens are used in the program sites? Are they consistent with the international standards? (also in MDR section)
 - What could be made to ensure replication of potential positive experience from USAID program sites to other regions to improve DOTs?
- MDR-TB: epidemiology, diagnostic capacity for MDR-TB and XDR-TB, recording and reporting, treatment regimens, second-line drug availability, drug management, drug quality
 - Are TB program managers from USAID-supported sites sufficiently aware of MDR/XDR TB challenge? How they get information on the number of MDR TB cases in their provinces?
 - How USAID program influenced the improvement of MDR TB cases detection and diagnosis in the program sites as compared to other Russian provinces?
 - What was the role of USAID's TB program in the process of GLC approval of Russian provinces for DOTS Plus?
 - What are the differences in MDR TB rates in various provinces and regions? Is USAID's program covering a representative sample of regions in terms of MDR TB prevalence? What could be done to increase coverage?
 - What is the availability of drug susceptibility testing (DST) in USAID program sites and countrywide? What proportion of laboratories have DST capabilities? What can be done under USAID program to make it more effective?
 - What treatment regimens are used in the program sites? Are they consistent with the international standards?
 - Are SLDs available locally? What type of assistance has USAID provided to ensure availability of SLDs of proven quality, efficacy and safety on domestic pharmaceutical market (e.g. prequalification of domestic drugs manufacturing)?

- What might USAID do more or to improve SLDs procurement, distribution and rational use?
- What operational research is needed to identify deficiencies and/or new priorities
- Laboratory performance, quality control and assurance:
 - What progress has been made in developing and defining a quality assurance system of peripheral laboratories network? What was the role of USAID TB control program in this process?
 - How do laboratories in USAID-supported regions measure up to international quality control and assurance standards versus other regions?
 - What USAID contributions to this effort should be continued to further develop and scale up in Russia? (e.g. new regulations and SOPs, Centers of Excellence, policy dialogue under HLWG, others)
 - Should USAID contribute more to DST rapid testing and molecular technologies? Given the current economic environment, would that be sustainable? How much emphasis should USAID place in this area?
 - What additional efforts in USAID TB program sites and countrywide could be made to improve the TB laboratory network?
- TB/HIV co-infection: service coordination, epidemiology, recording and reporting, access to diagnostic and care and treatment services, availability of ART, stigma and discrimination, confidentiality:
 - What are the main issues for addressing TB and HIV co-infections and how much progress has been made in developing integrated systems or referrals? At USAID-supported sites? Which components need improvement?
 - What is the proportion of TB patients tested for HIV in USAID TB program sites and countrywide? What can be done to disseminate USAID program experience?
 - Are patients with TB/HIV co-infection stigmatized and discriminated and what correctional measures may be recommended to resolve this problem?
 - What specific activities focusing on TB/HIV patients are currently implemented in the penitentiary sector?
- Infection control knowledge and practices:
 - Is the concept of infection control (IC) known, understood and accepted by TB program managers and specialists? What is the role of USAID TB control program in introducing of IC concept in TB control practice in Russia?
 - Which regulations on IC in TB currently exist in Russia? How they were developed and what was the role of USAID program in the process?
 - Are basic IC measures implemented as appropriate at TB facilities in USAID program sites (including administrative, personal protection/working habits and ventilation)? What are the current deficiencies in IC implementation?
 - What measures could be undertaken under USAID TB Control program to disseminate the positive experience in IC more broadly?
 - What is the role of the Vladimir Center of Excellence on IC in TB? What is the long term plan for USAID support or expansion of this and other sites?
- Advocacy, communication and social mobilization (ACSM) activities, including public education and civil society mobilization for TB control:
 - What ACSM activities are currently being implemented? Which organizations are involved in ACSM activities with GOR support? With USAID support?
 - What are the priorities needing greater advocacy and policy work with federal and regional policy makers?
 - Which are the most effective communication strategies for Russia?
 - What are the priority issues for social mobilization and behavior change for the community, families and individuals?
 - What additional activities might strengthen this program component?
 - What has been the role of USAID in the strengthening the civil society institutions (e.g. NGOs, Red Cross) involvement in TB control in Russia?

- Has this been effective, if yes, how might this be scaled up?
- What should be the priority focus for NGOs, civil society? To better impact on treatment adherence/completion?
- What other types of innovative patients support programs could be introduced?

Reporting Requirements.

The final report will document all relevant findings, observations, conclusions, and recommendations for the future programming. The report should not exceed 40 pages, including executive summary. Additional information, if any, should be placed in annexes. A format of the final report should be in accordance with the following guidelines and include the following components:

- List of acronyms used
- Table of contents
- Executive Summary. Briefly describes the purpose of evaluation, presents major findings, conclusions and recommendations. Should not exceed three pages.
- Introduction. Evaluation purpose, topics and audience. Should not exceed one page.
- Background. Information about the national TB control program in Russia and relevant components of the medical care delivery system, statistical data critical for understanding and interpretation of findings and conclusions, and description of environment in which the USAID TB Control program is implemented. Should not exceed four pages.
- USAID assistance approach. Description of USAID response to the development challenge. Not to exceed one page.
- Finding and Observations. Self-explanatory. Not to exceed twenty pages.
- Conclusions and Recommendations. Self-explanatory. Not to exceed ten pages.
- List of Key Persons Met/Interviewed.

Annex III. Itinerary of the evaluation visits

October 18, Sunday

Team arrival in Moscow

October 19, Monday

Morning – briefing at USAID, discussion

Afternoon – meeting at WHO Russia

October 20, Tuesday

Morning – meeting at Central TB Research Institute (CTRI)

Afternoon – meeting at Federal Service for Sentence Execution, FSSE (Federal prison administration)

Afternoon – meeting at the International Federation of Red Cross and Red Crescent Societies (IFRC)

October 21, Wednesday

Morning – participation in HLWG meeting (F. Luelmo), meeting with the American International Health Alliance and the University Research Corporation on TB/HIV (M. Arias, O. Radzisyevska)

Afternoon – meeting at the Center for TB care of HIV infected. Departure for Belgorod (air)

October 22, Thursday

Morning - Meeting in the Department of Health and Social development of the Belgorod oblast administration. Meeting at the Belgorod Oblast TB Dispensary (BTBD). Visit to the Management and Surveillance Department and Pulmonary TB ward #1, outpatient and inpatient departments, MDR TB and surgical wards.

Afternoon – Visit laboratory of BTBD. Meeting with heads of wards and physicians of BTBD and with penitentiary system representatives. Visit to national museum.

October 23, Friday

Morning – Visit Belgorod branch of Russian Red Cross. Visit to the PHC City outpatient clinic (Policlinic) #6. Visit TB outpatient unit of Prokhorovskiy Central Rayon Hospital (rural district). Visit Zvonitsy memorial and Prokhorovka National Memorial complex

October 24, Saturday

Travel to Moscow (air)

October 25, Sunday

Night - Departure for Chuvashia (air)

October 26, Monday

Morning – Visit departments of TB Dispensary and bacteriological laboratory, discussions. Meetings with officials from the Department of Federal Service for Sentence Execution for Chuvashia

Afternoon – Visit to City (General) Hospital #1

October 27, Tuesday

Morning – Visit to Chebosksary Central Rayon Hospital.

Afternoon - Meeting with Dr N. V. Suslonove, Deputy Prime-minister and Minister of health and Social Development of the Republic of Chuvashiya, debriefing. Departure to Moscow.

October 28, Wednesday

Morning – meeting at the Research Institute of Phthisiopulmonology of the I.M. Sechenov Moscow Medical Academy (RIPP)

Afternoon - meeting at Russian Health Care Foundation (principal recipient of GFATM R4 TB grant)

October 29, Thursday

Morning - Travel to Vladimir (by car). Visit to Center of Excellence on infection control (IC) in TB; presentation of Vladimir policy and results, visit to inpatient wards of the TB dispensary.

Afternoon – Visit to general city hospital. Meeting with the Deputy head, Department of Health

October 30, Friday

Morning – Debriefing at USAID

Afternoon – Meeting at Ministry of Health and Social Development (MoHSD)

Annex IV. Key persons interviewed and institutions visited

Institution	Key persons	Position
USAID Russia	Elisabeth Kvitashvili	Deputy Mission Director, USAID/Russia (Acting Mission Director at the time of evaluation)
	Cheryl Kamin	Director, Office of Health, USAID/Russia
	Dr. Nikita Yu. Afanasiev	Senior Infectious Diseases Advisor, Office of Health, USAID/Russia
	Dr. Nina B. Khurieva	TB Program Specialist, Office of Health, USAID/Russia
	Dr. Erika Vitek	Consultant, US/CDC, Russia
	Carolyn Mohan	TB Advisor, USAID/Washington DC
World Health Organization, Russia - Moscow Office	Dr. Luigi Migliorini	WHO Special Representative in Russia, WHO Russia
	Dr. Richard Zaleskis	Regional TB Advisor, WHO Euro
	Dr. Dmitri Pashkevich	Acting Coordinator, WHO TB Control Program in Russian Federation
	Dr. Elena Yurasova	Medical Officer, WHO Russia
	Dr. Vadim Testov	Medical Officer, WHO Russia
	Dr. Evgeniy Belilovskiy	Medical Officer, WHO Russia
	Dr. Alain Disu	Technical Officer, WHO Russia
	Dr. Irina Daniliva	Medical Officer, WHO Russia
Central TB Research Institute, Russian Academy of Medical Sciences (CTRI)/WHO Collaborating Center on Tuberculosis in Russia	Prof. Vladislav V. Erokhin	Director, CTRI
	Prof. Olga V. Demikhova	Deputy Director for Science, CTRI
	Prof. Viktor V. Punga	Chief, Science Management Division, CTRI
	Prof. Larisa Chernousova	Head, Microbiology Department, CTRI
	Dr. Irina A. Vasilyeva	Head, TB Clinical Department, CTRI
Federal Service for Sentence Execution (FSSE)	Dr. Alla S. Kuznetsova	First Deputy Head, Medical Department, FSSE
	Dr. Svetlana V. Sidorova	Chief TB Specialist, Medical Department, FSSE
	Dr. Svetlana G. Safonova	Chief Bacteriologist, Medical Department, FSSE

International Federation of Red Cross and Red Crescent Societies (IFRC Russia)	Jaap Timmer	Regional Representative, IFRC, for Belarus, Moldova, Russia and Ukraine
	Dr Davron Mukhamadiev	Regional Health Coordinator, IFRC, for Belarus, Moldova, Russia and Ukraine
	Dr Yuriv Kokotov	TB Program Coordinator, IFRC, for Belarus, Moldova, Russia and Ukraine
	Tatyana Toichkina	TB Program Manager, IFRC, for Belarus, Moldova, Russia and Ukraine
	Veronica Agapova	TB Program Coordinator, Russia Red Cross
TB High Level Working Group Meeting		
American International Health Alliance (AIHA),	Dr. Inna Jurkevich	Country Director, AIHA Russia
University Research Corporation (URC) - meeting in AIHA Russia Office	Dr. Victor Boguslavsky	Country Director, URC Russia
	Dr. Olga Chernobrovkina	Director, TB/HIV project, URC Russia
TB/HIV Health Care Center (Center for TB Care in HIV-infected people), MoHSD	Dr. Olga P. Frolova	Head, TB/HIV Health Care Center , MoHSD and Head, TB/HIV Department, Research Institute of Phthisiopulmonology n.a.M.A. Sechenov, Moscow Medical Academy
Research Institute of Phthisiopulmonology, M.A. Sechenov, Moscow Medical Academy (RIPP)	Prof. Mikhail Perelman	Director RIPP, Chief TB Expert of the Russian Federation
	Prof. Batarbek M. Maliev	Deputy Director for Science, RIPP
Russian Health Care Foundation	Dmitriy Goliaev	Global Fund Project Director
Ministry of Health and Social Development of the Russian Federation	Ludmila Mihaiylova	Head, Statistical Recording and Reporting and Quality Control Division, Medical Care Organization Department, MoHSD
	Prof. Elena Skachkova	Head, Federal Center for TB Monitoring, National Monitoring Research Center
	Eugeniy Slastnykh	Head, International Cooperation in Health Division, MoHSD
	Alexander Denosov	Head of Protocol, International Cooperation
	Pavek Suslov	Consultant
Health and Social Support Department, Belgorod Oblast Administration	Aleksandr Bondarev	First Deputy Head, Health and Social Support Department, Belgorod Oblast Administration
Belgorod Oblast TB Dispensary	Dr. Aleksandr Stukalov	Chief Physician, Belgorod Oblast TB Dispensary
	Dr. Andrey Maslennikov	Deputy Chief Physician for treatment, Belgorod Oblast TB Dispensary
	Dr. Alexey Makrinov	Deputy Chief Physician for outpatient care, Oblast TB Dispensary
	Dr. Tamara Malyhina	Deputy Chief Physician for statistical-methodological activities, Oblast Dispensary
	Dr. Elena Turina	Head, Bacteriological Laboratory, Belgorod Oblast TB Dispensary
	Dr. Tatyana Afanaseyeva	Head of the policlinic, Belgorod Oblast TB Dispensary
Belgorod Oblast Department of Federal Service for Sentence Execution	Dmitryi Starodubov	Head, Medical Service, Oblast Department of Federal Service for Sentence Execution

Belgorod Branch of Russian Red Cross	Nina Ushakova	Chairlady, Belgorod Branch of Russian Red Cross
	Elena Koroleva	Medical Coordinator, Belgorod Branch of Russian Red Cross
	Tayana Ushakova	Social Support Coordinator, Belgorod Branch of Russian Red Cross
Belgorod City Outpatient Polyclinic #6	Dr. Olga Karpachova	Chief Physician, Belgorod city polyclinic #6
Belgorod Oblast HIV Center	Yuriy Bonchuk	Chief Physician, Belgorod Oblast HIV Center
Rayon hospital, Prokhorovskiy	Galeena Muzuleva	Chief OPD
	Antonina Pryadkina	Chief doctor
Chuvashia Republic TB Dispensary	Dr. Zhanna Elenkina	Chief Physician, Chuvash Republic TB Dispensary
	Dr. Lira Afanasova	Chief TB Specialist of the Chuvash Republic, Deputy Chief Physician for outpatient care
	Dr. Irina Savinova	Deputy Chief Physician for medical care, Chuvash Republic TB Dispensary
	Dr. Olga Steblovskaya	Head, Bacteriological Laboratory, Chuvash Republic TB Dispensary
Ministry of Health and Social Development of the Republic of Chuvashia	Nina V. Suslonova	Vice-prime Minister of Chuvash Republic – Minister of Health and Social Development
	Elena Barsukova	Deputy Ministry of Health and Social Development of the Chuvash Republic
	Dmitryi Medvedev	Head, Department of Organization of Medical Care, Ministry of Health and Social Development of the Chuvash Republic
Rural Central District Hospital, Morgaushskiyi district, Chuvash Republic	Dr. Vladislav Danilov	Chief Physician, Central District Hospital, Morgaushskiyi district,
	Dr. Olga Mihailova	TB Specialist, Central District Hospital, Morgaushskiyi district,
Office of general health practice, Shatmanosinskiy district, Chuvash Republic	Dr. Elvira Petrova	General practitioner, Shatmanosinskiy Office of general health
Chuvash Republic Department of Federal Service for Sentence Execution	Vyacheslav Volkov	Head, Chuvash Republic Department of Federal Service for Sentence Execution
	Oleg Chernov	Head, Medical Division,
Vladimir Oblast TB Dispensary	Dr. Grigiriy Volchenkov	Chief Physician, TB Dispensary – Oblast Chief TB Specialist
	Dr. Tatiana Kuznetsova	Deputy Chief Physician for medical care, Oblast TB Dispensary
	Dr. Olga Efimova	TB Specialist, Statistical-methodological unit, Oblast TB Dispensary
	Dr. Natalia Kaunetis	Head, Laboratory, Vladimir Oblast TB Dispensary
	Dr. Marina Volodina	Head, Pulmonary TB Treatment Department #2, Oblast TB Dispensary
Vladimir City General Hospital # 5, microscopy center	Dr. Vasiliy Tarakanov	Deputy Chief Physician for out-patient care, Vladimir City General Hospital # 5,
	Dr. Galina Chichindayeva	Head of the Laboratory, Vladimir City General Hospital # 5

Annex V. Reported incidence and treatment outcomes

TABLE 1. TB notification rate per 100 000. All new cases, including pulmonary and extra-pulmonary TB, from both civilian and prison sectors, in WHO pilot regions compared to the Russian Federation

Regions	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Vladimir	95.3	105.6	75.3	76,4	78,9	72.1	73.3	81.1	79.8	80.5
Ivanovo	73.0	97.6	78.6	65,2	61,9	52,0	58.4	61.4	53.3	56.5
Orel	71.4	81.3	77.1	67,5	59,4	61.4	59.7	59.7	58.4	57.4
Chuvashia	73.1	78.2	73.7	85,5	71,2	83,1	81.3	81.6	77.4	84.8
Russia	85.2	90.7	88.2	86.3	83.2	83,1	84.0	82.6	83.3	85.1

TABLE 2. TB notification rate per 100 000. New smear positive pulmonary cases from both civilian and prison sectors in WHO pilot regions compare to the Russian Federation

Regions	2003	2004	2005	2006	2007	2008
Vladimir	33.0	29.1	30.3	27.0	26.5	29.1
Ivanovo	25.8	23.0	22.7	25.5	21.0	21.2
Orel	31.7	30.8	32.1	32.1	26.5	25.9
Chuvashia	35.3	38.4	42.8	38.7	38.3	40.2
Russia	20.1	21.6	24.1	23.2	23.8	23.9

TABLE 4. Treatment outcomes: new smear positive cases in WHO regions and Russia (civilian sector) cohort 2005-2007

	Success rate (%)			Failure (%)			Died (%)			Defaulted (%)			Transferred out (%)		
	2005	2006	2007	2005	2006	2007	2005	2006	2007	2005	2006	2007	2005	2006	2007
Orel	81.2	75.7	81.5	6.9	9.4	10.7	10.2	10.6	7.3	1.2	3.9	0.5	0.5	0.4	0
Ivanovo	70.9	70.8	74.1	12.8	13.6	10.2	11.5	10.5	9.8	2.6	3.5	4.2	2.1	1.6	1.9
Vladimir	66.4	69.2	69.8	13.2	9.5	9.2	12.4	13.4	10.8	7.2	5.6	5.1	0.8	2.3	5.1
Chuvashia	69.7	63.4	66.0	17.5	18.0	19.9	6.1	10.6	8.2	5.1	6.5	4.8	1.6	1.5	1.1
Russia	57.2	58.2	57.8	14.4	14.5	15.5	13.5	13.1	12.7	11.0	10.1	10.0	3.8	4.1	4.0

Table 5. Treatment outcomes: Relapses and other retreatment cases in WHO regions and Russia (civilian sector) cohort 2007

	Success rate (%)		Failure (%)		Died (%)		Defaulted (%)		Transferred out (%)	
	Relapses	Other retreatment	Relapses	Other retreatment	Relapses	Other retreatment	Relapses	Other retreatment	Relapses	Other retreatment
Orel	64.0	67.6	28.0	24.3	4.0	5.4	4.0	2.7	0	0
Ivanovo	53.2	35.7	25.5	35.7	10.7	9.5	8.5	9.5	2.1	9.5
Vladimir	36.4	38.5	31.8	28.8	11.4	13.4	15.9	13.5	4.5	5.8
Chuvashia	34.5	33.3	45.3	34.8	8.4	10.2	11.8	20.3	0	1.4
Russia	45.8	31.0	25.0	27.3	12.6	16.1	13.7	19.5	3.0	6.1

Table 6. Tuberculosis reported incidence data. Sites supported by USAID through WHO and IFRC and Russian Federation, 2008

SITE	Pop. in 1000s ¹⁶	USAID financial support		TB notification ¹⁷		All cases 2008 ¹⁸		#/rate PTB cases 2008 ¹⁹		New PTB cases cohort 2008 ²⁰					
		Through	Start date	Number	Per 100 000	No.	Per 100 000	New plus relapse cases S+ or C+ ²¹	New cases smear or C+ ²²	No. in cohort	Smear positive		Culture positive		Not confirmed diagnosis (%)
											No.	%	No.	%	
Orel	822	WHO	1999	472	57.4	808	98.3	336 / 40.9	307 /37.3	368	196	53.3	297	80.7	61 (31%)
Vladimir	1449	WHO	2000	1167	80.5	1966	135.6	543 / 37.5	480 /33.2	831	389	46.8	426	51.3	351 (42%)
Pskov	705	IFRC	2002	669	94.9	1276	180.9	429 / 60.8	382 /54.2	531	234	44.1	370	69.7	149 (28%)
Belgorod	1519	IFRC	2002	960	63.2	1298	85.4	554 / 36.5	461 /30.3	798	279	35.0	442	55.4	337 (42%)
Chuvashia	1283	WHO	2002	1087	84.8	1709	133.2	772 / 60,2	671 /52.3	897	474	52.8	628	70.0	226 (25%)
Khakasia	537	IFRC	2002	605	112.6	1676	312.0	355 / 66.1	299 /55.6	522	184	35.2	292	55.9	223 (43%)
Adygea	441	IFRC	2006	375	85.0	718	162.7	244 / 55.3	154 /34.9	316	119	37.7	151	47.8	162 (51%)
Jewish Aut. O	186	IFRC	2007	352	189.7	746	402.1	200 / 107.8	166 /89.5	336	85	25.3	142	42.3	200 (60%)
Khabarovsk	1404	IFRC	2005	1947	138.7	3218	229.2	852 / 60.7	721 /51.4	1512	530	35.1	562	37.2	791 (52%)
Total Russia	142009			120835	85.1	270544	190.5	52115 / 36.7	47690 /33.6	91805	30328	33.0	37573	40.9	47115(51%)

¹⁶ Population – from national reporting form #4

¹⁷ National new TB cases report #8

¹⁸ National all TB cases report registered in MoH&SD facilities, #33

¹⁹ Cohort reporting form #7-TB for MoH&SD facilities, pulmonary TB cases (civilian sector)

²⁰ Reporting form #7-TB and #8-TB from MoH&SD facilities (civilian sector)

²¹ Both new TB cases and relapses sputum smear + or/and culture+

²² New TB cases sputum smear+ or/and culture+

Table 6. Tuberculosis TB treatment outcome data. Sites supported by USAID through WHO and IFRC and Russian Federation, 2008

Site	Outcomes 2007 ²³ , New smear positive PTB cases					Outcomes 2007, ²⁴ All new PTB cases				
	Success (%)	Failed (%)	Default (%)	Died (%)	Transferred out (%)	Success (%)	Failed (%)	Default (%)	Died (%)	Transferred out (%)
Orel	81.5	10.7	0.5	7.3	0	87.1	7.3	0.5	4.7	0.3
Vladimir	70.0	9.2	5.1	10.8	5.1	79.3	5.3	3.7	6.0	5.5
Pskov	55.1	17.4	9.7	15.4	1.4	70.1	10.6	8.7	9.1	1.5
Belgorod	78.3	7.2	3.2	9.4	1.8	84.7	4.7	1.9	6.1	2.6
Chuvasia	66.1	19.8	4.8	8.1	1.1	74.9	12.7	5.0	6.4	1.0
Khakasia	55.0	24.9	8.5	10.5	1.1	65.8	17.6	7.4	7.2	1.9
Adygea	54.7	18.9	7.4	9.5	7.4	59.4	15.9	9.2	8.1	7.5
Jewish Aut. Oblast	44.3	28.9	13.4	10.3	3.1	64.7	15.6	9.7	7.6	2.4
Khabarovsk	42	12.3	27.2	17.0	1.4	60.7	6.8	21.6	9.0	1.9
Total Russia	57.8	15.5	10.0	12.7	4.0	68.8	10.2	9.1	7.7	4.1

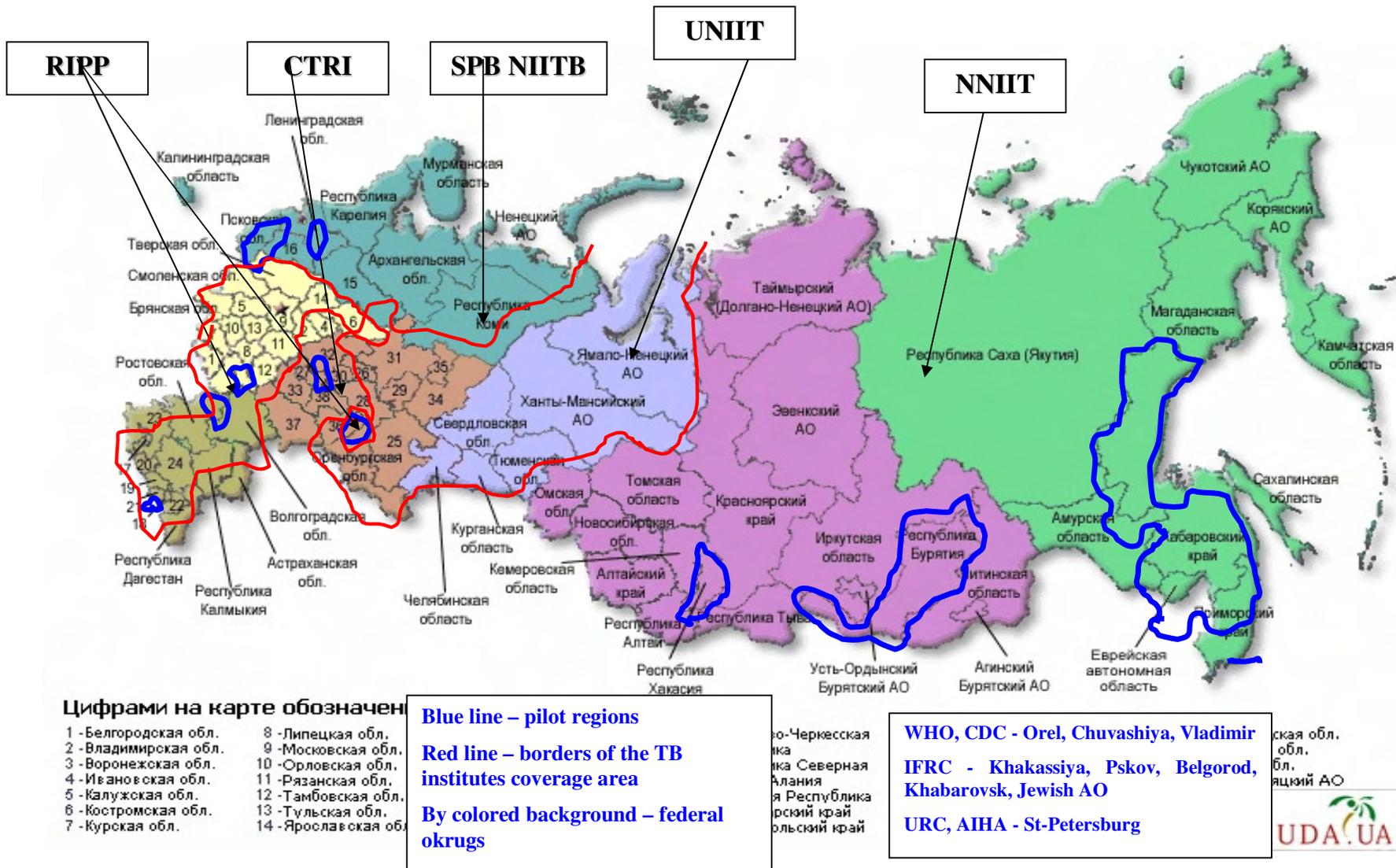
²³ Reporting form #8-TB from MoH&SD facilities (civilian sector)

²⁴ Reporting form #8-TB from MoH&SD facilities (civilian sector)

Annex VI. Russian Federation oblasts with population >800 000 and density >25 000 per km²

	Region	Population	Density per sq. km		Region	Population	Density per sq. km
1	Moscow Oblast	6629703	141057	19	Vladimir Oblast	1487219	51283
2	Krasnodar Krai	5100250	67108	20	Penza Oblast	1422736	32933
3	Sverdlov Oblast	4428229	22732	21	Ulianov Oblast	1350713	36212
4	Rostov Oblast	4334353	42999	22	Bryansk Oblast	1346548	38583
5	Bashkortostan Republic	4078807	28403	23	Yaroslavl Oblast	1338736	36778
6	Tatarstan Republic	3768515	55419	24	Chuvashia Republic	1299306	71000
7	Chelyabinsk Oblast	3551424	40403	25	Kursk Oblast	1199123	40239
8	Nizhniy Novgorod Oblast	3445341	44802	26	Ryazan Oblast	1194753	30170
9	Samara Oblast	3201272	59725	27	Lipezk Oblast	1189889	49372
10	Kemerovo Oblast	2855043	29895	28	Tambov Oblast	1144817	33376
11	Stavropol Krai	2717955	40871	29	Chechnya Republic	1141362	72698
12	Volgograd Oblast	2655180	23311	30	Ivanovo Oblast	1114925	51143
13	Saratov Oblast	2625728	26204	31	Kaluga Oblast	1021503	34163
14	Dagestan Republic	2621820	52123	32	Smolensk Oblast	1019040	20462
15	Voronezh Oblast	2334049	44542	33	Astrakhan Oblast	998225	22635
16	Tula Oblast	1621908	63109	34	Kaliningrad Oblast	944979	62581
17	Udmurtia Republic	1552759	36882	35	Kabardino-Balkaria Republic	896938	71755
18	Belgorod Oblast	1511603	55778	36	Mordovia Republic	866631	33077

ANNEX VII. COVERAGE OF SUPPORT TO REGIONS BY IMPLEMENTING PARTNERS AND RESEARCH INSTITUTES



Annex VII. References

	Document	Organization	Date
1	Global tuberculosis control: Epidemiology, strategy, financing	World Health Organization (WHO) 2009	
2	Tuberculosis in the Russian Federation, 2007. An analytical review of the main tuberculosis statistical indicators used in the Russian Federation. Edited by M.I. Perelman and Y.V. Mikhailov		2008
3	Europe and Eurasia Regional Tuberculosis Evaluation	USAID	June 16 - July 3, 2002
4	Grant No. 118-G-00-99-00112-08 TB Control	World Health Organization (WHO)	Jan.1 2009 - Sep. 30,2010
5	WHO TB Control Programme in the Russian Federation 1999-2009	USAID	19-Oct-09
6	Progress Report to the USAID From the Stop TB department of the WHO on the advanced development of the Tuberculosis control project in the Russian Federation	WHO	December 2008 - May 2009
7	Semi-Annual Report 14: Comprehensive Model of Tuberculosis Control in the Regions of the Russian Federation	International Federation of Red Cross and Red Crescent Societies, USAID	September, 2008
8	Decentralization of HIV care and integrating Tuberculosis (TB) screening of HIV patients into the general health care system in St. Petersburg, Russian Federation	USAID	July, 2009
9	Improving Tuberculosis (TB) Control in the Russian Federation (RF): Russia/Europ/Europ Project Report	Centers for Disease Control (CDC)	27-Apr-09
10	Semi-Annual Report 15: Comprehensive Model of Tuberculosis Control in the Regions of the Russian Federation	International Federation of Red Cross and Red Crescent Societies, USAID	October 2008- March 2009
11	External review of the internationally supported TB control projects Russian Federation	WHO, Open Health Institute	July 2- 13, 2006
12	Welcome to TB Control Programme PowerPoint Presentation	USAID	September, 2009
13	Order # 50: On consummation of registration and reporting documentation for tuberculosis monitoring	Ministry of Health of the Russian Federation	13-Feb-04
14	Document # 4: Statute: High level working group (HLWG) on TB in the Russian Federation Draft	High Level Working Group on TB in the Russian Federation	November, 2005
15	Federal Law #77 of the Russian Federation: Federal Law on Preventing Tuberculosis Dissemination in the Russian Federation	Russian Federation	18-Jun-01
16	Order # 109: On the improvement of tuberculosis control activities in the Russian Federation	Ministry of Health of the Russian Federation	21-Mar-03