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SITUATIONAL ANALYSIS OF TB-HIV CO-INFECTION IN RUSSIA AND FOUR QAP PROJECT REGIONS: SAMARA, SARATOV, ORENBURG, AND ST. PETERSBURG

QUALITY
ASSURANCE
PROJECT

TECHNICAL
REPORT

JULY 2005

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DISCLAIMER

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TABLE OF CONTENTS

I. INTRODUCTION	1
II. TB AND THE HIV/AIDS EPIDEMIC	1
A. TB EPIDEMIC	2
B. TB-HIV CO-INFECTION	2
III. MAJOR FEDERAL REGULATIONS AND EFFORTS REGARDING CARE DELIVERY	3
IV. MAJOR INTERNATIONAL DONOR EFFORTS IN THE FIELD OF TB-HIV	5
A. WHO	5
1. High Level Working Group	5
2. WHO TB Control Program	5
B. OPEN HEALTH INSTITUTE CONSORTIUM	5
C. WORLD BANK	6
D. THE GLOBAL FUND	6
E. OHI AND PARTNERS IN HEALTH	7
V. QAP ASSESSMENT RESULTS	8
A. EXISTING HEALTHCARE DELIVERY SYSTEM FOR TB AND HIV/AIDS PATIENTS	8
1. TB Services	8
2. HIV/AIDS Services	8
B. EPIDEMIOLOGICAL PICTURE AND CURRENT CLINICAL PRACTICES	10
1. Samara	10
2. Saratov	10
3. Orenburg	10
4. St. Petersburg	11
C. PATIENT ADHERENCE	11
D. AVAILABILITY OF MICROSCOPY	12
E. PROVIDER KNOWLEDGE AND SKILLS AND QUALITY ASSURANCE MECHANISMS	12
F. AVAILABILITY OF DRUGS	12
G. PATIENT RECORDS AND INFORMATION PROCESSING TO DETERMINE PROGRAM EFFECTIVENESS	13
VI. CONCLUSIONS	13
VII. OBJECTIVES FOR IMPROVEMENT ACTIVITIES	14
REFERENCES	15
ATTACHMENT I	16
ATTACHMENT II	18

LIST OF TABLES AND BOX

Table 1: Distribution of HIV Cases by Year	2
Table 2: Care Delivery for TB and HIV/AIDS Patients	9
Table 3: Co-Infection Prevalence in the Four Project Regions and Russian Federation, 2004	10
Box 1: Regulatory Framework for TB-HIV Co-infection	4

LIST OF ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CDC	U.S. Centers for Disease Control and Prevention
CSW	Commercial Sex Workers
DOTS	Directly Observed Treatment, Short Course
HIV	Human Immunodeficiency Virus
IDU	Injecting Drug User
IEC	Information, Education and Communication
MOH	Ministry of Health
MOHSD	Ministry of Health and Social Development
MSM	Men who have sex with men
NGO	Nongovernmental Organization
OHI	Open Health Institute
PLWHA	People Living with HIV/AIDS
QAP	Quality Assurance Project
SES	Sanitary Epidemiological Service
TB	Tuberculosis
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Several international and domestic efforts have been made in Russia over the last decade to control its dual epidemics of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) and tuberculosis (TB). Some success has been achieved in a number of regions, but much more needs to be done. The World Health Organization has targeted a third of the country to be covered by Directly Observed Treatment by 2005. Resource constraints remain a challenge, however, and dictate more concerted and targeted efforts. The United States Agency for International Development (USAID) plans to contribute to achieving the target and anticipates that internationally recognized approaches to TB treatment and HIV/AIDS prevention will be fully accepted in Russia by the end of 2005.

USAID's Quality Assurance Project (QAP) began working with health authorities in four Russian regions (Samara, Saratov, Orenburg, and St. Petersburg) in March 2004 to design a model system of treatment, care, and support for patients with HIV/AIDS. Over the next two years, the QAP team will work closely with various healthcare organizations and other essential stakeholders in these regions. In addition to benefiting people with HIV/AIDS, tackling TB-HIV co-infection presents an opportunity to significantly improve care for TB patients.

The Quality Improvement Collaborative method, which QAP brought to Russia in 1998, has proved especially suitable for problems, such as HIV/AIDS and TB, that require an interdisciplinary solution. To initiate the TB-HIV co-infection work, QAP conducted a situational analysis to review the TB-HIV co-infection prevalence in Russian, especially focusing on four regions selected by USAID/Moscow. The analysis identified existing TB and HIV/AIDS system practices and coordination mechanisms and opportunities and strategies for addressing TB-HIV co-infection piloted through the USAID-funded HIV/AIDS project.

The results of the analysis showed that:

- The number of TB patients with HIV is currently small but growing rapidly;
- Very few TB patients with HIV receive antiretroviral treatment, because of a lack of drugs;
- While the majority of TB patients are tested for HIV, TB case finding among HIV-positives is weak;
- The care of TB patients with HIV lacks coordination with AIDS centers and primary care institutions, especially in ambulatory settings;
- Infectious disease specialists at AIDS centers have not received guidance on administering TB-preventive treatment for HIV-positives, so treatment is not given;
- HIV-positives are mainly drug addicts who have low awareness of the risk for tuberculosis development, rendering them unlikely to seek TB testing;
- Many TB patients with HIV are hard to reach for hospitalization or to keep in the hospital, often as a result of lifestyle-related difficulties;
- Social protection services have little appreciation of the issue and are largely uninvolved in the process of support;
- Few if any community-based organizations exist to support patients with TB; and
- Evidence on patient adherence to TB treatment regimens is lacking.

To address the needs of patients co-infected with HIV and TB, QAP will assist the federal and local health departments in developing appropriate tools to enhance coordination between different health agencies as well as increase compliance with federal and international treatment guidelines. QAP will assist the departments of health in the four project areas to use the collaborative improvement methodology to develop and implement a continuum of care model for people co-infected with TB-HIV.

I. INTRODUCTION

Numerous international and domestic efforts in Russia over the last decade to control the Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) and tuberculosis (TB) epidemics have demonstrated success, but more effort is necessary, as this report details. The World Health Organization (WHO) is leading an effort to cover a third of the country by Directly Observed Treatment, Short Course by 2005. Resource constraints dictate more concerted and targeted efforts than have been attempted previously. The United States Agency for International Development (USAID) seeks to support efforts to reach the goal and anticipates that by the end of 2005, internationally recognized approaches to TB treatment and HIV/AIDS prevention will be fully accepted in the country, based on their demonstrable impact in targeted regions of the country (USAID 2002).

The unprecedented scale of the HIV and TB epidemic in Russia demands effective and urgent action. HIV-TB co-infection needs more attention and represents a challenge: There is an increasing recognition that TB is a leading cause of HIV-related morbidity and of the extent to which HIV is fuelling tuberculosis in high HIV prevalence populations. The risk of TB development in HIV-infected patients is 10 times greater than in patients without HIV. At the same time, the presence of *M.tuberculosis* in HIV-infected patients creates more rapid replication of HIV that accelerates the progression of non-symptomatic HIV infection to AIDS (WHO 1997). This overlap justifies a strengthened, unified strategy to control TB among people living with HIV/AIDS (PLWHA) as an integral part of the HIV/AIDS strategy. In sum, tackling TB must include tackling HIV, the most potent force driving the TB epidemic, and tackling HIV must include tackling TB, a leading cause of death among PLWHA (WHO 2002).

In March 2004, QAP began work with health authorities in four Russian regions (Samara, Saratov, Orenburg, and St. Petersburg) for the purpose of designing a model system of treatment, care, and support for patients with HIV/AIDS. This activity represents a unique opportunity to strengthen the healthcare system capacities with regard to TB-HIV co-infection and to develop and implement a functional integration of TB and HIV services. To initiate this work, QAP conducted a situational analysis in the selected regions that focused on the following objectives:

1. Review the TB-HIV co-infection prevalence in Russia and the regions selected by USAID/Moscow for QAP work;
2. Identify the existing federal and regional regulatory frameworks that identify coordination between TB and HIV/AIDS services;
3. Identify existing TB and HIV/AIDS system practices in each region and mechanisms of coordination between TB and HIV services with regard to co-infection; and
4. Identify opportunities and strategies for addressing TB-HIV co-infection that can be put in place through the project.

II. TB AND THE HIV/AIDS EPIDEMIC

The HIV/AIDS epidemic in Russia is the fastest growing in the world (UNAIDS 2004). Since 1996–97, the incidence of HIV infection increased 33-fold, reaching 308,817 of HIV-positive and 1,234 AIDS cases by December 2004; 6,016 of the HIV-positives have died, 885 from AIDS (Ladnaya, Pokrovsky, and Sokolova 2004). A sharp increase in HIV detection was noticed in 2000 and corresponds to the massive utilization of intravenous drugs. In the majority of the regions, 90% of the epidemic increase is due to expanding intravenous drug use (MOH 2003). The distribution of new HIV cases by region and year is presented in Table 1.

Table 1: Distribution of HIV Cases by Year

Region	1999	2000	2001	2002	2003
Samara	31	4655	7876	4067	2970
Saratov	363	1495	1986	885	602
Orenburg	63	3562	3921	2375	1659
St.Petersburg	304	4235	9193	5077	3353
Russia Federation	19,991	59,275	88,577	52,349	39,699

According to Dr. Natalia Ladnaya, Researcher at the Department of Epidemiology of the Russian Federal AIDS Center, the main populations at risk are:

- Sex partners of injecting drug users (IDUs): 9 million
- Men who have sex with men (MSM): 2.7 million
- Clients of commercial sex workers: 1.3–2.5 million
- Injecting drug users: 0.5–3.5 million
- Commercial sex workers (CSW): 500,000–700,000

While the figures on HIV positives in Russia are based on the records of cases by regional AIDS centers, many experts agree that the real number of HIV-infected people might be much higher; estimates range from 1 to 1.5 million (UNAIDS 2004).

A. TB Epidemic

The incidence of tuberculosis continues to increase simultaneously with HIV incidence in the country. The reported TB cases have doubled over the past 10 years. The estimated incidence by 2003 was 83.2 cases per 100,000 population; 86% of cases are pulmonary. The incidence in children is 16 cases per 100,000 population. Mortality from TB remains high—21.9/100,000 population—and seems to be increasing. The most affected populations are females 18–29 years of age, and males 25–39 years of age (Punga 2004). The number of primary multi-drug resistant TB cases remains high and in 2003 was reported as 3,438 cases. The prison population has been hit much harder: 1,652 TB cases per 100,000 prisoners were recorded by end of 2004 (Kuznetsova 2004). According to a Russian Ministry of Justice estimate, the rate is below one in 10 Russian prisoners.

Treatment effectiveness is measured by two major indicators: percentage of negative smears and percentage of closed lung cavities. In 2003, these indicators were 73 and 64, respectively.

B. TB-HIV Co-infection

According to the Ministry of Health and Social Development (MOHSD) TB Healthcare Delivery Center for HIV-Infected Patients, TB had been diagnosed in 7,679 HIV-infected patients as of August 2004. The number of HIV-infected patients with TB is growing continuously. For instance, in Kalinigrad Oblast, this number almost doubled in 2003 compared to 2001 (89 cases versus 48) (Frolova 2004). Over 80% of these cases of TB co-infection were detected at early stages of HIV. The patients are mainly intravenous drug users (89%) and/or the homeless (68%). An analysis of patients who died of AIDS revealed that 53% had tuberculosis. According to Dr. Kuznetsova, Deputy Director of Medical Department of the Ministry of Justice, HIV-positive prisoners represent 11% of the total number of HIV-infected persons registered in Russia, and 2.9% of them have TB-HIV co-infection. If they are not adequately treated now,

the future prognosis is unfavorable. The largest number of HIV cases in Russia (over 70,000) was diagnosed during 2001. Given the average “lag” of six to seven years following the HIV epidemic, a sharp increase in TB incidence should be expected by 2008–09 (Frolova personal communication). WHO predicts that a third of the HIV-positives will develop TB during their lifetime and gives several reasons for this (WHO 2002):

- HIV increases the risk of *M.tuberculosis* infection,
- HIV promotes progression to active tuberculosis in people with recently acquired and with latent *M.tuberculosis* infection,
- Increasing tuberculosis cases in people living with HIV poses an increased risk of tuberculosis transmission to the general public, and
- HIV increases the risk of recurrent tuberculosis.

III. MAJOR FEDERAL REGULATIONS AND EFFORTS REGARDING CARE DELIVERY

Key milestones in the development of federal regulations affecting TB-HIV co-infection are summarized in Box 1. In 2002, the Federal TB Healthcare Delivery Center for HIV-Infected Patients was established under the Ministry of Health. A number of activities in this field are already underway. First, Russian and international specialists in the Thematic Working Group of the WHO/Russia High Level Working Group on TB prepared recommendations for management of TB in HIV infected patients: Those recommendations have been made available in “TB in HIV infected.”

This group recommended creation of the position of TB-HIV care coordinator. While the location, qualifications, and scope of work are yet to be determined, the coordinator is expected to be responsible for coordinating care to the TB-HIV patients and keeping patient records. During August–September 2004, the TB Healthcare Delivery Center for HIV-Infected Patients sponsored by the WHO/Russia TB Program initiated three-day training seminars for the regional TB specialists who will be responsible potentially for treatment coordination of TB patients with HIV. Seminars took place on the following dates:

- *August 24-27, 2004*: for representatives from North-Western and Central Regions of Russia (includes St. Petersburg)
- *August 31–September 3, 2004*: for representatives from Southern, Volga and Ural Regions of Russia (includes Samara, Saratov and Orenburg);
- *September 14-17, 2004*: for representatives from Siberia and the far east regions.

Training curricula focused on TB detection, TB treatment and prophylaxis in HIV-infected, coordination between TB and HIV/AIDS services, and other issues related to TB in HIV-infected patients.

On December 14–15, 2004, a National TB-HIV Workshop was held in Moscow with support of WHO, the Russian Ministry of Health and Social Development, the Federal AIDS Center and the Federal Center of TB Care for HIV-Infected Patients. The purpose of the workshop was to analyze the situation with TB, HIV/AIDS, and TB-HIV; discuss appropriateness of TB-HIV collaborative interventions and of mechanisms of coordination between the TB and the HIV/AIDS national programs; and review recent initiatives on TB-HIV in the Russian Federation. The workshop resulted in the development of recommendations on TB-HIV collaborative interventions in Russia and in drafting a joint plan for TB-HIV control interventions.

Box 1: Regulatory Framework for TB-HIV Co-infection

1995: The federal law “On prevention of HIV infection in the Russian Federation,” was adopted, assuring free medical care, confidentiality of information, and social support to HIV patients as well as setting out voluntary principles of HIV testing for all citizens of the Russian Federation, with the exclusion of donors of blood, other physiological fluids, and organs, as well as certain categories of medical workers.

1995: The MOHSD Order (termed “prikaz”) #295 was issued on October 30 and regulates the list of indications for HIV testing in an aim to improve HIV infection diagnostics. In accordance with the Order, healthcare workers are required to recommend HIV and TB testing for selected groups in the population at risk for infections.

1996: The Federal Target HIV Prevention Program was developed.

2002: The Federal Target Program “Prevention and Control of Socially Afflicted Diseases in the Russian Federation” was established and combined the HIV Prevention Program and “Urgent Measures on Combating TB in the Russian Federation.”

2003: The MOH Order #109 “On improving TB treatment in the Russian Federation” issued on March 21. The order regulates standard TB treatment regimens, including HIV patients who should be treated for TB. The text of the Order is in Attachment I.

2003: The MOH Order #547, issued on November 13, instituted the reporting form #263/y-TB. The Order is a major document that currently regulates the recording of TB cases diagnosed among the HIV-positives.

Three working groups were created with the following areas of responsibility:

- *Group 1:* Creation of collaboration mechanisms for organization and provision of TB care for HIV-positives.
- *Group 2:* Implementation of TB-HIV control activities at regional and municipal levels. Creation of models of collaboration in the fields of TB and HIV prevention.
- *Group 3:* Implementation of activities necessary to improve TB-HIV recording and reporting forms.

The working groups made the following recommendations:

- Establish TB and HIV/AIDS care-coordinating mechanisms at federal and regional levels;
- Train healthcare providers and relevant nongovernmental organizations (NGOs) on intensified TB-case finding;
- Improve voluntary counseling and testing for HIV;
- Implement TB preventive treatment among HIV-positives;
- Establish a care coordinator specialist in the regions to be responsible for TB treatment in HIV-infected patients;
- Establish a monitoring system for TB patients with HIV in accordance with the recording form #263/y-TB (see Box 1);
- Develop innovative approaches for community-based organizations, patients’ relatives, and volunteers in providing TB patients with the necessary support;
- Create a social rehabilitation system for TB patients with HIV; and
- Set up a system of TB education and prevention among HIV-positive individuals and in the general population.

While more fine-tuning work is to be done at service delivery sites, the meeting set a baseline for communication between providers of TB and HIV/AIDS services and decision-makers at federal and regional levels.

IV. MAJOR INTERNATIONAL DONOR EFFORTS IN THE FIELD OF TB-HIV

A. WHO

1. High Level Working Group

A High Level Working Group on TB was set up in August 1999 at the initiative of the WHO and Russia's Ministry of Health for the purpose of establishing a mechanism for effective dialogue between Russian and international experts on TB control. Urgent measures to prevent and control TB in individuals with HIV had to be taken in response to unfavorable estimates of the spread of TB in HIV-infected populations. To develop such measures, a Thematic Working Group on TB in HIV-infected individuals has been created within the framework of the High Level Group. The group includes Russia's leading experts in TB and HIV control as well as representatives of the WHO. One of the main tasks of the Thematic Working Group is to set up a national system of TB management in HIV-infected patients.

2. WHO TB Control Program

The main activities of the WHO TB Control Program are:

- Collaboration with the Government and technical assistance in national TB control policy revision and development (i.e., the work of the High Level Working Group),
- Assistance in coordination of international partners and mobilization of resources,
- Implementation of pilot demonstration projects (7 projects in 19 regions),
- The TB control cost-effectiveness project,
- Maintenance and development of a TB library, and
- Development of training and health education materials and advocacy.

WHO/Russia is in the process of preparing the proposal for TB-HIV control projects in Kalinigrad Oblast, which will be the first project to pilot the TB-HIV control recommendations. At the same time, WHO/Russia is considering involving their five TB DOTS implementation sites (Orel, Ivanovo, Vladimir, Pskov, and Chuvashia) into this work. WHO/Russia welcomes the QAP initiative to address the TB-HIV co-infection and has proposed close coordination and collaboration in the area.

B. Open Health Institute Consortium

On October 2003, a consortium of five NGOs, led by the Open Health Institute (OHI) and including the AIDS Foundation East-West, AIDS Infoshare, Focus Media, and Population Services International, was awarded a US\$ 88 million grant by the Global Fund to address four major objectives:

1. Support prevention programs to reduce the transmission of HIV/AIDS among youth and the general population;
2. Support prevention programs to reduce the transmission of HIV/AIDS among vulnerable groups;
3. Advocate improvement in the national health infrastructure and building capacity to reduce the impact of HIV/AIDS on infected, affected and vulnerable people; and

4. Provide treatment, care, health promotion and social support to PLWHA,

Anticipated activities under the latter objective include:

- Providing equitable access to treatment for PLWHA;
- Building capacity for palliative and hospice care for people with HIV/AIDS;
- Social and psychological support for PLWHA;
- Creating and supporting local and national networks of PLWHA and information centers;
- Prevention of mother-to-child-transmission of HIV and providing treatment, care, and support to parents and/or their children who are living with HIV/AIDS; and
- Promoting human rights, solidarity, and tolerance towards PLWHA among the general population.

Of 10 regions initially selected, eight were the final grant recipients: the four oblasts of Krasnoyarski Krai, Nizhegorodskaya, Orenburgskaya, Tverskaya, and Tomskaya; two republics, Buryatia and Tatarstan; and the City of St. Petersburg. The program officially began on August 15, 2004.

C. World Bank

A long-term \$150 million loan to tackle tuberculosis and HIV/AIDS in Russia was approved by the World Bank on April 3, 2003. This loan supports the Federal Targeted Program of “Prevention and Control of Communicable Socially Afflicted Diseases 2002–06.” The major components are:

- *Tuberculosis control* will support the implementation of new policies, strategies, and protocols that were developed by Russian officials in agreement with World Health Organization (WHO) and the Bank. It will improve surveillance, monitoring, quality control, and quality assurance; strengthen case detection, and improve case management.
- *HIV/AIDS control* will improve policies and strategies, support public information campaigns, strengthen surveillance and monitoring, improve laboratory service to ensure that the use of antiretroviral (ARV) drugs can be properly monitored, enhance blood safety, and support the earliest stages of work on HIV vaccines in Russia. Crucially, the project will deliver preventive interventions to those at high risk of being infected, taking into account findings from serological and behavioral surveillance (studies of patterns of infection and behaviors related to the spread of HIV).
- *Project management, monitoring, and evaluation* will support operations of the project implementation unit, monitoring and evaluation, training for staff of the implementation unit, and project audits.

Over 80 administrative regions of the Russian Federation will benefit from the loan. At present, the needs assessment has been completed. Negotiations with the regions to finalize the assistance efforts will take place August–September 2005. In addition to training and materials, the loan will also support procurement of laboratory equipment and anti-TB drugs. Implementation of the loan is managed by the Russian Health Care Foundation.

D. The Global Fund

Negotiations with The Global Fund to Fight AIDS, Tuberculosis and Malaria have resulted in the awarding of a \$120.5 million grant in June 2005. The primary recipient is the Russian Health Care Foundation, a nongovernmental organization established by the Government of Russia. The goal of the grant is to reduce HIV-related morbidity and mortality by expanding access to HIV prevention, treatment, care, and support for PLWHA with a specific focus on the most at-risk populations. Initially, the project will start in seven regions and by the end of the second year will expand to 14: 75,000 people with HIV/AIDS will be able to receive antiretroviral therapy (ART) by the fifth year of the project.

E. OHI and Partners in Health

OHI and Partners in Health support a project, “On improving collaboration of regional health services to control HIV/TB in high risk groups.” The project provides financial and technical support to TB-HIV pilots based on harm reduction projects in Tomsk, Krasnoyarsk, Tver, Kazan, and St. Petersburg and aims to develop a model for TB-HIV control in high-risk populations. The assessment of the situation was based on interviewing 100–300 active intravenous drug users (IDUs) in each of five cities. The assessment’s key findings were (Bobrik 2004):

- More than 50% of IDUs have a history of incarceration;
- 4–6% of IDUs have a history of TB and about half of them did not complete the full course of treatment;
- In 2003, 70–80% of harm reduction clients were tested for HIV, but more than 50% of IDUs were not tested for TB;
- 95.2% of respondents agreed to be tested for TB. They were also ready to be treated, if diagnosed with TB;
- According to the TB service, just 15–20% of registered PLWHA were tested for TB in the past year;
- Based on sputum microscopy and X-ray in 50–200 IDUs in each city, 2.5–5% were diagnosed with TB compared to 0.08–0.1% in the general population;
- HIV prevalence among IDUs in those cities is 1–20%;
- There is a lack of efforts on the part of the TB service to motivate TB-infected IDUs to seek treatment; and
- Interaction of health services in control of HIV and TB among IDUs is rather fragmented and inconsistent.

The project has produced the following preliminary results:

- Information exchange between the TB and AIDS services has intensified;
- Work via harm reduction sites has encouraged cooperation of IDUs and their preparedness to be tested for TB and HIV; and
- There are early signs of improved treatment adherence among problematic patients:
 - In Kazan 10 IDUs who previously interrupted TB therapy were identified, and two were persuaded to resume treatment; and
 - Out of 15 IDUs treated in the TB hospital since July 2004, only one interrupted the course (formerly 75% of IDUs were not able to stay in the hospital for 4 months).
- Key elements of effective work with IDUs were identified:
 - Reducing the number of barriers to health services,
 - Simplified schemes of referrals,
 - Moving the health services nearer to the target group,
 - Free and anonymous testing, and
 - Entrusted and designated physician.
- Controlled administration of TB drugs to IDUs is possible at low-threshold sites (e.g., harm reduction sites); and
- Treatment and chemoprophylaxis of TB in HIV-infected patients can be the first step to develop and ensure adherence to ART.

V. QAP ASSESSMENT RESULTS

A. Existing Healthcare Delivery System for TB and HIV/AIDS Patients

1. TB Services

Russian doctors, scientists, and decision-makers adhere to traditional methods of diagnosing and treating tuberculosis. These practices are based on passive case identification (through presenting clinical symptoms, X-ray, and subsequent bacteriological confirmation), active case finding among household contacts, and regular screening of groups considered to be at risk (e.g., prisoners, teachers, and health-care workers). Treatment is focused on in-patient services that are administered in TB hospitals for up to six months. Once discharged, the patient is followed by a local TB dispensary until the diagnosis is closed. Such practices are not an effective intervention for coping with the TB epidemic.

Health officials need to be presented with strong evidence about the effectiveness of modern treatment in order to improve TB program planning, financing, and management. Public awareness of tuberculosis and related issues, for example, is still low. In 1998, USAID's tuberculosis treatment and control program introduced the World Health Organization's internationally recognized methods¹ and worked with health, social protection, and penitentiary officials to improve coordination of TB control and prevention. The program was designed to provide comprehensive TB care to both civilian and prison populations in five oblasts and to perform periodic cohort analyses of treatment outcomes.

By 2002, the treatment success rate in Orel, Ivanovo, and Vladimir was estimated at over 70% (USAID 2002). Results from prospective data collected on the 349 patients initiated in October 1999 in Orel Oblast showed that by 2000 treatment success (i.e., patients confirmed cured bacteriologically and those who completed treatment) was 88% of new and 60% of retreated TB patients (CDC 2001). According to the WHO/Russia TB Program Coordinator, the coordinated international assistance effort was responsible for the positive results. Following the introduction of the MOH Order #109, 26 oblasts are implementing DOTS and another 37 expect to join the effort during the upcoming year. WHO/Russia expects that, by the end of 2005, 85% of Russian regions will be implementing DOTS.

2. HIV/AIDS Services

The funding for regional AIDS centers comes from the federal and regional budgets, and this determines the staffing capacities of each center. The AIDS centers serve as a specialized care institution. With some variation between regions, each AIDS center is staffed with an infectious disease specialist, obstetrician-gynecologist, TB specialist, dermatologist, sexually transmitted infection specialist, pediatrician, ear, nose and throat specialist, ophthalmologist, neurologist, dentist, physiologist, social worker, nurses, and lab personnel. Each specialist working at these centers receives a significant salary adjustment to compensate for the high risk of dealing with HIV. The system of care for TB and HIV/AIDS patients is summarized in Table 2.

¹ The standard WHO-recommended short course consists of a chemotherapy regimen (isoniazid, rifampin, ethambutol, and pyrazinamide for two months followed by isoniazid and rifampin for four months) for patients not treated previously for TB.

Table 2: Care Delivery for TB and HIV/AIDS Patients

Resources and Levels of Care	TB Services	HIV/AIDS Services
Resources	<p>TB Hospitals: 117 TB Dispensaries: 390 TB Dispensaries with bacteriological labs: 216 TB sanatoria: 228 TB Research Institutes: 5</p>	<p>Federal Research and Methodology Center for AIDS Prevention and Control Regional AIDS centers: 6 Territorial AIDS centers: 96</p>
Primary Care Level	<p>Generally diagnosed by chest radiography and passive detection of symptomatic cases at a polyclinic. Once identified, a patient is referred to a TB dispensary for bacteriological confirmation. Where available, microscopy is performed at a polyclinic lab, but normally the results do not play an informative role in the final diagnosis. Lag time between the initial diagnosis and anti-tuberculosis treatment sometimes takes two months.</p>	<p>Diagnosis occurs at a polyclinic or woman's consultation during medical examination due to illness, pregnancy, or mandatory requirements for examination. If HIV is suspected, the patient is counseled to take an HIV test. Results of the test are sometimes not available for 2–3 weeks. If found HIV positive, an infectious disease specialist at a polyclinic and an epidemiologist from a local Sanitary Epidemiological Service (SES) implement an investigation of contacts. The patient is counseled to visit an AIDS center. It is often unclear who should be counseling the patient during the post-test period. This lack of clarity generates other delays.</p>
Secondary Care Level	<p>The referred patient undergoes a second microscopy test and, if necessary, is followed by bacteriological confirmation at a TB dispensary. Once infection is confirmed, the patient is referred to a TB hospital for treatment.</p>	<p>Not involved.</p>
Tertiary	<p>Depending on whether the patient comes from a city or a rural district, the patient is treated at the city or oblast TB Hospital. The duration of treatment is up to six months but takes longer in some cases. Once treatment is completed, the patient is discharged and referred to a local TB dispensary for further follow up in an ambulatory setting.</p>	<p>A second confirmation of HIV status is given at the AIDS center. The patient is advised to undergo a thorough medical examination by center specialists (“dispensarization”) and is recommended to visit the center every six months. Dispensarization sometimes takes weeks and adds to a patient's time burden. ART is administered by the AIDS center.</p>

B. Epidemiological Picture and Current Clinical Practices

A summary of the estimated HIV and TB-HIV co-infection prevalence in the four project regions and the Russian Federation by the end of 2004 is presented in Table 3.

Table 3: Co-Infection Prevalence in the Four Project Regions and Russia, 2004

Region	Population (2002)	HIV	TB-HIV
Samara	3,239.8	23,137 (0.7%)	257
Saratov	2,669.3	6,728 (0.2%)	337
Orenburg	2,177.5	14,501 (0.7%)	242
St. Petersburg	4,669.4	25,178 (0.5%)	212
Russian Federation	145,181.9	308,817 (0.2%)	7,679

1. Samara

During the first six months of 2004, the TB incidence rate in the oblast was 75/100,000 population. There are 6,000 active TB patients. Since May 2002, the oblast participated in a program of controlled TB treatment, implemented with technical assistance from the London Imperial College. According to Dr. Fedorin, Chief Oblast TB Specialist, a cohort of 1,000 patients was formed and was followed through October 2004. Based on the 5-month follow-up period, effectiveness of treatment was estimated at 81%. X-ray coverage is 76%. As a result of actions by local health authorities and supported by international efforts, all oblast laboratories at the polyclinic level are now supplied with necessary means to implement microscopy. Training in microscopy has been provided to 150 lab personnel (100 in polyclinics and 50 at TB dispensaries). Two labs of the oblast prison system also have the necessary tools for microscopy. Quality control is periodically implemented by the Central Research Institute of Tuberculosis and the reference lab at the London Imperial College. Microscopy is confirmed with bacteriological testing, with results of test difference ranging from 7 to 12 %. By the end of 2004, 257 patients with TB and HIV were registered among 23,137 HIV-positives; 108 of them reside in Togliatti, stage 3 and 4B. Very few patients with TB-HIV receive ARV treatment.

2. Saratov

Since first detection of HIV in 1996 to the end of 2004, the cumulative number of HIV-infected cases in the oblast reached 6,728. The majority (74%) are in stage 2B and occur among 20–29 years olds (62%). The ratio of the mode of HIV transmission (injection versus sexual) in 2004 reached 1:1.5. According to the oblast AIDS Center, 150 patients currently need ART, but only 29 are actually receiving it. Compliance with the treatment guidelines requires further analysis. According to a specialist at the AIDS center, only seven patients are treated in compliance. Tests on CD4 are not regularly available due to the lack of resources.

There are 8,000 active TB patients in the oblast. The TB incidence rate in 2004 is estimated to be 80 per 100,000 people. All newly discovered TB cases require testing for HIV. Between 1996 and December 2004, 337 TB-HIV co-infected patients were registered in the oblast. Thirty-seven patients have developed AIDS.

3. Orenburg

There were 14,501 HIV-positive clients registered in the oblast by the end of 2004. Almost 50% of patients are infected through drug injection, and 75 % of HIV-positive people are between 15 and 30 years old. This number is a bit lower compared to 2003, when the same age group comprised 81%. The male/female ratio of HIV-positives among drug users is 6:1. HIV is detected in 40% of the unemployed.

Since the first reporting of HIV in the oblast, 431 HIV patients have died. Ten deaths from AIDS from among 22 patients were reported during the first half of 2004.

In 2004, TB incidence in the oblast was 72/100,000 population. There are 5,500 active TB patients, and 242 patients with TB-HIV co-infection have been registered since 2001. None of the patients received ART. Most of these patients are former prisoners. According to specialists at the City TB dispensary and the AIDS center, the number of TB-HIV patients in prisons in the oblast ranges from 90 to 160.

4. St. Petersburg

The incidence of TB in St. Petersburg is 38 per 100,000 population. By the end of 2004, 25,178 HIV-positive people had been detected, 212 of whom had TB-HIV. Registration of TB-HIV in the city began in 2001. All TB-HIV patients are treated at the City TB Hospital No.2, which uses a separate clinical department created in 2001 with 50 beds allocated for these patients. The profile of the majority of patients (97%) is “under 35 years, low-income drug user, former prisoner.” Between 2001 and 2003, 244 patients went through treatment in this department: 30% of them show a CD4 count of less than 100. Due to their disrupted lives, almost 80% of the patients leave the hospital treatment course without finishing treatment.

Out of 340 TB-HIV patients, only 50 received ART. While the patient is in the TB hospital, treatment is controlled by a City AIDS Center specialist, who either visits the patients weekly or provides consultations with the personnel in the TB-HIV department. After completion of in-hospital treatment, patients are supposed to be followed in an ambulatory setting. In reality, the follow-up for this group of patients is irregular and incomplete. Data on patients’ adherence to treatment regimen is not valid and practically nonexistent. Preventive treatment of TB for HIV-positive people is not administered.

C. Patient Adherence

Adherence remains a cornerstone of TB treatment. Currently, patients who are discharged and come to ambulatory settings for further follow-up are not normally followed for adherence to treatment regimens. Part of the reason is that the “profile” of a TB or HIV patient does not meet established societal perceptions, so there is very little or no interest on the provider side to follow the patient’s treatment regimen. Although there is an official recording form, N01-TBY “Medical Card of a TB Patient,” that is supposed to be completed by a doctor or nurse for each patient and that follows the treatment, it is not completed at the ambulatory stage of treatment. Part of the reason is can be found in the way the TB and HIV care delivery systems function. Neither is integrated into the general healthcare system. Furthermore, performance and outcomes do not drive their budgets. Instead, their financing principles are oriented to inputs and processes, so performance is judged on the basis of resources consumed, clinical beds occupied, and number of patients visited.

Various attempts have been made to promote strategies for patient adherence to treatment. For instance, patients who receive therapy sign an agreement to participate in the treatment. In return, they receive a month’s supply of drugs. The agreement places more responsibility on the patient side to follow the regimen. At the same time, there is very little evidence that TB doctors and nurses follow patients for adherence. Despite numerous requests, no records showing such follow-up were presented.

In some regions, patients and their family members receive tickets providing free transport to the clinics. Other solutions appeared to be successful in Samara City and Toliatti, where TB patients were given free packaged meals in return for visits to TB dispensaries to receive drugs. This practice was introduced by the London Imperial College during oblast participation in the DOTS TB treatment project. The project is ending in 2005, and no further sustainable strategy is foreseen. The social services and community organizations are not much involved.

D. Availability of Microscopy

In accordance with MOH Order #109 (Attachment I), the microscopy test is required at every primary healthcare facility (polyclinic) where a patient is suspected of having TB. Tests are not equally available in the four project oblasts. While Samara introduced microscopy at the primary care level, for instance, TB diagnosis in Saratov still depends on X-ray examination as the primary mean of case detection. However, even when microscopy tests are performed in polyclinics, the results are not used to initiate treatment. In the case of a positive result, the patient is still referred to the TB dispensary, where he/she is supposed to undergo another microscopy test for bacteriological confirmation. The patient receives treatment only after results are found positive at the TB dispensary. Such practices create a significant delay between the first visit to the doctor and the time when the actual treatment is administered. A 60-day delay between the first visit and the TB confirmation was revealed in an analysis performed in 2000 by the Research Institute of Phthisiopulmonology of Sechenov Moscow Medical Academy in 27 Russian oblasts. The three participating oblasts (Samara, Saratov, and Orenburg) demonstrated such a delay in 35–40% of cases.

The sensitivity and specificity of microscopy tests will require a more thorough analysis. In Samara Oblast, for example, a comparison in 2000-2002 of microscopy tests with bacteriological confirmation showed a difference in 7–12% of tests. According to the oblast chief TB specialist, these results were due to the fact that the oblast was involved in the international project with London Imperial College. This participation allowed the training of all laboratory personnel (50 from TB dispensaries and 100 from general health facilities) for performing microscopy tests. Regional budget support also allowed the oblast labs to be supplied with the necessary equipment and materials. Such a situation, however, is exceptional compared to other regions of Russia.

E. Provider Knowledge and Skills and Quality Assurance Mechanisms

The postgraduate education of doctors involved in TB care delivery has seriously deteriorated over the last decade. Because of the lack of funds available to support formal postdoctoral education, the majority of doctors seek a variety of ad hoc training opportunities in order to build or maintain their credentials. As result, their knowledge and skills are not systematically updated and are often deficient.

Quality assurance for TB treatment takes a traditional “top-down” inspection approach. At the regional level, the performance of the TB system is reviewed through periodic visits implemented by lead specialists from central or district-level TB research institutes. The oblast specialists evaluate the performance of a TB facility through their periodic meetings at “doctor-expert committees.” The committee normally reviews the basic statistics (prevalence, mortality, and number of patients seen). None of the four project regions was able to demonstrate qualitative and quantitative evidence on providers’ compliance with the federal or regional clinical practice guidelines.

F. Availability of Drugs

According to officials in the four oblast departments of health, the regions are adequately supplied with TB drugs. For 70–80% of drug costs, funding comes from regional budgets, the rest from federal. Beginning in 2005, regions will be expected to assume the entire funding of drugs, and only federal institutions in the regions will be funded by federal budgets. While the situation remains more favorable with regard to TB, access to ART will be greatly affected. Unless the national political leadership demonstrates a strong will to lower prices for ARV medicine, Russia will have to rely on external assistance.

G. Patient Records and Information Processing to Determine Program Effectiveness

In order to improve epidemiological surveillance and treatment control of tuberculosis, on February 13, 2004, the Russian Ministry of Health issued Order #50, “On introduction of recording and reporting documentation for monitoring of tuberculosis.” This order introduced forms that bring the Russian system of TB registration and evaluation of treatment effectiveness into compliance with international indicators. During 2004, 38 regions, including Samara and Saratov, were identified for introducing the new statistical policies.

To improve monitoring of TB in HIV-infected patients, the Russian MOH issued Order #547 on November 13, 2003. The order is a major document that regulates the use of a reporting form, #263/y-TB, the “TB-HIV patient identity card.” Its major requirements are:

- The form is filled out for each TB patient who has HIV or died of HIV.
- Each AIDS center that discovered TB in an HIV patient fills out the form and forwards it to the TB regional specialist assigned to treating TB patients with HIV.
- If HIV is discovered in a patient at a TB facility, the form is filled out and must be communicated to the TB specialist in the region responsible for treating the TB patients with HIV.
- The pathologist who diagnosed TB in an HIV patient sends the pathological confirmation to the TB specialist in the region responsible for treating the TB patients with HIV. The specialist fills out the form.
- If pathological confirmation has not been done, the healthcare facility where the patient death has been recorded reports about the death to the TB specialist in the region responsible for treating the TB patients with HIV.
- The regional TB specialist responsible for treating the TB patients with HIV is obligated to report TB patients with HIV by the fifth of the month to the MOH TB Healthcare Delivery Center for HIV-infected patients.

A case-based reporting form for patients with HIV-related TB is presented in Attachment II.

VI. CONCLUSIONS

The findings of this situational analysis suggest the following conclusions:

- The number of TB patients with HIV is currently small, but the number is rapidly growing.
- Very few TB patients with HIV receive ART, because of the lack of ARV drugs.
- While the majority of TB patients are tested for HIV, TB case finding among HIV-positives is low.
- Care for TB patients with HIV lacks coordination with AIDS centers and primary care institutions, especially in ambulatory settings.
- The infectious disease specialists at AIDS centers are not guided on how to administer TB preventive treatment for HIV-positive clients, so no treatment is given.
- HIV-positives are mainly drug addicts who have low awareness of the risk for TB development, so their motivation for being tested for TB is low.
- Many TB patients with HIV are hard to reach for hospitalization or to keep in the hospital because of their difficult situations.
- The social protection services have little appreciation of the issues and are practically not involved in the process of support.

- Community-based organizations to support patients with TB practically do not exist.
- Evidence on patient adherence to TB treatment regimens is lacking.

VII. OBJECTIVES FOR IMPROVEMENT ACTIVITIES

Over the next two years, the QAP team will work closely with various healthcare organizations and other essential stakeholders on designing an HIV/AIDS treatment, care, and support system in the four Russian regions. The opportunity to tackle TB-HIV co-infection represents a unique opportunity for the project that will benefit both people living with HIV/AIDS, and those with TB. The quality improvement collaborative method QAP brought to Russia in 1998 has proved to be especially suitable for issues that are interdisciplinary in nature and depend on factors that are not in the control of a single institution. Bringing practitioners from different health and non-health organizations to work in a structured way on improving certain aspects of services seems to be the only viable solution for problems such as TB and HIV/AIDS.

QAP proposes to form an interdisciplinary team made up of providers from TB dispensaries, AIDS centers, polyclinics, drug clinics, the prison system, social support services, and community organizations. QAP will involve them in a series of meetings where they can learn about best practices and quality methods, share experiences, and find mutually feasible solutions for “weak” points that prevent effective delivery of care to TB patients with HIV. With this method, the project aims to implement a model TB-HIV continuum of care while institutionalizing quality assurance functions in these facilities through professional and organizational development.

QAP objectives with respect to improving systems of care for TB-HIV co-infected persons include:

- Develop a system that ensures that all HIV/AIDS patients receive TB services, including preventive treatment.
- Develop a system whereby all TB patients who are HIV-positive get referred for ART and receive it, if appropriate.
- Promote provider compliance with established federal and international clinical practices.
- Promote patient adherence with treatment regimens.
- Promote linkages between healthcare delivery organizations, social protection services, and community-based organizations.
- Establish quality assurance mechanisms at facilities offering TB and HIV services.

These objectives align with recommendations proposed by the Ministry of Health and Social Development and WHO. Close coordination of activities in the four regions with MOHSD and WHO activities is crucial for the project as such coordination will facilitate the geographic expansion of improvement efforts in a relatively short period.

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ATTACHMENT I

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION ORDER

March 21, 2003

Moscow

#109

On the improvement of tuberculosis control activities in the Russian Federation

The tuberculosis epidemic situation in the Russian Federation has aggravated in the early '90s. Compared to 1990, the number of new tuberculosis cases has more than doubled by 2003, tuberculosis mortality has increased by 1.5 times, and the tuberculosis incidence among children has gone up. An especially grave situation is observed at penitentiary facilities.

In terms of clinical forms of tuberculosis, there are more patients with extended, advanced and complicated cases, as well as patients with drug-resistant *M. tuberculosis*; the efficacy of treatment for tuberculosis patients has decreased.

The primary measures targeting the implementation of a tuberculosis care strategy in the Russian Federation are defined in the sub-program "Urgent tuberculosis control measures in Russia" of the federal targeted program "Prevention and control of socially-afflicted diseases (2002-2006)" approved by the Resolution of the Government of the Russian Federation #790 dated November 13, 2001 (Compilation of legislation in the Russian Federation, 2001, #49, p. 4620).

Stabilization of tuberculosis-related rates observed in 2001 demonstrates the efficiency of tuberculosis control measures and confirms the need for further development of tuberculosis care system for population of the Russian Federation.

In pursuance of implementing the Federal Law dated June 18, 2001, #77-FZ "On prevention of tuberculosis dissemination in the Russian Federation" (Compilation of legislation in the Russian Federation, 2001, #26, p. 2581), the Resolution of the RF Government #790, dated November 13, 2001 "On implementation of the Federal law "On prevention of tuberculosis dissemination in the Russian Federation", and with the purpose of efficient implementation of the sub-program "Urgent tuberculosis control measures in the Russian Federation" of the federal targeted program "Prevention and control of socially-afflicted diseases (2002-2006)", as well as to improve the strategy and tactics of organizing tuberculosis control activities

I ORDER:

1. To approve:
 - 1.1. Instructions on the centralized control over dispensary monitoring of tuberculosis patients (Annex #1).
 - 1.2. Instructions on clinical classification of tuberculosis (Annex #2).
 - 1.3. Instructions on application of ICD, 10th revision, for statistical registration of tuberculosis-related data (Annex #3).
 - 1.4. Instructions on tuberculin skin testing (Annex #4).
 - 1.5. Instructions on vaccination and re-vaccination against tuberculosis with BCG and BCG-M vaccines (Annex #5).
 - 1.6. Instructions on chemotherapy of tuberculosis patients (Annex #6).
 - 1.7. Instructions on organizing dispensary monitoring and registration of patients at tuberculosis facilities (Annex #7).
 - 1.8. Provisions on organizing day hospitals at tuberculosis facilities (Annex #8).
 - 1.9. Instructions on work arrangements for bacteriology laboratories at tuberculosis facilities (Annex #9).
 - 1.10. Instructions on uniform methods of microscopy examinations used to detect acid-fast bacilli at clinical and diagnostic laboratories at healthcare facilities (Annex #10).
 - 1.11. Instructions on uniform microbiology methods for detection, diagnostics and treatment of tuberculosis (Annex #11).
 - 1.12. Guidelines on antiepidemic measures in tuberculosis niduses (Annex #12).
 - 1.13. Provisions on organizing consultative-diagnostic and rehabilitation centers for children with various manifestations of tuberculosis infection (Annex #13).

Minister

Stamp

Yu.L. Shevchenko

ATTACHMENT II

CASE-BASED REPORTING FORM FOR A PATIENT WITH HIV-RELATED TB

1. Patient name: _____
2. Patient's identification number: _____
3. Sex: _____
4. Age: _____
5. Place of work: _____ Occupation: _____
6. Place of residence: _____
7. Date of HIV detection: _____
8. In case of lethal outcome – the date of death: _____
9. Detection methods: X-ray, bacteriological, morphological _____
(underline and/or specify, if necessary)
10. TB contact: family members, co-workers, neighborhood, including nosocomial contacts

(underline and/or specify, if necessary)
11. TB detection setting: rayon polyclinic, general hospital, TB dispensary _____

(underline and/or specify, if necessary)
12. Context of TB detection: complaints, active case finding, post mortem detection

(underline and/or specify, if necessary)
13. History of TB: _____
(indicate the surveillance group or the date of putting a patient off the records, etc.)
14. Incarceration: none, less than a year, 1-3 years, more than 3 years _____
(underline)
15. TB diagnosis: _____

(according to the national clinical classification)
16. MBT excretion confirmed by: smear microscopy, culture, PCR _____
(underline and/or specify, if necessary)
17. Anti-TB drug resistance: not done, pending, polyresistance, MDR, resistance to one drug

(underline and/or specify, if necessary)
18. Date of HIV detection: _____
19. Timing of getting HIV infection*: _____
20. Mode of HIV transmission: injecting drug use, sexual intercourse, unknown _____
(underline and/or specify, if necessary)

21. Other HIV-positive family members: _____
(specify)

22. HIV infection stage: _____ CD4 count: _____ Lymphocytes: _____

23. Secondary diseases caused by HIV**: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 (circle)

24. Concurrent pathology: _____

25. In case of lethal outcome – major cause of death (direct): _____

Job title of a responsible person and his/her first/second name: _____

Telephone: _____ and Sender's address: _____

* A sample of a questionnaire aimed to clarify the issue is presented on the reverse side of the Form.

** Numbers corresponding to secondary diseases listed on the reverse side of the Form should be circled too.

Reverse side of the Form

List of questions that may help to find out tentative timing of getting HIV infection

1. When (prior to HIV detection) was the patient tested as HIV-negative?
2. In case of drug abusers: When did the first and the last episode of intravenous drug use take place?
3. In case of casual sex: When did a casual sexual intercourse happen?
4. Do any of the patient's friends or relatives prove to be HIV-positive? Has it happened to them before or after the case in question? If it has happened before, then could HIV be transmitted from them? What is a tentative date of that event?
5. In case of blood transfusions: When was the first and the last transfusion?
6. When did skin-piercing procedures (e.g., tattooing or ear piercing) take place in the absence of adequate sterile conditions?

List of secondary diseases

Candidiasis
Coccidioidomycosis
Cryptococcosis
Cryptosporidiosis
Cytomegalovirus infection
Infection due to herpes zoster virus
Kaposi's sarcoma
Lymphoma
Other types of mycobacteriosis or unspecified mycobacteriosis
Pneumocystic pneumonia
Toxoplasmosis
Other

Guidelines for completing case-based reporting Form for a patient with HIV-related TB

A “TB-HIV identity card” (hereinafter referred to as “the Card”) is to be completed, providing that another concurrent pathology is detected or death caused by the latter is registered.

Once an HIV-positive patient is diagnosed at the AIDS Control Center as having either TB or relapse of TB, his/her Card should be completed and then passed on to the designated TB specialist responsible for tuberculosis management in HIV-infected individuals at the level of a sub-National body of the Russian Federation.

Similarly, if the TB facility finds that a TB patient is HIV-positive, his/her Card should be filled in and passed on to the designated TB specialist responsible for tuberculosis management in HIV-infected individuals at the level of a sub-National body of the Russian Federation.

The designated TB specialist responsible for tuberculosis management in HIV-infected individuals at the level of a sub-National body of the Russian Federation should keep the Card original in the filing system while its duplicate should be submitted to the TB Healthcare Delivery Center for HIV-infected Patients of the Ministry of Health of the Russian Federation. The Card duplicate will contain anonymous data under encoded patient’s name.

A pathologist should submit a duplicate of his/her report on autopsy findings to the designated TB specialist responsible for tuberculosis management in HIV-infected individuals at the level of a sub-national body of the Russian Federation. On the basis of the received report on autopsy findings, the said specialist will complete the Card and forward its copy to the TB Healthcare Delivery Center for HIV-infected Patients of the Ministry of Health of the Russian Federation

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