



Delivery of Effective Tuberculosis Treatment to Drug Dependent HIV-positive Patients

Andrey Rylkov Foundation for Health and Social Justice

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Summary

Individuals with co-morbid conditions, such as HIV-infection, drug dependence, and tuberculosis (TB) are among the most vulnerable to co-infection. At the same time, they are most likely to face difficulty in accessing timely diagnostics and effective treatment. The vulnerability of this group is dictated by many factors. Heightened stigma surrounding drug use and marginalization of drug users manifests in severe underutilization of health services by this group. Because of repressive drug policies and practices enacted by judges, drug users are heavily criminalized and are incarcerated in large numbers. Prisons, in our country, are the main breeding ground for TB-infection. State ban on the use of methadone and buprenorphine for treatment of drug-dependence leads to lowered effectiveness of HIV prevention effort and failure in early detection of HIV and TB among this group, as well as provides for decreased treatment adherence rates for both HIV and TB patients.

Gaps in organizing an effective process for diagnosing and treating TB, absence of evidence-based treatment standards that would allow to improve treatment outcomes and answer the specific needs of patients – all lead to low rate of treatment enrollment and high rate of drop-out among patients with co-morbid conditions. This significantly decreases the effectiveness of treating regular TB, leads to development of drug-resistant forms of TB, and causes heightened mortality in this group of patients.

This report summarizes the results of a study that investigated the specifics of treatment delivery to individuals co-infected with HIV and TB. The study was conducted between March and November, 2010 by Andrey Rylkov Foundation for Health and Social Justice in collaboration with project “Simona+.” Investigators collected quantitative data on in-patient treatment of TB in 13 Russian cities and conducted in-depth interviews with co-infected individuals, who have had a history of TB treatment, and treatment and medical care practitioners in three cities (Kursk, Perm, Saint Petersburg). The study results allow insight on the situation in Russia's TB hospitals and increase our understanding of barriers, encountered by patients with co-morbid conditions, when accessing TB treatment services. Based on the analysis of interviews and data, we present concrete recommendations for improving access to and effectiveness of TB treatment for patients with co-morbid conditions.

Key Findings:

- **Drug-dependent HIV-positive patients are the most vulnerable risk group in TB treatment**

Among patients with TB/HIV co-infection mortality is exceptionally high, when undergoing TB treatment: *in three cities co-infected patients represented almost 100% of all those TB patients who died during treatment.*

The majority of patients co-infected with HIV and TB (78%) are drug dependent (the percentage varied from 50 to 86% in different cities, only in one city this indicator was at 10%)

The rate of drop-out from in-patient TB treatment is extremely high for TB/HIV co-infected patients and reaches an average of 30%. Drop-out rates were even higher for those co-infected patients who are drug dependent – 41%. In some cities, the rate of drop-out among drug-dependent patients with co-infection was at 100%.

Patients with co-infection develop resistance to two or more drugs much more frequently than those TB patients without HIV (on average, every third patient develops drug resistance).

➤ **HIV and TB prevention and testing interventions for drug dependent individuals are not conducted at adequate levels**

The study underlined the lack of adequate prevention interventions for both diseases among drug dependent individuals. Late detection of HIV and late initiation of HIV treatment serve as key barriers to effective treatment of co-infection among this population. These factors are a direct result of poor interactions between health service providers and this group and inadequate prevention efforts. Though harm reduction and outreach work projects, allowing continuous contact with drug users, operate in the cities where the survey was conducted, the reach of these projects is not significant enough due to poor financial and organizational support and lack of their integration with other health services.

Practitioners pointed to the fact that current approaches used to diagnose TB among HIV-positive individuals are not effective. The lack of early detection of TB is connected to the absence of contemporary diagnostic materials at harm reduction programs and in medical institutions that are the first point of contact for difficult-to-reach patients (such as polyclinics, infectious disease hospitals etc). Additional complicating factor in diagnosing TB in HIV-positive patients is the length of the process, often halted by atypical results. Test systems, allowing to conduct rapid diagnosis of TB and drug resistance are not procured by Russian Federation.

➤ **A poor link between TB services and infectious diseases services**

In half of the cities surveyed, almost every fifth (and in some cities every second) patient of a TB hospital is HIV-positive. Despite this, the level of collaboration between TB and infectious diseases services is extremely low. The following are seen as the key issues in establishing a link between TB and other services: lack of special training and knowledge about treating HIV-positive patients among TB professionals and lack of similar specialized knowledge about TB among infectious disease professionals; difficulties in conducting viral load and CD4 testing and prescribing and accessing ART for patients; limited abilities in terms of delivering TB treatment for HIV-positive patients at AIDS Centers.

➤ **Lack of effective drug treatment services for patients with co-infection**

The absence of effective drug treatment services at TB hospitals and in general is the most serious structural barrier to effective in-patient TB treatment for patients with co-infection. The majority of drug-dependent patients with TB drop out of treatment: *in some cities the level of drop out from in-patient treatment among this group is at 100%*. Inability of the health system to offer adequate drug treatment creates an institutionalized “trap,” when drug dependent patients are excluded from stable TB treatment de-facto.

The following are identified as key barriers to effective treatment of drug dependent patients with co-infection: the legal ban on methadone and buprenorphine substitution treatment programs for treating drug dependence, in disregard of the fact that these programs are a part of WHO protocols on managing patients with co-morbid conditions such as HIV, TB and drug-dependence; under the current law, the dysfunctional system for prescribing medications that could be used for alleviating the symptoms of the withdrawal syndrome among TB hospital patients; lack of psychological and social rehabilitation for patients, undergoing treatment in TB

hospitals; lack of awareness and knowledge in the area of drug-dependence among TB service professionals.

➤ **Emphasis on in-patient treatment and underdevelopment of DOTs in the community**

The approach to TB treatment in Russia is focused on maximum length of stay in in-patient treatment. Our interviews demonstrate that prolonged in-patient treatment is connected to an array of problems: high cost for the health system, poor conditions for patients, complications in having patients adhere to treatment and stay in hospitals, the “treatment exhaustion” syndrome that many patients acquire after lengthy, multi-month hospital stays. Global practice and pilot projects in Russia have demonstrated that the in-patient treatment is not as effective and often less effective than a well-organized out-patient treatment service, such as so called direct observed therapy (DOTs) in the community, when patient treatment and care occur where the patient lives and the medications are delivered daily under the surveillance of a social worker at home. Overall, global practice demonstrates a trend towards decreasing hospital stays. The aforementioned modality of approaches was lacking in the studied cities. The decrease of time of hospitalization was also complicated by the lack of testing systems, allowing to conduct TB diagnosis and drug resistance tests in the shortest time period possible.

➤ **Drop-out of patients during the transitional stages of treatment**

The lack of well-established cooperation within the TB services is expressed in the following problems: absence of a system for managing patients, when they transfer from one TB institution to another; absence of a unified patient data base, allowing patients to continue treatment of TB if they move (for example in a case of being released from prison, or internal migration); absence of motivation among out-patient TB service providers to work with HIV-positive patients.

➤ **Lack of professional training in the area of work with drug dependent patients among health care practitioners**

Poor professional training in the area of drug dependence and existing attitudes towards this condition among health practitioner manifest into a lack of motivation to engage with drug dependent patients and improve the conditions that would increase their adherence to treatment.

Main Recommendations

Prevention

- Expand and support prevention programs (programs reducing harm associated with drug use) for difficult to reach population groups, vulnerable to HIV-infection and TB, particularly those programs that actively engage drug users through outreach work. Harm reduction programs reduce the risk of TB among drugs users by increasing access to prevention, information and early diagnosis.

Diagnostics

- Increase access to HIV testing and counseling for “hidden” population groups, such as drug users, including street outreach programs that would utilize express testing systems, and also by directing clients to low-threshold programs.
- Increase access to modern diagnostic systems that can diagnose tuberculosis and drug resistance in the shortest time possible and make them accessible through the wider medical services network.

Treatment

- Review possibilities for shortening hospital stays and developing socio-medical treatment services, utilizing directly observed methodologies in the community (where the patients live). These services may be realized through close collaboration of medical institutions and programs, serving drug users, in particular harm reduction programs, as well as through relatives, social workers and junior medical staff.
- Lift the legal ban on methadone and buprenorphine substitution treatment programs in Russian Federation. These programs are recommended by the WHO and are a key element of HIV and TB prevention, drug dependence management, and increasing treatment adherence (both in-patient and out-patient HIV and TB treatment) for drug dependent patients.
- Scale up work to provide additional training to medical practitioners (doctors, medical staff, and public health program managers) in the area of co-infection and managing patients with co-morbid conditions, such as HIV, TB and drug dependence

Integration of Services

- Scale up efforts in retaining patients in treatment during transfer, i.e. when a patient is referred from one treatment institution to another (for example from a hospital to an out-patient clinic), or during release of a TB patient from prison and transfer to the civilian health sector: increase collaboration between systems and professional trainings for staff, provide thorough social support and case management services, improve the system for transferring data on the patient and on the patient's treatment status.
- Strengthen collaboration between TB and infectious disease services and increase the level of service integration at all points of service delivery: at harm reduction sites, at the AIDS Centers through scale up of TB diagnosis and prevention, and at TB clinics through diagnosing, monitoring, and treating HIV among TB patients.

Monitoring and access to data

- Systematically collect data, conduct situational analysis, and monitor treatment outcomes and quality of treatment for patients with co-morbid conditions. Make this information publicly available and use it for developing health policies.
- One concrete step that the health system can make is to systematically study the factors that influence treatment interruption or drop-out among patients, and implement appropriate interventions based on these findings.

Introduction. HIV, TB and injection drug epidemiology in Russian Federation.

The TB crisis in Russian Federation continues to amplify. According to the World Health Organization (WHO), in 2009 Russia was eleventh among 22 countries with the highest TB prevalence in the world, and in the WHO European region, 36% of all new cases of TB infection identified for the first time were “supplied” by Russia.¹

According to the Federal Center on TB Control in Russian Federation, at the end of 2009 the number of people first diagnosed with active TB was at 117,200 (82.6 per 100,000 population). And 262,700 were registered in the national TB registry (185,1 per 100,000 population).² In the last several years, the TB epidemic in Russia has acquired the following characteristics: increase in patients with resistance to two or more TB drugs, high mortality among patients with TB in the context of other infectious diseases (particularly among patients with TB/HIV co-infection), increase in the cases of TB/HIV co-infection, and high prevalence of TB in the penitentiary system.³

In the last three years, Russian Federation has also become one of the three top countries in terms of multi-drug-resistant TB (MDR-TB),⁴ in 2007 there were 43,000 cases of MDR-TB registered.⁵ MDR-TB prevalence has increased by 10.2% in one year (18.6 per 100,000 population in 2008 and 20.5 per 100,000 population in 2009). Mortality among MDR-TB patients continues to grow and has reached 3.2 per 100,000 population in 2009.⁶ Also, in 2008, Russia was the world leader in the share of MDR-TB diagnoses among newly identified cases of TB infection.

At the same time, the HIV epidemic in Russia shows no signs of recession.⁷ Based on official data, at the end of 2009 there were 529,828 registered cases of HIV. In 2009, 58,448 new cases were registered, which exceeded the 2008 statistics by 8%.⁸ Available data also indicates that

¹ WHO (2010). Global Tuberculosis Control. Geneva. Available at:

http://whqlibdoc.who.int/publications/2010/9789241564069_eng.pdf

² Central Scientific Research Institute on Structuring and Information Gathering for Public Health at the Ministry of Health and Social Development of Russian Federation (2010). Epidemiological assessment of TB situation in Russian Federation, December 31, 2009. Available at:

http://duma.hivpolicy.ru/assets/files/15_04_2010/TB.pdf

³ Frolova O.P., Belilovskiy E.M., Yakuboviyak V., et al. (2008). «HIV-infection in Russian Federation and its influence on the prevalence of Tuberculosis». Tuberculosis in Russian Federation, 2007: Analytical review of main statistical indicators on tuberculosis used in Russian Federation. Editors: Perlman MI, Mikhailova UV. Pp.: 87-97.

⁴ MDR-TB — a form of tuberculosis that can not be treated with the standard six-month course of first line medications. MDR-TB either develops as a result of infection with resistant bacteria, or because of unsuccessful previous treatment.

⁵ WHO (2010). Multidrug and extensively drug-resistant TB (M/XDR-TB): 2010 global report on surveillance and response. Available at:

http://whqlibdoc.who.int/publications/2009/9789241598866_eng.pdf

⁶ Central Scientific Research Institute on Structuring and Information Gathering for Public Health at the Ministry of Health and Social Development of Russian Federation(2010). Epidemiological assessment of TB situation in Russian Federation, December 31, 2009. Available at:

http://duma.hivpolicy.ru/assets/files/15_04_2010/TB.pdf

⁷ According to Rospotrebnadzor data, in the first 6 months of 2010, 25,500 new cases of HIV-infection were registered, and since 1987 a total of 544,000 HIV-positive individuals have been registered in Russia (380 per 100,000 population). Electronic bulletin of Russia's Country Coordinating Mechanism on HIV and TB eradication. Issue 10, July 2010. Available at: <http://hivrussia.ru/files/skm/bulletin10.pdf>

⁸ Rospotrebnadzor (2010). Progress report of the Russian Federation to the United Nations General Assembly Special Session (UNGASS) Declaration of Commitment on HIV/AIDS, adopted in June, 2001. Reporting period: January, 2008 to December, 2009.

from 1987 to 2008, nearly 80% of all cases of HIV-infection were connected to injection drug use.⁹ Approximately 37.2% of drug users in Russia are living with HIV,¹⁰ in some regions, HIV-prevalence in this group reaches 60-75%.¹¹ HIV prevention work among drug users is not supported by the state. According to the report of the Ministry of Health and Social Development of Russian Federation “The increase in HIV infection among injection drug users is connected with inadequate prevention efforts among vulnerable groups... Nearly 80% of the budget, assigned to curbing HIV-infection, was directed to treatment and care. Financial resources, allocated for prevention mostly targeted blood bank safety, VCT services, and vertical transmission prophylaxis”.¹²

Because of the progressing HIV epidemic, each year the situation with TB/HIV co-infection also becomes more dire. TB is a known leading opportunistic infection resulting from the development of immunodeficiency;¹³ manifestation of TB in HIV-positive individuals is frequently atypical; the disease is difficult to diagnose and develops, on average, 4-5 years in the course of HIV-infection.¹⁴

According to the Federal Center on TB Control in Russian Federation, in 2009 there were 7,387 new registered cases of TB/HIV co-infection. The total number of registered cases of co-infection was 27,400.¹⁵ 66,5% of cases of HIV-related death were due to TB.¹⁶ According to data from 2008, for 75% of men and 54% women living with co-infection, injection drug use was the main route of HIV transmission.¹⁷

TB prevalence is especially high in prisons. In 2009, 40,700 cases of TB (1,306 per 100,000 population) were registered there¹⁸, and prisons are referred to as the main source of TB in

⁹ Rospotrebnadzor (2010). Progress report of the Russian Federation to the United Nations General Assembly Special Session (UNGASS) Declaration of Commitment on HIV/AIDS, adopted in June, 2001. Reporting period: January, 2008 to December, 2009.

¹⁰ [Mathers BM](#), [Degenhardt L](#), [Phillips B](#), et al., (2008). Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. *Lancet*: Nov 15; 372(9651): 1733-45.

¹¹ Rospotrebnadzor (2010). Progress report of the Russian Federation to the United Nations General Assembly Special Session (UNGASS) Declaration of Commitment on HIV/AIDS, adopted in June, 2001. Reporting period: January, 2008 to December, 2009.

¹² Ibid.

¹³ Among HIV-positive individuals the following “secondary” infections were most prevalent: Candidiasis (26%), Herpes Simplex Infection (15%) and then TB (14%). “The state of the HIV-positive patients”, 2007. Narishkina S.L., Frolova O.P. Presentation “Problems with diagnosing TB in the late stages of HIV-infection.” Available at: <http://tbpolicy.ru/news/index.php?year=2009&month=05&count=100&id=227>

¹⁴ Panteleev DM. “Delivering TB treatment to HIV-infected individuals in a city TB hospital.” Available at: <http://ostrov.socspb.ru/articles/tuberculosis/tubercules08.phtml>

¹⁵ Central Scientific Research Institute on Structuring and Information Gathering for Public Health at the Ministry of Health and Social Development of Russian Federation (2010). Epidemiological assessment of TB situation in Russian Federation, December 31, 2009. Available at: http://duma.hivpolicy.ru/assets/files/15_04_2010/TB.pdf

¹⁶ Russian Public Health Foundation (2010). Round table “Experience of collaboration between regional TB services and AIDS Centers in testing HIV-positive individuals for TB.” Available at: <http://hivpolicy.ru/news/?id=3917&word=7387&logic=OR>

¹⁷ Frolova OP. (2009). Presentation “Epidemiology of TB/HIV co-infection.” Available at: <http://www.tbpolicy.ru/news/index.php?id=227&file=201>

¹⁸ Central Scientific Research Institute on Structuring and Information Gathering for Public Health at the Ministry of Health and Social Development of Russian Federation (2010). Epidemiological assessment of TB situation in Russian Federation, December 31, 2009. Available at: http://duma.hivpolicy.ru/assets/files/15_04_2010/TB.pdf
http://duma.hivpolicy.ru/assets/files/15_04_2010/TB.pdf

Russia.¹⁹ Today, Russia ranks second in the world in the size of prison population. The number of prisoners has varied in the last few years from 850 000 to more than 1,000,000 persons yearly. Russia's prisons are drastically overcrowded, which provides for a poor living environment, absence of adequate sanitary conditions, and lack of adhering to the standards of infectious disease control.²⁰ The overcrowding of prisons is connected to the high level of criminalization of the population and repressive law-enforcement practices that prioritize incarceration over alternative methods of punishment. This is especially true for drug dependent individuals, who are criminalized at an exceptionally high rate. Studies demonstrate that in different cities from 28 to 65% of drug users have had a history of incarceration.²¹ Heavy criminalization of drug users is a direct result of repressive policies and judicial practice of Russian Federation.

Considering the aforementioned epidemiological situation, the importance of treating TB among HIV-positive drug dependent individuals is clear. According to expert estimations,^{22,23} 50 to 80% of patients in this group drop-out of treatment, which leads to chronic manifestation of TB, development of drug resistance, increase of lethal outcomes among co-infected patients and overall further spread of concurrent epidemics of HIV and TB in Russia.²⁴ High percentage of drop-out of patients with co-infection from treatment programs at various stages demands a thorough study and understanding of barriers to effective treatment and development of strategies for increasing adherence.

Study Goals and Methodologies

The main goal of this study was in identifying the barriers to TB treatment program enrollment and adherence for patients with co-morbid conditions, such as drug dependence, HIV and TB. Based on these findings, the recommendations for overcoming these barriers were then developed.

TB treatment services must identify the factors that could force the patient to interrupt or stop the treatment and act appropriately

WHO: Pursue high-quality DOTs expansion and enhancement.

The study methodology had a quantitative and a qualitative component. The quantitative component included a standardized questionnaire for TB hospital doctors in 12 regions of Russian Federation: Zima, Zlatoust, Kaliningrad, Krasnoyarsk, Kursk, Naberezhnie Chelni, Novorossiysk, Orenburg, Orsk, Saint Petersburg, Ufa, and Khabarovsk. Questionnaires were

¹⁹ Sarang, A. (2011). [Russian prisons as a source of tuberculosis](http://blogs.bmj.com/bmj/2011/04/28/anya-sarang-russian-prisons-as-a-source-of-tuberculosis/). British Medical Journal Blog. Available at: <http://blogs.bmj.com/bmj/2011/04/28/anya-sarang-russian-prisons-as-a-source-of-tuberculosis/>

²⁰ Bobrik A., Danishevski K., Eroshina K., McKee M. (2005). Prison health in Russia: the larger picture. *J Public Health Policy*; 26: 30-59.

²¹ Sarang, A., Rhodes, T., Platt, L., Kirzhanova, V., Shelkovnikova, O., Volnov, V., et al. (2006). Drug injecting and syringe use in the HIV risk environment of Russian penitentiary institutions. *Addiction*, 101: 1787–1796.

²² Frolova O.P., Batirov F.A., Novoselova O.A. (2009). Recommendation on curbing TB/HIV co-infection among individuals who use psychoactive substances. Materials from the Third Russian applied science conference with international participation “Multi-drug-resistant Tuberculosis in HIV-infected patients.” Bulletin 7. Editors: Frolova O.P. Pp: 61-64.

²³ Kononchuk O.N. Presentation on the “Evaluation of effectiveness and early outcomes of treating TB/HIV co-infection”. Available at: <http://tbpolicy.ru/news/index.php?year=2009&month=05&count=100&id=227>

²⁴ Ibid.

comprised of 26 questions and included queries on the number of patients in the last year, number of patients who interrupted treatment, and also on quantitative data regarding patients with co-infection, drug-dependence, main reasons for release from in-patient treatment etc. These questionnaires were filled during personal interviews with practitioners. The survey was conducted in the framework of project “Simona+” as a part of the thematic study on access to HIV, TB and drug treatment services.²⁵

The qualitative component included in-depth interviews with medical professionals from infectious disease and TB services, and also with patients, suffering from co-morbid conditions. We received assistance in recruiting participants from partner non-governmental organizations in three cities. A total of 16 interviews were conducted in Kursk, Saint Petersburg, and Perm (see Table 1). All interviews were transcribed verbatim and coded with the assistance of Nvivo - a specialized system for processing quantitative data.

Table 1. Respondents (qualitative component) distributed according to groups and regions.

City	Medical Professionals (doctors)	Junior Medical Personnel	Patients		TOTAL:
			HIV+TB	HIV-negative with TB	
Saint Petersburg	2	-	3	-	5
Kursk	3	1	4	-	8
Perm	1	-	-	2	3
TOTAL:	6	1	7	2	16

The staff of Andrey Rylkov Foundation, possessing a breadth of experience in qualitative surveys, conducted the in-depth interviews. The level of professionalism and the expertise of the interviewers is reflected in the high quality of the acquired data. At the same time, some of the data were missing from the questionnaires due to the overall unpreparedness among medical personnel to present data, and the absence of a system within the medical system to systematically collect data on various indicators. Thus, some questionnaires were excluded from the analysis (from 19 questionnaires, only 12 qualified for analysis).

Problems in the course of the study: Regional correspondents of “Simona+” encountered a variety of problems, when attempting to collect statistical information. The main issue was in the absence of data, tracking patients in different categories. In some regions, the issue with collecting the data was also in the strained relationships between regional correspondents (representing AIDS-service NGOs in a particular region) and local health institutions. Thus, already at the point of data gathering, the problem of access to information for the community, the wider public, and the TB service professionals arose. Regional correspondents from several cities were denied access to information on the current state of affairs in the region's TB institutions and even to general data, describing the TB epidemiology of the region.

Limitations at the stage of analyzing the data. When analyzing the study data, we focused on the three main issues, described by all respondents as the key barriers to maintaining adherence among patients with co-morbid conditions. Interviews, conducted with patients and medical professionals, gave a rich perspective and listed a wide range of problems for analysis, but because of limited resources (financial and time constraints), this report could not include all the

²⁵ More information on Simona+ is available online: <http://www.itpcorg.ru/info/484.html>

topics of concern. Unfortunately, the report does not address such important aspects of the topics discussed as: the influence of Russia's drug policy on TB spread; prisons as the main source of TB-infection; social factors influencing the quality of treatment; detailed medical aspects of the problem; the scope of informing and counseling patients; quality of drugs and the supply chain; additional co-infection with Hepatitis C and access to HepatitisC in Russia, etc. Understanding these topics is extremely important for creating a full picture of the environment in which TB treatment delivery occurs in Russia. We also would like to note, that all quantitative data were collected in in-patient clinics, thus making this report less focused on the work, conducted in out-patient facilities. This omission, in no way indicates our disregard for the importance of the work that occurs in these clinics.

1. Results of qualitative data analysis

Analysis of qualitative data (see Tables 2-5) allows an insight on the overall number of patients in 2009 and the numbers and characteristics of patients, who dropped out of TB treatment for various reasons. We were also able to establish the level of drop-out from treatment among different patient groups. As a result of data analysis, the main problems for patients undergoing treatment in hospitals were identified:

- the majority of TB/HIV co-infected patients (78%), undergoing in-patient treatment, are drug-dependent;
- the percentage of drop-out from TB treatment (30%) is very high among patients with co-infection, and especially high (41%) among co-infected patients who are also drug-dependent;
- high percent (63%) of patients, whose co-infection was first identified, while undergoing TB treatment
- among patients with co-infection, drug resistance to two or more drugs, is far more common than among other patients (30% compared to 19%);
- among all the patients who died in in-patient TB treatment, the percentage of those with co-infection was extremely high in 2009 (34%), in three cities, patients with co-infection were responsible for almost 100% of TB hospital mortality.

1.1 TB/HIV co-infection in TB institutions in 2009.

The portion of the patients with co-infection among TB hospital contingent is rather high. On average, it reaches 10%, but varies from one city to another. In five cities (Khabarovsk, Naberezhnie Chelni, Kursk, Krasnoyarsk, Zlatoust) the portion of HIV-positive patients among patients of TB hospitals was less than 10%. In Saint-Petersburg, Zima, Orenburg and Ufa, the percent of patients with co-infection was between 14 and 23%. In Orsk, co-infected patients represented almost 50% of all TB hospital patients, and in Novorossyisk, where the HIV epidemic is in much later stages, compared to other cities, co-infected individuals represented 100% of TB hospital patient population.

The survey results show that a large portion of co-infection cases is first identified when enrolling in in-patient TB treatment. On average, 63% of patients with co-infection first discovered their HIV status while in TB treatment. But in Zima (Irkutsk region), Kursk, Naberezhnie Chelni (Tatarstan) in 2009, all cases of co-infection among patients undergoing in-hospital treatment were first identified when admitted to TB treatment (100%). In Zlatoust (Chelyabinsk region) and Orenburg co-infection was first identified half of the time, and in Khabarovsk 39% of the time. In the rest of the cities, co-infection was first identified in over 70% of cases.

Table 2a. Total number of Patients in TB Hospitals, and Patients by TB and TB/HIV co-infection status (2009)

City(n (%))	Number of Patients receiving in-patient treatment in TB hospitals in 2009	The number of patients with newly identified TB*	The number of patients with co-infection*	Co-infection was first identified in 2009**
Zima	28	8 (29%)	4 (14,5%)	4 (100%)
Zlatoust	320	87 (27%)	24 (7,5%)	12 (50%)
Kaliningrad	1000	800 (80%)	-	-
Krasnoyarsk	1541	740 (48%)	65 (4%)	-
Kursk	1800	800 (44%)	10 (0,5%)	10 (100%)
Naberezhnie Chelni	1500	204 (14%)	24 (2%)	24 (100%)
Novorossyisk	61	22 (36%)	61 (100%)	-
Orenburg	689	398 (58%)	138 (20%)	69 (50%)
Orsk	200	160 (80%)	98 (49%)	80 (82%)
Saint-Petersburg	2500	1250 (50%)	350 (14%)	250 (71%)
Ufa	3000	500 (17%)	700 (23%)	500 (71%)
Khabarovsk	2700	1150 (43%)	66 (2,4%)	26 (39%)
City Totals:	15339	6119 (40%)	1540 (10%)	975 (63%)

*Divided by the total number of patients, receiving in-patient TB treatment in 2009.

**Divided by the total number of patients with co-infection in 2009.

1.2 Drop-out of patients from TB treatment programs in 2009.

The results show that the percentage of drop-out of patients with co-infection from TB treatment is near 30%. In almost all of the cities the rate of drop-out was not less than 20% and in some, it reached 100%. In Zlatoust, Orsk, and Ufa nearly 20% of patients didn't complete treatment; in Kursk and Novorossyisk this indicator was at 30%, in Saint-Petersburg at 50%, in Zima at 75%, in Krasnoyarsk 92%, and in Naberezhnie Chelni at 100%.

The rate of drop-out from treatment was especially high among patients with drug dependence: on average it was at 41%: in Zlatoust, Naberezhnie Chelni and Orsk – at 100%, in Saint-Petersburg at 70%, in Krasnoyarsk – 77%, and in Kursk -60% (see Table 2b).

Table 2b. Patients with co-infection: totals, newly identified cases, treatment drop out, and drug-dependence in 2009.

City(n (%))	Number of patients with co-infection	Number of patients with co-infection who completed in-patient treatment*	Number of drug-dependent patients with co-infection*	Number of drug-dependent patients with co-infection who did not finish treatment**
Zima	4	3 (75%)	-	2
Zlatoust	24	5 (21%)	12 (50%)	12 (100%)
Krasnoyarsk	65	60 (92%)	52 (80%)	40 (77%)
Kursk	10	3 (30%)	5 (50%)	3 (60%)
Naberezhnie Chelni	24	24 (100%)	20 (83%)	20 (100%)
Novorossyisk	61	18 (29,5%)	-	-
Orenburg	139	28 (20%)	125 (90%)	13 (10%)

Orsk	98	21 (21%)	10 (10%)	10 (100%)
Saint-Petersburg	350	175 (50%)	273 (78%)	245 (70%)
Ufa	700	125 (18%)	600 (86%)	125 (21%)
Khabarovsk	66	-	-	-
Totals:	1540	462 (30%)	1096 (78%)*	450 (41%)

* Divided by the total number of patients with co-infection in 2009

** Divided by the number of drug-dependent patients in treatment in 2009

*** Missing data were considered in these calculations

1.3 Drug treatment for patients with drug-dependence in TB clinics in 2009.

The study shows that the majority of patients with co-infection, being treated for TB (78%) are drug-dependent (see Table 2b). For example, in Zlatoust, from 24 patients with TB and HIV in 2009 exactly half were also diagnosed with drug dependence. A similar situation was observed in Kursk. In other cities, drug dependence was identified among nearly 80% of all co-infected patients. The following numbers demonstrate the share of drug-dependent patients with TB and HIV: in Krasnoyarsk – 52/65 (80%), in Naberezhnie Chelni – 20/24 (83%), in Orenburg – 124/138 (90%), in Saint-Petersburg – 273/350 (78%), in Ufa – 600/700 (86%).

The study clearly demonstrates that patients with drug dependence drop out of TB treatment more frequently than others. Drug-dependent individuals with co-infection almost never finish the course of in-patient TB treatment.

Despite these glaring facts, we received affirmative answers to the question “Do you provide drug treatment services at your hospital?” from TB professionals in only 4 cities (Krasnoyarsk, Kursk, Saint-Petersburg, and Khabarovsk). The other 9 cities do not offer such services in their TB institutions. The follow up question “What drug treatment services are provided to patients with drug dependence” yielded imprecise answers, such as “counseling,” “decreasing the manifestations of the withdrawal symptoms,” “support of remission.” But even in the four clinics where doctors stated that some form of drug treatment was provided, drug treatment was evaluated by the respondents as “ineffective.” This situation, in which drug treatment for TB patients with drug dependence is either unavailable, or ineffective, indicates a glaring gap in health service delivery in this area.

1.4 Development of resistance to two or more drugs.

One of the most serious outcomes of ineffectively organized TB treatment is the development of drug-resistant forms of TB. Drug-resistant TB was identified in 19% of patients, undergoing in-patient treatment in 2009. In Zlatoust and Naberezhnie Chelni, resistance to two or more drugs was found in less than 2% of the *total number of* patients, in Kursk and Saint-Petersburg – in approximately 8%, in Khabarovsk and Zima – up to 14%, in Kaliningrad – in 18%, in Ufa – in 33%, in Novorossyisk – in 36%, and in Krasnoyarsk and Orenburg – in 42% and 45% respectively.

However the rate of drug resistance was much higher among co-infected patients and averaged at 30%; in Khabarovsk- in 8%, in Zlatoust - in 17%, in Orenburg and Ufa – in approximately 30%, in Novorossyisk and Saint-Petersburg – in approximately 40%, and in Kursk - in 50% (see Table 3)

Table 3. Number of patients in TB hospitals and patients with identified drug-resistance (2009).

City (n (%))	Number of patients, receiving treatment in your hospital in 2009	Number of patients who were identified to be resistant to two or more drugs in 2009.*	Number of patients with co-infection in 2009.	Number of patients with co-infection who were identified to be resistant to two or more drugs in 2009.
Zima	28	4 (14%)	4	-
Zlatoust	320	5 (1,6%)	24	4 (17%)
Kaliningrad	1000	175 (17,5%)	-	-
Krasnoyarsk	1541	653 (42%)	65	-
Kursk	1800	130 (7%)	10	5 (50%)
Naberezhnie Chelni	1500	21 (1,4%)	24	0 (0%)
Novosibirsk	61	22 (36%)	61	22 (36%)
Orenburg	689	310 (45%)	138	41 (30%)
Orsk	200	-	98	-
Saint-Petersburg	2500	200 (8%)	350	140 (40%)
Ufa	3000	1000 (33%)	700	200 (29%)
Khabarovsk	2700	350 (13%)	66	5 (7,6%)
Total:	15339	2870 (19%)*	1540	417 (30%)*

* Divided by the number of patients, who received in-patient treatment in 2009

** Divided by the number of patients with co-infection in 2009.

*** Missing data were considered in these calculations

1.5 Mortality in TB Hospitals in 2009

The study shows that the level of mortality among patients of TB hospitals is extremely high, particularly among patients with co-infection. In Zima and Novosibirsk all of the patients who passed away, were co-infected, in Naberezhnie Chelni, 92% of those who died had co-infection, in Orsk – 51%, in Saint Petersburg – 57,5%, in Ufa– 38,4%, in Zlatoust - 33%, and 23% in Krasnoyarsk (see Table 4).

Table 4. Lethal outcomes in in-patient clinics in 2009.

City (n (%))	Number of patients, who received in-patient treatment in your institution in 2009	Approximate number of patients, who passed away while receiving in-patient treatment.*	Out of those who passed away, the number of patients with co-infection**
Zima	28	1 (3,6%)	1 (100%)
Zlatoust	320	12 (4%)	4 (33%)

City (n (%))	Number of patients, who received in-patient treatment in your institution in 2009	Approximate number of patients, who passed away while receiving in-patient treatment.*	Out of those who passed away, the number of patients with co-infection**
Krasnoyarsk	1541	89 (6%)	20 (23%)
Kursk	1800	50 (3%)	4 (8%)
Naberezhnie Chelni	1500	24 (2%)	22 (92%)
Novorossyisk	61	24 (40%)	24 (100%)
Orenburg	689	87 (13%)	17 (20%)
Orsk	200	67 (33,5%)	34 (51%)
Saint Petersburg	2500	200 (8%)	115 (57,5%)
Ufa	3000	250 (8,3%)	96 (38,4%)
Khabarovsk	2700	194 (7,2%)	1 (0,5%)
Total: Sum across all cities	14339	998 (7%)	338 (34%)

* Divided by the number of the total number of patients who received in-patient treatment in 2009 (see Table 3).

** Divided by the number of patients, who passed away in in-patient treatment in 2009.

2. Reasons influencing co-infected patient drop out from TB treatment programs

In the survey, TB practitioners were asked the following question: “What are the main reasons for the drop-out of patients from treatment in your institution?” In response, the following reasons were commonly cited by practitioners: “patient decided to leave the hospital,” “breaking the code of inter-hospital conduct,” “drug or alcohol use,” “refusal to be treated,” “death.” Additional in-depth interviews with patients and with practitioners were directed at understanding why patients “decide to leave” or “refuse” treatment, without finishing it, what are the reasons for their lowered motivation to be treated and what are some opportunities for having them finish the treatment with success.

As a result of data analysis, we identified the main stages at which the risk of treatment drop-out is especially high for patients with co-infection:

- The stage where the co-infection is identified and the patients are directed into HIV and/or TB treatment.
- In-hospital treatment stage.
- Periods of “transition” - when the patient is transferred from in-patient treatment into out-patient or released from prison.

Patients drop-out from TB treatment programs leads to the following negative outcomes:

- development of drug-resistance;
- a cyclical and gradually worsening condition of patient, manifested in multiple hospitalizations and the disease becoming chronic (relapse of TB infection);
- unintentional spread of TB infection within immediate social networks and eventually, outside of them to the general population ;
- death.

This report highlights the most pressing issues that cause the drop out of drug-dependent patients from tuberculosis treatment at different stages of service provision.

2.1. Drop-out at the stage of diagnosis

One of the most common problems we've observed was in the late detection and delayed initiation of treatment for HIV, and late identification of TB among patients with HIV. These delays mean that the condition of the patient necessitates the parallel introduction of TB treatment and ART. Late detection of co-infection is caused by:

- low level of access of medical practitioners to high risk groups, such as drug users;
- low contact with AIDS Centers among HIV-positive individuals – the majority of people, living with HIV do not go through regular check ups or monitor their health status;
- lack of TB diagnosis capabilities among medical institutions that frequently come in contact with drug users (such as infectious diseases clinics, district polyclinics etc.);
- complex labyrinth of patient referral from one health system service to another, overall service disintegration;
- the lengthy process of TB diagnosis.

The issue of late diagnosis of HIV, TB and the problem of poor contact between medical practitioners and difficult-to-reach populations, such as drug users, was described as the most pressing by medical professionals:

“The other 90% are left overboard: they don't know what they can do, what they should do. How can we find them? Where are they? They are in the basements and drug-dens... Our HIV-positive army is at least, 40 thousand-strong – but registered cases are just at the top of an iceberg. It's unrealistic to deal with such a workload, to find all these patients and to do something with them...” (TB Doctor, Saint-Petersburg)

Many medical practitioners mentioned, that the majority of HIV-positive patients either didn't know about their HIV status, or were not registered at an AIDS Center, before their TB diagnosis and were not regularly tested for immunodeficiency:

“We can say with confidence that up to 90% of patients with co-infection, at least here [in Saint-Petersburg], were never registered at an AIDS or infectious disease center. Knowing about their status, they were not seeking regular testing and care. The majority of our patients are in the worst stages of immunosuppression. Thus, we have unsatisfactory results with high level of lethal outcomes.” (TB Doctor, Saint-Petersburg)

Many TB practitioners said that because patients arrive in advanced stages of HIV disease with progressed immunodeficiency, initiation of TB treatment is difficult, and at the outset, envisioned treatment outcome is unfavorable. Practitioners stressed the necessity for more proactive work in establishing contact with most affected population groups, particularly strengthening harm reduction work, peer-counseling in the area of HIV

Recommendations of Russian practitioners are in line with WHO recommendations

“Pre-ART care includes harm reduction for people who inject drugs (supportive environment, opioid substitution therapy and the provision of clean needles and syringes). This not only reduces HIV transmission but has the potential to stabilize the persons' lifestyles by limiting active drug use in preparation for ART initiation.”

WHO. Antiretroviral therapy for HIV infection in adults and adolescents. Recommendations for a public health approach. 2010 Revision.

treatment preparedness and TB testing and counseling about other health issues.

Even though harm reduction programs functioned in the cities where the study was conducted, their reach and volume were severely limited, due to limitation of financial resources – all international-aid based from such sources as the Global Fund to Fight AIDS, TB and Malaria.

The lack of basic diagnostic equipment to test for TB became clear for geographically remote areas. For example, in Kursk, an AIDS Center staffer noted that in remote districts far from the city even TB skin tests are unavailable, and residents of these districts have to find time and financial resources to come and get tested in the city. In some cities, practitioners noted that the early TB detection system in AIDS Centers had a low level of effectiveness. In Kursk, a practitioner noted, that despite regulations, requiring bi-annual testing of AIDS Center patients for TB, the AIDS Center lacks any resources to conduct such testing (even though a TB doctor staff position factually exists at the center).

«[Currently, are there any diagnostic activities conducted at the AIDS Center?] At this stage, no. There is no fluorography machine, no skin tests, no trained staff. Not even a separate room. It's a problem for many centers. [Why aren't these things realized?] It's a big financial [problem].» (Infectious-diseases practitioner, Kursk).

The complex labyrinth of referrals from one service to another at the stage of diagnosis and treatment initiation, becomes a critical point of drop-out for many patients. The case below illustrates the degree of risk of drop-out, connected to the lack of cooperation between TB and infectious-diseases services:

“She [treating doctor from infectious-diseases clinic] gives me a referral [to the TB hospital]. I go there. They reject me, they say – on what grounds would we treat you? Even though I have a note from the doctor, clearly saying that I need to be tested and hospitalized. I was sick. They motivated their decision with the fact that I didn't have the X-rays of my lungs with me. I don't think that's proper motivation. They are a TB hospital, they could have made the X-rays there. Tested me there. They just ignored me. I had to sleep on the street near the hospital.” (Patient, Kursk)

Referral, as a process, requires a large investment of time and effort from the patients, forced to move back and forth between institutions, losing hope with every interaction. The bureaucratic “ping-pong” the medical establishment plays with the patients could be the main source of patient drop-out at this stage.

2.2. Patient drop-out at the stage of in-patient treatment

The quantitative data from TB hospitals showed that in some cities the level of drop-out from treatment at the in-patient stage reaches 100%, especially among drug-dependent patients. In our interviews we tried to identify the main reasons for this situation. The key issues, identified by patients and practitioners were:

- lack of specialized care for patients with drug-dependence;
- lengthy in-hospital treatment and poor conditions of hospitals;
- lacking integration between TB and infectious diseases services.

2.2.1 Lack of specialized care for patients with drug-dependence

According to the quantitative survey, almost 80% of patients with TB/HIV co-infection undergoing in-hospital treatment in 2009 were drug dependent. Drug-dependent patients drop out from treatment with a much higher frequency than others (see Table 4). In some hospitals the level of drop-out of co-infected patients with drug-dependence reached 100%. The most serious structural barrier to effective treatment of such patients and ensuring their adherence to treatment is the lack of effective drug treatment services.

TB-infected individuals can not enroll in in-patient drug treatment programs. At the same time TB hospitals lack the resources needed to alleviate or ease the symptoms of the withdrawal syndrome, or to treat drug dependence. Thus, patients with drug-dependence automatically are put into a situation where they can not receive stable TB treatment:

“If the patient has active TB, the drug treatment center won't admit this patient to alleviate withdrawal – they can't do it by law. A specialized infectious diseases ward for HIV-positive drug-dependents will also not admit such a patient, because he is infectious. And we can't do anything about his withdrawal because we don't have the medicine or a professional to deliver such intervention.” (TB hospital practitioner, Perm)

Key barriers to effective treatment of drug-dependent patients with co-infections are:

- Lack of drug treatment services at TB hospitals in the majority of the cities and ineffectiveness of these services, where they are available;
- Lack of legislative tools to provide effective treatment for drug-dependence (ban on substitution treatment programs with the use of methadone and buprenorphine in Russian Federation);
- Absence of financial and technical resources for the alleviation of the withdrawal syndrome within the current legal framework (inability to prescribe opioid analgesics in TB hospitals);
- Lack of understanding of drug-dependence among practitioners, lack of professional training and motivation to work with this group of patients.

In the majority of TB hospitals (nine out of twelve) that took part in the study, provision of drug treatment services was not envisioned in any form. It was suggested that patients, admitted into TB treatment, would resolve issues connected to withdrawal on their own.

A very subjective and stigmatizing view of drug-dependence and drug-dependent patients is common among practitioners. Medical professionals are often inclined to blame patients for their diseases. Patient drop-out is not viewed as a structural health services problem, expressed in an inability to provide adequate drug treatment, but rather as

WHO classifies drug-dependence overall and the state of withdrawal in particular, as a condition, requiring special attention and specialized medical assistance to the patient:

«Withdrawal state — A group of symptoms of variable clustering and degree of severity which occur on cessation or reduction of use of a psychoactive substance that has been taken repeatedly, usually for a prolonged period and/ or in high doses. The syndrome may be accompanied by signs of physiological disturbance. Opioid withdrawal is accompanied by rhinorrhoea (running nose), lacrimation (excessive tear formation), aching muscles, chills, gooseflesh, and, after 24-48 hours, muscle and abdominal cramps. Drug-seeking behaviour is prominent and continues after the physical symptoms have abated.

WHO

the patient's way to “act out” or as their “careless attitude towards their own health.” Typical manifestations of drug dependence often are surprising to practitioners, which demonstrates complete lack of knowledge about this medical condition among them.:

“Mainly I encounter patients who don't want to be treated. They behave badly. Consume alcohol. Break the rules. Leave the ward. I inject drugs. Or maybe sniff them, I don't know. Or just leave the hospital and that's it...” (TB hospital professional, Kursk)

Typically, practitioners described drug-dependence as a patient's whim or as their refusal to treat TB:

“[At the TB hospital] everyone is using, no one is in remission. I am surprised, because some patients come in and the doctors wonder if the person will live till tomorrow. I once helped the doctors to carry someone in. I t was a young man. In three days they were able to stabilize him and the first thing he said when he started walking was 'I need a hit!' I talked to the hospital manager and she said, 'I am doing everything I can, I prescribe everything I can, but if the patient doesn't want to be treated, I can't force him!'” (Patient, Perm)

In the case cited below, the symptomatic treatment of withdrawal with weak painkillers, initiated by practitioners, was expected to not only eliminate symptoms (pain in connection with withdrawal), but to also treat drug-dependence. Inability of the patient to fulfill the hopes of the drug treatment doctor led to the doctor's refusal to repeatedly treat the patient. The next obvious result was the patient's drop-out from TB treatment:

“And he [the patient suffering from drug-dependence] started complaining and saying that he is in so, so much pain. At first painkillers were prescribed. But it went on and on, and we thought that it should stop. The doctor looked at him and said that it should have stopped in 3-5 days. But it wasn't stopping. Then then patient started asking for drugs. I guess he remained addicted. We couldn't do anything. And then he left and we released him. I don't even remember.” (TB doctor, Kursk)

But even in hospitals where a drug-dependence specialist was on staff, the services were assessed as infective because offered interventions could not offer real relief to patients:

“We have a drug-treatment doctor, we have a social worker, we have a psychotherapist. But even this gives us very little, because in reality we lack professionals and methodologies, conditions and financial resources for conducting adequate drug treatment. And ensuring that patients stay in remission.” (TB doctor, Saint-Petersburg)

In reality, having a drug-treatment professional accessible in a TB hospital is a formality in the absence of an ability to provide real help to patients:

“We can put someone on a relanium drip, or give them some geptral**” (Infectious disease doctor, Kursk)*

* moderate strength tranquilizer also a street drug

** for easing liver function, also considered a mild antidepressant

“Q: Well, don't you have a drug treatment doctor here?”

A: Yes, we do, but we don't have the medicines, because we don't have the permission.

Q: So when someone is admitted and withdrawing, what happens to them?”

A: Nothing... Thorazine, Haldol, Pheanzepam.** Lite stuff. No drug treatment. We attempted to guide several patients through withdrawal. One was under our surveillance for 24 hours and then ran away. We had special nurses, who wouldn't let him out. He was really locked up. He couldn't leave the ward. He was left here on purpose, to try it out, because no one was injecting on our ward and we even got some half-decent medications. But still, the bastard came back on the fourth day completely high. He got out somehow. It's useless.” (Social worker, Saint-Petersburg)*

* Anti-psychosis drugs used to treat schizophrenia

**A benzodiazepine used to treat neurological disorders

“I came to the drug treatment doctor first. He said 'Ok, well, do you want me to prescribe you some dimedrol shots?' Then he came to check on me, 'Are you sleeping, are you sleeping?' I said, 'No I am not, I can barely feel this at all.'” (Patient, Saint-Petersburg)

From survey answers, it is clear that drug treatment doctors in TB hospitals are mainly there to demonstrate that a problem of drug dependence is being addressed. They are there with no other purpose, but to show that some work is being done and that there is at least some collaboration between services. The presence of a drug treatment doctor in TB clinics also has a positive psychological effect on other staff: performing a role of a buffer, drug treatment separates the drug-using patients from TB doctors and symbolically shares the responsibility for patient drop out (if a drug treatment professional couldn't handle such a patient, what could other practitioners do?).

The presence of a drug treatment specialist also puts moral responsibility on the patient. It gives medical practitioners an “out” in terms of being able to blame the patient for treatment ineffectiveness – it is easier to prove that everything is being done for the patient, but he/she is just not interested in preserving their own health. Thus, without offering a structural solution for patients with drug dependence, the health system provokes a conflict amongst patients and medical professionals and strains their relationship, with one side blaming the other for treatment failure. It is impossible to find a solution for this problem, given the way that the health system is currently organized as it creates an institutional trap for a patient: while the health system makes it impossible for the patient to complete treatment, it manages to put the blame for treatment failure on the patient.

In these conditions, when drug treatment is ineffective, patients and practitioners try to find their

own approaches to solving the problem. Patients often procured drugs while in treatment and all surveyed practitioners were well aware of drug use among patients. When the health system doesn't offer better solutions, patients and practitioners have to settle on one of their own:

“Frankly, I support it - use drugs [but] only for supporting the body. We can keep our eyes closed to this. If the person is calm and stable, and fixes at night only to support their overall well-being.” (TB specialist, Saint-Petersburg)

Patients develop various strategies, which can help them stay in TB treatment, for example, planning detoxification – on their own or with the help of professionals:

“Before I got admitted for the first time, I went to a drug treatment center to have a bit of a remission or to decrease my doze. I had a closed form of TB and the building was nearby, so the doctors negotiated that I would stay in drug treatment for a little bit to get sober. I got sober, but then I didn't have enough strength and started using again.” (Patient, Perm)

Another strategy was in changing the system of drug use, to one that is more acceptable for someone in in-patient treatment. One respondent started using street methadone – a drug that metabolizes longer than heroin:

“You use it once in two days. It substitutes [heroin] for this period. You can stretch it for a week even, and you don't need heroin.” (Patient, Saint-Petersburg)

But experience demonstrated that these “solutions” result into expulsion from TB treatment for breaking the hospital code of conduct:

“So you go somewhere to get high and then come back. You get the first warning, and then there is no second one. They just come up to you and say, 'Pack up.' What for? For drug use! No one listens to explanations. Not their problem. And no one thinks that you are off somewhere untreated.” (Patient, Saint-Petersburg)

Patients are left to their own devices to deal with drug-dependence:

“If someone is in a condition to go through withdrawal, they do it at home. Those who need special assistance, we can't provide that.” (TB practitioner, Saint-Petersburg)

Hospital discharge is the main disciplinary action taken against people, who can not treat their condition on their own. A formality, but what a functional one – the health system has created a perfect alibi – the patient carries full responsibility for his/her deteriorating condition, “refusal of treatment,” breaking the code of conduct. In the meantime, patients, unable to receive treatment for drug-dependence, are in an ultimate trap, and lacking strength to escape it:

“About those who die, there is a well-oiled system. We discharge the patient for breaking the code of conduct. He doesn't get any sort of out-patient treatment. Then we get him again in a really bad condition. We either discharge him again or he runs away. The third time he is here to die. He arrives in a condition that we can't do anything about. That's the system.” (TB hospital practitioner, Saint-Petersburg)

In the rest of the world, to ensure adherence to in-hospital and out-patient TB treatment among

patients with drug dependence, substitution therapy with methadone or buprenorphine is used.²⁶ In accordance with WHO guidelines for treating drug dependent patients with TB/HIV co-infections, substitution treatment is the key to success of treatment of patients with this trifecta of conditions. Opioid Substitution Treatment (OST) is recommended by UN General Assembly, Commission on Narcotic Drugs, UN Economic and Social Council, and International Narcotics Control Board. WHO states that among all researched drug treatment approaches, OST paired with psychological assistance was found to be the most effective. Methadone and buprenorphine are also in WHO Essential Medicines List. But Russia bans the use of substitution treatment.²⁷

The possibility of using substitution treatment in TB hospitals is considered by practitioners as a way to retain drug-dependent patients in treatment:

“[Substitution therapy] would make a person tied to the clinic. I am not trying to be sarcastic here at all. Say we have all these people laying at home thinking: 'Should I go to the TB hospital and get on those pills that make me so nauseous' –but now they have this place, where they could get relief in a form of this maintenance therapy, the pendulum would swing our way. These people would say, 'Ok, let me get myself together and get to this place.' (Infectious diseases doctor, Saint-Petersburg)

“[Substitution therapy] is just a necessity for us. I look at these guys – they are trapped. This would be their only rescue. Not for all of them, for some. I am now for substitution therapy! Not for everyone of course. Of course, very selectively. But at this point, we just need it, it's a necessity.” (Social worker, Saint-Petersburg)

While the ban on methadone and buprenorphine - essential medicines for treating drug dependence – is active, other drugs could be used for in-hospital and out-patient maintenance – agonists or agonists-antagonists, permitted for use in Russian Federation, such as tramal and nabulfin. The use of these drugs would allow at least some patients to get relief from withdrawal and remain in treatment (see analytical review of the possibility of use of these drugs in the Annex).

2.2.2 Prolonged in-hospital treatment.

Additional barriers to successful treatment of TB in patients with co-morbid conditions are in the unfoundedly long required hospital stays and in an inadequate system for out-patient support, in particular, absence of internationally acclaimed system for TB drug delivery under direct observation at home (community DOTs). Patients are forced to stay in hospitals for months; some stay for a year or even longer:

“The length of hospital stay for [in-patient] treatment is 12, 18, 24 months. If there is drug-resistance – even longer. We try to stick to these timeframes, but will the patient stick to them? To leave your family for half a year? And then we get these guys with drug-dependence, it's especially hard for them. They end up getting multiple hospitalizations: they stay, then leave, then are hospitalized again, we continue to treat them.” (Doctor, Perm)

²⁶ Page 20. Political Declaration on international cooperation against the world drug problem (UN General Assembly Resolution A/RES/64/182); see also Resolution 53/9 ratified by UN Commission on Drugs, 2010; Resolution of UN Economic and Social Council, Resolution 2004/40; International Narcotics Control Board Report 2008, pp. 24- 25; Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence WHO, 2009.

²⁷ Federal law «On narcotics and psychoactive substances», article 31(6) (January 8, 1998).

As mentioned, drug-dependence worsens the situation:

“I started at the hospital, but because I am addicted, I couldn't stay long. I was there for two months, maybe less, and then stopped. My condition became worse, I started getting fevers, in five months I had to go back to the hospital. They took me in right away. In the process, medications stopped working, I was using [drugs] at the time. They were saying that this was not helping, but I had to continue using, because I couldn't function without it. Medications were not working, TB turned into an active form, and I would go to the hospital for a little bit, then would leave. I was in a state, I couldn't figure out where to go, and was trapped in a corner.” (Patient, Perm)

Of course inadequate financial support for the hospitals and the deteriorating conditions, in which patients are forced to stay, are also an important factor. In many cities, hospitals are located in very old buildings, in dire need of repair. Conditions for patients are extremely poor. Patients named the following problems of hospital stay: overcrowding, absence of laundry facilities, lack of repairs and dampness in rooms, inadequacy of meals, lack of medications, lack of organized activities for occupying patients outside of treatment etc.

“We have 8 people per room. It should be 3-4. The patients are weak. It's hard to be among them. They are not well, they have a fever, so it's not advisable to open the windows for some fresh air. The conditions should be better. Our hospital is in need of repair, everything is old. They need more medications.” (Nurse, Kursk)

Both patients and practitioners identified the issue of poor nutrition, connected to recent budget cuts, as the most pressing:

“It was better before, now not so great. Now everything is getting cut. [When did it change?] Maybe 3-4 years ago. Before, the food was great.” (Nurse, Kursk)

“I spent a month there, and we never got any fruit. There was an order there or an article from some paper that the resources for meals should be cut. I can't tell you the exact details, but I remember that I paid attention to the fact that I think from federal budget, or somewhere else, each patient gets 50 rubles per day. I was even shocked -what can you eat for 50 rubles?” (Patient, Perm)

Practitioners and patients mentioned that the length of treatment leads to “hospitalism,” or a “treatment exhaustion syndrome,” among patients. Exhaustion from treatment and from staying in closed quarters was mentioned even by patients, who were described by staff as “conscientious”, with a set goal of getting fully treated. Based on their comments, hospital exhaustion was one of the main reasons for early leave:

“You feel stronger, like you can do something, go somewhere. But they are limiting you in what you can do. It was a problem for me. I couldn't stay still, didn't know what to do. I read, solved cross-word puzzles. Closed quarters. I felt like I was in prison the entire time. I went home. Then came back to the hospital. I thought that the doctor would discharge me, but he didn't. And the next weekend I left, and didn't come back.” (Patient, Saint-Petersburg)

For many female patients, prolonged hospital stay doesn't mix well with child care that is passed onto immediate relatives during hospitalization.

TB practitioners reasoned that the lengthy stay is often necessary because of the following: complications in the patient's condition, continued process of producing bacteria, necessity for

injecting medications, or importance of ensuring adherence to medications and screening the patient's condition. Practitioners also pointed at the absence of modern express testing systems allowing to diagnose the disease, identify bacterial activity, and drug resistance in the shortest possible time frame (some modern system allow to do this in several hours).

Systems, used in Russian Federation, stretch the time of diagnosis to several months.

Another reason that practitioners cite for retaining patients in hospital treatment is the fear to “lose” the patient because of inadequacy of out-patient treatment services. In cities where

the study was conducted, out-patient treatment services encountered great problems in retaining patients, but these problems were not included in the scope of this study, and demand separate attention and investigation. The most obvious problem is in how inconvenient out-patient service provision is for patients. The out-patient services are organized in such a way that patients are required to go to a TB clinic daily. Which demands huge time and financial investment for transportation.

At the same time, all cities that participated in the study lacked the model of delivering treatment at home. This model has already demonstrated high effectiveness in comparison to the “traditional” model of out-patient treatment not only outside of Russia, but also in Russian cities like Tomsk and Kaliningrad.

This model requires reorganization of the treatment system and puts a bigger accent on education of junior medical staff, social workers and family members, who could realize the delivery of the treatment at home.

Of course the issues connected with

organizing this type of a system in big cities, with a large patient base, should be considered. But even taking all the complexities into consideration, this model allows to avoid a whole range of problems, caused by lengthy hospitalizations – from the financial aspect of the issue to the psychological weariness of “treatment exhaustion.” For patients, suffering from drug dependence, this model combined with substitution therapy and social support would ease access to uninterrupted treatment.

WHO recommends to treat TB predominantly in out-patient settings.

According to leading international practice, hospitalization of TB patients is only conducted in rare cases, for example when:

- The patient is in critical clinical condition, demanding intensive chemotherapy and treatment of respiratory, cardiovascular, kidney and liver deficiency, coping with severe side-effects, stopping massive hemorrhages etc.
- The patient's social status is assessed as low (absence of housing, necessity for care and food, susceptibility to stigma, etc.

Azerbaijan. Protocols for treating patients with TB.

Promoting community-based care – which is accessible, well-accepted by patients, and promotes adherence (16). As WHO has recognized, “community-based care provided by trained lay and community health workers can achieve comparable results [to hospitalization] and, in theory, may result in decreased nosocomial spread of the disease. In addition, community-based care reduces burdens on health-care facilities and is more cost effective than facility-based treatment, thereby enabling governments with limited resources to serve the greatest proportion of those in need.

WHO. Guidance on on ethics of tuberculosis prevention, care and control.

2.2.3. Lacking integration between TB treatment and infectious diseases services

In the range of cities, working and collaborating with infectious disease specialists came out as one of the main problems of TB service delivery. Surveyed practitioners noted that attempts to fix this issue exist, and in some cities they have been very successful. Collaborative models can either include infectious disease specialists as consultants or provide for an infectious diseases practitioner staff position at a TB hospital. Still, many problems in collaboration between these two services are system-wide. They are:

- lack of special training and experience in treating HIV-positive patients among TB doctors;
- difficulty in arranging for CD4 and viral load testing and access to ART at TB hospitals;
- limitations in conducting TB chemoprophylaxis among HIV-positive patients in infectious disease clinics.

Lack of system-wide collaboration and informational exchange between TB doctors and infectious disease specialists was named by practitioners as one of the key issues. For example, a TB doctor from Kursk underlined the immediate need for close and stable collaboration between practitioners from different fields and the problem in the exchange of information:

“They [infectious disease specialists] come [to the TB hospital], we collect the specimens for the [HIV] tests, they take them and conduct their tests in their institution. We often have no opportunity to view the results... ART is started, chemotherapy is started. We should be in daily contact. There are complications connected with their treatment. There are some connected with mine. I am not an infectious disease specialist. I have difficulty understanding everything.” (TB doctor, Kursk)

In many TB hospitals the work with infectious disease professionals is overall inexistent. Patients are forced to organize for their own HIV-related testing, because these services are completely unavailable at the TB hospital:

“We don't have an infectious disease specialist, but we have a special counselor, and we have an agreement with the AIDS Center. According to this agreement, the counselor comes to our patients. If they don't have an active form of TB, we refer them to the AIDS Center to get updated information on CD4 testing” (TB services professional, Perm)

Another problem in organizing effective collaboration is in the lack of an officially mandated mechanism for transfer of medicines between services TB drugs are procured from the budget (federal or local) of the TB services, ART drugs from the budget of infectious disease services. This leads to infectious disease doctors having to drive out ARTs to TB clinics and rely on personal connections to TB doctors to acquire TB drugs for HIV-positive patients with TB. This leads to the inability of infectious disease hospitals to prescribe a course of TB prophylaxis for people with HIV:

“If an HIV-positive patient is suspected to have TB, he is hospitalized [in the infectious disease hospital]. But we have no budget, this hospital has no TB drugs... And the TB services can't give us the drugs: there are no mechanisms that would dictate how these drugs should be reassigned from one place to another. So that's what we have. This kind of collaboration...” (Infectious diseases specialist, Kursk)

Practitioners specified that to ensure such collaboration introducing federal regulations would be necessary. These regulations should describe the process of collaboration and interaction between services. Such regulations have been in discussion for several years, but their implementation is constantly delayed and practitioners are forced to find local solutions. The effectiveness of these solutions is conditional on personal connections between practitioners, resources of medical institutions, and the initiative displayed by the institution's leadership and practitioners.

2.3. Drop out of patient during times of transition – for example when transferring from hospitals to out-patient treatment, or being released from prison.

An additional problematic step identified, where the risk of drop-out is especially high is the process of transfer of patients from one service to another – both within the TB services, and during interaction with other institutions. Practitioners from in- and out-patient services said that the lack of functional collaboration between the institutions within the TB service presents a barrier to effective treatment, highlighted by the following problems:

- lack of solid system for collaboration and transfer of patient data between institutions (for example in the case of release from prison, or internal migration);
- lack of case management services for patients during the transfer from one TB institution to another;
- lack of preparation and motivation among out-patient clinic practitioners to work with HIV-positive drug dependent patients.

As an indicator pointing at the lack of collaboration there is a problem connected to “*vipiska*” or release. The current mechanism of preparing a “*vipiska*” - series of documents that are filled for the patient being discharged from a TB hospital (or after being treated in prison) and are sent, usually by mail - lead to a complete failure of any sort of collaboration from the start. Difficulties arise if the patient was released not because he was successfully treated, but because of code of conduct violation. In this case, the patient has no opportunity to find out the details of his or her course of treatment at the hospital or the status of his or her disease progress. The situation worsens if the patient lives in the area that is not covered by the out-patient institution where the “*vipiska*” was sent – such patients are lost for the system. When a patient is re-enrolled in a TB institution, their treatment history is a blank page. Perhaps the overall mechanism of the “*vipiska*” is not problematic, but because of the absence of the joint registry of TB patients, information exchange with the use of “*vipiska*” leads to many patients' disappearance from the reach of the TB services:

“We have a big problem in cooperation between hospitals with out-patient services. Well, the cooperation is absent. At least out-patient clinics call and ask to get a patient on a list, but the opposite end of the line is dead silent.” (Practitioner, Saint-Petersburg)

The lack of a case management system for patients, who are being transferred from one TB institution to another is a main factor, influencing patient drop-out from treatment. This factor is especially evident in situations, when a patient is being transferred from a prison TB service to a civilian sector TB institution and the other way around. The responsibility for enrolling in the civilian sector TB institution falls entirely on co-infected patients released from prisons:

“The prison sends a vipiska based on where the given patient lives, and the patient is required to come and register there. We do have TB cabinets, TB doctors in remote areas. The patient has to go there and be monitored.” (TB doctor, Kursk)

Many patients for different reasons (social dis-adaptation from prolonged imprisonment, drug dependence problems etc.) do not go to TB clinics, as required, and drop out of treatment. If a formerly incarcerated patient, doesn't appear for treatment, the mechanism for release of papers from the TB services of Federal Administration for Executing of Punishments (UFSIN) to the civilian sector TB services should be initiative. But this “one way communication” is extremely ineffective: in the labyrinth of referrals either release papers, or patients are lost:

“[When you were released from prison, did you come get tested here?] No. I had a vipiska from my medical card, where the prison TB doctor wrote, but I lost this paper. Or maybe it got stolen, I am not sure.” (Patient, Kursk)

“Well, who knows where he [the patient] will go? If he is friendly with the guards, they will hand him the vipiska. That he has had some treatment and that he needs to continue. Then he can come here, and we will figure it out. I have many of them in my sector- those who got released from prison and came here. I also have some vipiskas, just laying there, and the patients don't live at the address. They are lost somewhere, haven't made it here.” (TB service practitioner, Kursk)

Ensuring an uninterrupted supply of medications during transfer is another big problem, voiced by practitioners:

“And another big problem – getting the medications for patients that are being discharged. Because the drugs – they are a federal disability program. So when the patient is discharged, we have to send a request through Moscow. Because it's a federal program. So they wait up to two, three, four weeks for these drugs.”(Practitioner, Saint-Petersburg)

Aside from organizational problems, very pressing is the lack of special training that would prepare out-patient clinic professionals for work with HIV-positive and drug-dependent patients. Glitches in the health system often lead to hidden conflicts between practitioners from in- and out-patient services. These conflicts have the most direct impact on the patients:

“Of course there are problems at the out-patient level, and they are big problems. The attitude towards HIV-positive individuals is much worse there. It's not that they refuse to treat there, but they look for ways to refer the patient somewhere. In order not to give him the drugs, in order not to monitor him. They try, in any way possible, to send him back here to the hospital, but these attempts are completely unfounded.” (TB doctor, Saint-Petersburg)

Unfortunately, very frequently, this unwillingness to work with patients leads to disease progression and death:

“No so long ago, I don't even remember where this patient came from, but he wasn't treated at the out-patient clinic. They just wouldn't treat him. [What did they tell him? To wait?] Yes, they told him to wait for the hospital. [Because he was HIV positive?] I don't know what reasoning they had. The patient has died, unfortunately. Of course by the time he got here, our efforts were useless.” (Practitioner, Saint-Petersburg)

Conclusion

Data, interviews, and practitioner survey analysis allowed us to describe the main barriers, preventing delivery of effective TB treatment to patients with HIV, TB and drug dependence and provoking the drop-out from treatment at its various stages. The following problems are the most important and require immediate solution:

- At the stage of identifying the patients, the main issues were connected with the low level of access that medical practitioners have to difficult-to-reach target groups, such as drug users; low level of interaction of HIV-positive individuals with AIDS Centers; lack of TB diagnosing tools in medical institutions that come in frequent contact with drug users (infectious diseases clinics, district polyclinics etc.); a complex labyrinth of patient referral from one institution to another, services disintegration, leading to drop out of patients at the stage of diagnosis; time-consuming and especially lengthy process of TB diagnosis.
- At the stage of hospital treatment of TB, the key issues were found to be in the lack of specialized assistance to patients with drug-dependence, in particular the absence of methadone and buprenorphine substitution treatment programs; unfounded length of required hospital stay and poor conditions for patients; low level of integration between TB and infectious diseases services.
- At the stage of transfer from one service to another most pressing issues were seen in the lack of a concrete system for cooperation and data exchange between services (particularly in the case of release from prison and internal migration); lack of case management services for patient during transfer from one TB institution to another; lack of training and motivation among out-patient practitioners to work with HIV-positive and drug-dependent patients.

Overall, this study shows that patients encounter a multitude of problems, while undergoing treatment, the majority of which are impossible for them to resolve on their own. Practitioners are also incapable of solving the majority of these issues, because they are connected to the structural failures in the way that the health system is organized. These structural issues have to be thoroughly reviewed by public health leader of Russia. Our report offers not only a description of problems and barriers, but also key solution, introduction of which would allow to improve the conditions for medical practitioners, fighting for the lives of their patients, and also preserve the health and lives of people suffering from HIV, TB and drug-dependence.

Annex

Analytical Note: Opportunities for using Tramal (Tramadol) and Nalbufin for providing care to drug-dependent patient within the TB services system.

The use of Tramal (Tramadol) for alleviating the withdrawal syndrome in the TB service institutions is legal and possible as described by the current legislative framework. In accordance with Federal law from January 8, 1998 #3-FZ “On narcotics and psychoactive substances,” part 6, page 31, in Russian Federation treating drug addictionh narcotics and psychoactive substances in List II “List of narcotics, psychoactive substances and precursors, that are controlled in Russian Federation” (for example promedol, codein, omnopon). Tramal (Tramadol) is not in this list. Thus *the use of Tramal (Tramadol) for treating drug-dependence is perfectly legal,*

Russian standards for treating opiate dependence and managing opioid withdrawal syndrome recommend the use of Tramal (Tramadol). (Order of the Ministry of Health of Russian Federation from April 28 1998 #140 “On standards (protocol models) for diagnosing and treating narocological patients, p. 15.3-15.5)

According to a study conducted in 2008-2009,²⁸ the use of Tramal for detoxification is very common – 83% of the surveyed drug treatment doctors used this method and evaluated it as extremely effective. Some of them admitted, that detoxification without Tramal would be very difficult.

There are also no legal restrictions, stating that Tramal can only be used by drug treatment institutions. The drug can be prescribed by a drug treatment doctor and used in both drug treatment facilities and in any other medical institution (for example a TB hospital), if the given hospital has a license for providing drug-treatment services.

The only meaningful legal limitation, that concerns Tramal is that its release should be accounted for. (Order of Ministry of Health and Social Development (MHSD) of Russian Federation #109 from 12.02. 2007 “On changing the order of release of medications, ratified by the order of Ministry of Health #785”, p 3. Attachment 1.) Storing, record-keeping, and write off for Tramal (Tramadol) should be in order with attachment 5 to Order of Ministry of Health of Russian Federation 330 from 12.11.1997.

The detailed mechanism of storage, write off, according to a drug treatment doctor, includes:

“In accordance with he laws, we can store a 3 day supply of tramal on the ward; it is stored in a safe. After substantiating the use of tramal (for substantiating the use of the substance, on a drug treatment ward it's enough to give a patient the F11.30 diagnosis, i.e. diagnosis for the opioid withdrawal syndrome and describe allergies in the complaints section; there is no need to go into details, if the doctor prefers to be more detailed, they can say, for example: 'considering continuous use of opiates, prior cases of suffering connected to withdrawal; complaints that include drug craving, sweating, sneezing, diarrhea, pain in the joints; and results of an objective examination of the patient that showed moist skin, restlessness, widened pupils etc the patient needs tramal for coping with aforementioned symptoms'), the doctor makes a note in the prescription journal and signs it, also with a signature of the ward director.

²⁸ Torban M.N, Iliuk R.D., Krupitsky E.M., Haimer R. (2010) The study of drug treatment doctors and their view on the work of drug treatment services. Published by Saint-Petersburg Bekhterev Scientific Reseach Psychoneurological Institution, Page 59.

The nurse, when delivering prescriptions, also signs the prescription journal and marks the prescription in the patient's disease history. During the distribution of the drug, for each patient, we start a separate write off sheet, where we mention the patient's last name, date, time, dosing and form of the medication (pills, capsules, or liquid mixture) and the quantity of the drug (pills, capsules, or ml. of the liquid mixture), then the nurse signs this sheet and also gets the signature of the ward director. This sheet is kept for the entire time that the patient receives this medicine, then it is inserted into the patient's disease history.

After each distribution, the drug registration journal is also filled out with the date, time, patient's last name, dosage and form of the drug, quantity that was given to the patient, then the nurse signs this. And this is done for each patient for each round of giving out the medicine. The registration journal is then tabulated: how much drug did we distribute and how much we have left on the ward.

Tramadol is purchased in a centralized pharmacy for the hospital with the money allocated for medication supplies in the hospital budget. Procurement occurs through wholesale companies. If the patient has their own medicine that should be accounted for – we can't store it on our ward, because there is a problem with accountability.”

One of the inconveniences in using Tramal outside of a drug treatment clinic is the need for centralized purchasing of the drug by the medical institution as required by the rules and regulations on storage, accountability and write off.

Another possibility in the framework of TB hospitals, is the use of Nalbufin to alleviate the symptoms of the withdrawal syndrome. This drug is a short-acting opiate agonist-antagonist (should be prescribed for use twice a day). Nalbufin is not in the “List of narcotics, psychoactive substances and precursors, that are controlled in Russian Federation” and is not subjected to rigorous quantitative registry.

The use of Tramal and Nabulfin in practice of treating patients with TB/HIV co-infection could significantly ease the suffering of the patients in the framework of the current legislature. The use of these substances lacks such wide scientific or evidence base, as the use of methadone or buprenorphine.