Delivering HIV Care and Treatment for People Who Use Drugs:

Lessons from Research and Practice

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More than 1,000 patients have been receiving ART in 13 health institutions for up to 8 months, with about 15 percent of them in prisons. During this period, treatment retention has been approximately 95 percent.

The GLOBUS Project: First steps to Antiretroviral Therapy for Injection Drug Users in Russia

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Introduction

The first case of HIV infection in Russia was diagnosed in 1985, but the epidemiological situation started to significantly deteriorate in 1996, when a number of Russian regions reported serious HIV outbreaks among injection drugs users. Between 1996 and 2001, the number of new HIV cases grew rapidly, after which the registration of new infections slowed. The infection rates' rise and fall has been interpreted very differently by various analysts. Some question the decrease in incidence, noting weak surveillance systems and a significant decline in state-sponsored HIV testing concurrent with the change in reported incidence [1]. Others claim that the Russian HIV epidemic has stabilized and is developing according to a relatively optimistic scenario [2;3]. Another group views declin-

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ing incidence as temporary, attributed mainly to the epidemic's transition to a second phase characterized by transmission of HIV from primarily injection drug users (IDUs) to the general population [4]. By May 2006, the total number of officially registered cases of HIV in Russia exceeded 350,000 [5], but the actual number of infections seems to be much higher. According to UNAIDS data, a median estimate of 860,000 people are currently living with HIV/AIDS in Russia, with low and high estimates ranging from 420,000 people to 1.4 million [6;7].

Estimates of the number of HIV-related deaths in Russia during the last 10 years vary from 1,200 [2] to over 6,000 [5]. When interpreting these mortality data we should take into account that HIV infection started to rapidly spread in Russia only in the second half of the 1990s, and therefore the great majority of people living with HIV/AIDS (PLWHA) have not yet progressed to AIDS. Accordingly, the full picture of demographic losses and other consequences of HIV/AIDS for the country are not yet clear.

Estimates of the number of people in Russia in need of antiretroviral treatment (ART) vary as well. According to official data not more than 20,000 PLWHA had indications for HAART by May 2006 [2]. A number of national and international experts, however, believe that currently more than 50,000 Russians are in need of ART. As of May 2006, approximately 5,000 patients receive such treatment, meaning only about as 10 percent of the PLWHA needing therapy have access to it in Russia [5].

Institutionally, Russia's response to HIV/AIDS remains shaped by the legacy of the Soviet health system, which was characterized by a range of highly specialized vertical programs with very little horizontal integration even between closely-related subfields. The registration of the first cases of HIV in the Soviet Union in the 1980s led to the creation of a separate, centralized system of AIDS centers that bear sole responsibility for HIV testing and health care for PLWHA.

As a result of these decisions, HIV prevention and treatment was not integrated into primary health care, which undermined the system's ability to provide these services to the public and left health care providers untrained and uninformed about the disease. For many years, these centers suffered from universal underfunding, with the problem compounded by a policy that inappropriately allocated scarce resources for mass HIV screening of the population rather than for targeted surveillance of risk groups or on education, prevention, and treatment. Russia's systematic HIV testing of large population groups misses infections in the smaller high risk groups where they are most likely to occur. Furthermore, the system reports the names of those who test positive to a central registry, which likely inhibits voluntary counseling and testing because of the high level of homophobia, prejudice against drug users, general stigmatization of PLWHA, and limited availability of HIV treatments in Russia. These are the main reasons that official data on HIV incidence and prevalence, as well as the need for ART are widely considered to be understated by a significant factor [1].

The GLOBUS Project

At the end of 2004, with the financial support of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, an NGO consortium began an HIV/AIDS control program in Russia under the name GLOBUS. The overall goals of GLOBUS are to stimulate an effective national response to HIV/AIDS in the Russian Federation and to spearhead such a response in selected regions. GLOBUS pursues these goals by engaging in HIV prevention activities for the general population, youth, and vulnerable groups; providing treatment and care to PLWHA; and conducting advocacy to promote a more effective fight against the epidemic. Although, the major focus of the project is on HIV prevention, there is a significant treatment component, which is jointly implemented by the Open Health Institute (OHI) and AIDS Foundation East–West.

The major initial challenges of the HIV treatment component of GLOBUS were the high cost of antiretroviral (ARV) drugs registered in Russia, absence of national ART protocols, significant heterogeneity in clinical practice between different regions, and a traditional underestimation and under use of health personnel other than physicians. Taking into account the emphasis of GLOBUS on vulnerable populations, program implementers also recognized a crucial problem in the generally poor ability of government AIDS centers to reach IDUs or to routinely address their multiple complex needs such as overlapping comorbidities, social problems, and increased difficulties with adherence to medications. Moreover, specific clinical challenges for HIV/AIDS treatment in Russia include significant prevalence of hepatitis B and C, and tuberculosis co-infections.

Based on a comprehensive needs assessment in the 10 Russian regions covered by the program [8], the GLOBUS HIV treatment component aims to improve overall access to ART; to create conditions for sustainable HIV treatment programs; and to develop and implement a realistic model of ART for IDUs in Russia.

The first several months of the program were devoted to development of a proper supply chain and negotiations with the pharmaceutical companies to reduce ARV drug prices. Special software was developed to ensure strict individualized ARV drug inventory management. In the absence of national legislation, OHI also had to elaborate all the major documents, including treatment guidelines, and defining the GLOBUS framework of principles for HIV treatment. Taking into account the significant proportion of patients with a history of drug use, a special adherence promotion program was developed based on the experience of the Jumpstart project at Columbia Medical Center in New York City. To ensure the use of a similar approach based on accepted standards, a series of trainings was conducted with the involvement of international technical consultants for the health workers from all GLOBUS regions.

Following the development of documents and trainings, GLOBUS organized the delivery of ARV drugs and laboratory equipment to participating regions and the first

patients were started on HAART. Within several weeks after the initiation of the treatment program, international and Russian technical advisors visited all the regions to assist the treatment teams with this crucial stage of the project. Continuous technical support was provided via telephone and e-mail consultations and repeated visits of OHI experts to the regions.

ART Program Design

Treatment in all GLOBUS regions is provided at government institutions certified according to Russian legislation. In most cases, these institutions are AIDS centers, or in some cities, infectious disease hospitals. All clinical services within the framework of GLOBUS are provided free of charge. Currently, about 80 percent of the program's patients have a history of injecting drugs, including polydrug use (usually home-made opioids, heroin, vint—a form of injectable methamphetamine—and alcohol). Most of these patients have participated in some form of addiction treatment program in the past.

Despite their past addiction treatment program participation, the majority of patients are unaware of antiretroviral drugs and treatment. GLOBUS program sites have treatment teams to deal with these issues and other patient concerns, consisting of a clinician, a nurse, a social worker, and, at most sites, a trained peer educator. At all sites, AIDS center specialists are strongly encouraged to work closely with local infectious disease hospitals and TB clinics. Local harm reduction projects are actively involved in the program and provide patient recruitment from IDU populations, active social follow up, and referral.

Upon acceptance to the program, all the patients receive intensive education on HIV and the basics of HAART. For potentially problematic clients special efforts are made to adapt the complexity of interventions to the individual's ability to utilize treatment and care. For example, if the start of ART can be postponed, an active injecting drug user can at first be referred to harm reduction services and/or drug treatment.

Another common first step in the program is for patients to undergo evaluation and treatment of comorbid conditions (e.g. STI, TB) and prophylaxis of opportunistic infections to prepare them to cope with more complex ART regimens. Regular visits to the AIDS center also help the patient to adapt behavior conducive to long-term treatment. GLOBUS indications for ART are based on the WHO protocols for the CIS [9]. Generally, the preference is made toward simplified ART regimens that require taking medications twice a day [10].

All patients receive additional counseling and peer support after the start of ART. Patients receive small personal booklets with a list of scheduled events, including sched-

uled appointments and times to take medications. There are currently plans to distribute medications in segmented weekly pillboxes and focused medication adherence counseling. At the initial stage of treatment, medical staff prepare an individualized schedule of clinic visits for each patient, assess adverse side effects, and encourage adherence. Gradually patients reduce visits to the AIDS center to a monthly basis in order to collect medications, and receive clinical and laboratory follow-up. If a patient misses an appointment, an outreach worker from the local harm reduction site will make an inquiry. When patients show indications for decreased treatment adherence, additional counseling is administered, and, if judged necessary, the patient can be directed again to the AIDS center for more frequent visits.

In all GLOBUS regions, treatment is also provided in prisons on a pilot basis. The approach used there is much the same with respect to preparing the patients, counseling, clinical care, and follow-up with the only exception that ARV medications are dispensed under direct observation of prison medical personnel.

Lessons Learned

As of 2006, three rounds of ARV procurement (totaling 2,000 nine-month treatment regimens) have been successfully completed in the 10 GLOBUS regions. More than 1,000 patients have been receiving ART in 13 health institutions for up to 8 months, with about 15 percent of them in prisons. During this period, treatment retention has been approximately 95 percent. The duration of the treatment program to date is too short to draw firm conclusions about progress, and it is not yet clear which components of the project have contributed the most to its success. However, some initial lessons have been learned.

The high prevalence of comorbid medical conditions among patients suggests the need for ancillary services, including drug treatment, case management, and medical services that are not routinely available in AIDS centers. Unfortunately the existing referral system does not adequately address this issue.

The lack of antiretrovirals in most Russian cities has kept PLWHA and caregivers waiting for HAART for several years, and ART is often perceived as a last-minute lifesaving intervention. It is not yet considered by physicians and patients as an intervention that could be planned jointly and well in advance. As a consequence, initiation of treatment is often associated with concern and irrational fears. In St. Petersburg, for example, there is even a tendency to hospitalize patients for the first two weeks of treatment "to assess tolerance of and adherence to ART." The conclusion drawn from GLOBUS is that the initiation of treatment should be "demystified" in the eyes of both

patients and doctors, and the period preceding treatment initiation should be used to build mutual confidence and to plan appropriate follow up.

The current vertical organization of AIDS centers seriously limits the possibility of providing ART to people who do not live near these institutions. Special efforts should be made to gradually expand HIV treatment and care practices into the general health care system.

Finally, the legal restrictions on the use of opiate substitution therapies are a serious obstacle to expansion of ART in Russia. Access to these treatments remains severely limited and tightly controlled despite the fact that substitution therapy has been shown to reduce the use of illegal opioids, help normalize the lives of opiate dependent people, and support retention and medication adherence within HIV treatment programs. Considering the large proportion of IDUs among those who need ART in Russia, it is critical that projects like GLOBUS are replicated and expanded on a national level and given the opportunities to use all proven and effective drug treatment options available.