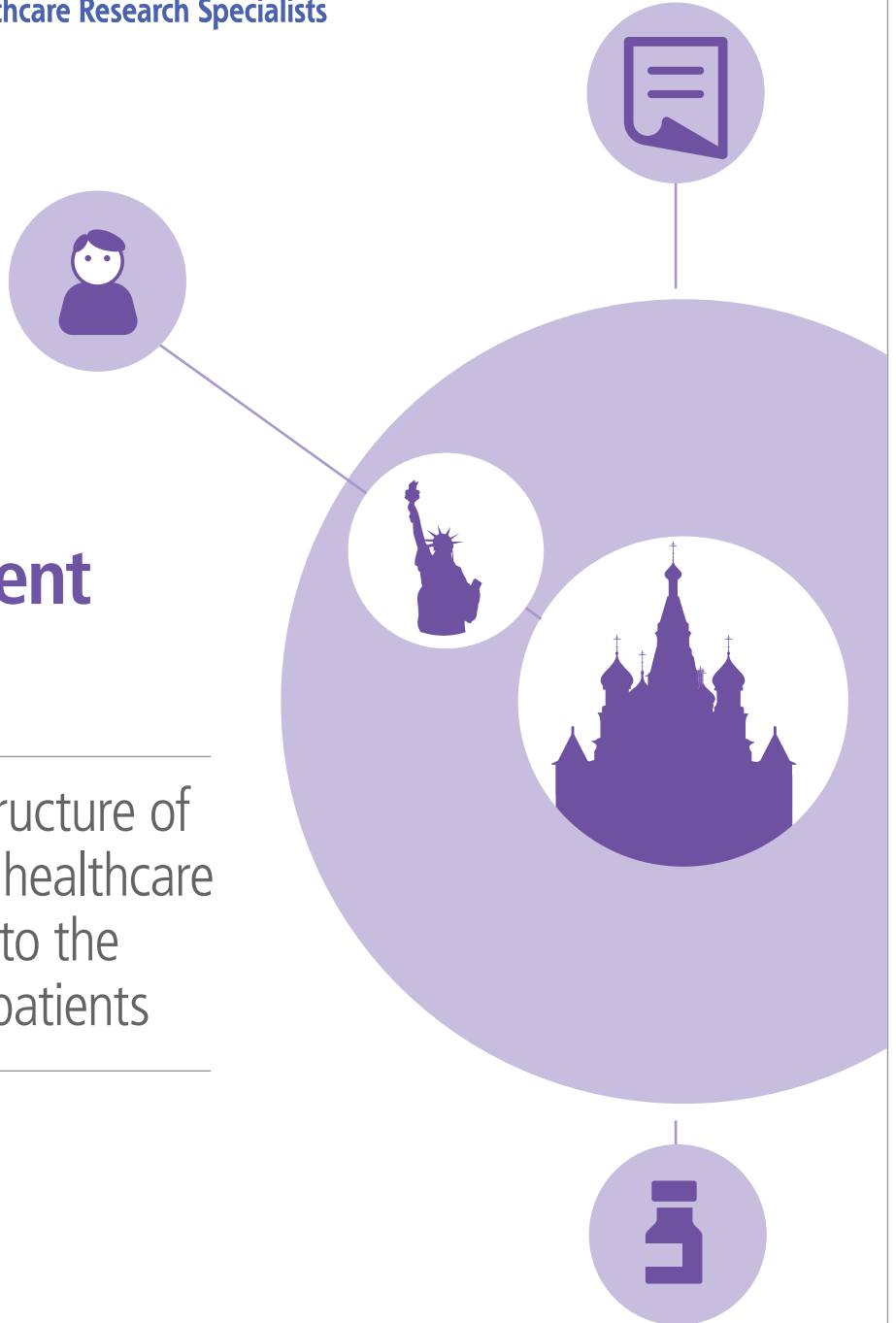




Ipsos Healthcare
The Healthcare Research Specialists



HIV Management in Russia

Examining the infrastructure of the Russian and USA healthcare systems with respect to the management of HIV patients

By The Global Virology Therapy Monitor Team,
Ipsos Healthcare

Victoria Allan

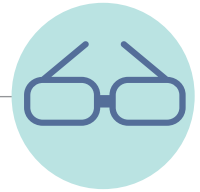
E: victoria.allan@ipsos.com

T: +44 (0)20 3059 4607



Ipsos Healthcare
The Healthcare Research Specialists

Agenda



1. Introduction
2. Epidemiology of HIV in Russia and USA
3. Healthcare funding for HIV in Russia
4. Infrastructure of healthcare system related to management of HIV in Russia
5. Treatment management of HIV patients in Russia
6. Limitations of Russian healthcare system and access to ARV treatment
7. Conclusions and Recommendations



1. Introduction

The Russian Federation today has one of the fastest growing epidemics of HIV. In 2011, an estimated 650,100¹ individuals were recorded as living with HIV and the proportion of newly-infected patients year on year is reported to be increasing continuously. In 2011, an estimated 62,385 individuals in the Russian Federation were newly infected with HIV compared to 55,475 in 2008. When this is compared to the HIV epidemic in the United States of America (USA) – although HIV prevalence rates are similar between the 2 countries (in 2011, an estimated 50,000 new infections were reported in the USA) – successful prevention schemes, awareness, education and widespread access to treatment have resulted in more stable incidence rates over time and, in particular, lower mortality rates. Although the deaths of individuals with an AIDS diagnosis can be due to any cause, in 2010 UNAIDS estimates that 15,000 people diagnosed with AIDS died in the USA. This number

is significantly lower than the estimated deaths of individuals with AIDS in Russia, which is estimated to be between 38,000-78,000 and strongly correlates with the lower treatment rates seen in Russia. Best estimates from independent world health agencies put the number of people who receive treatment in Russia as low as 30% of the total HIV diagnosed population in Russia.² Whereas in the USA it is estimated that approximately 68% of the HIV diagnosed population are receiving therapy³ and this is likely to increase in the future with new guidelines recommending that all patients (regardless of CD4 count) should be initiated onto ARV therapy.⁴

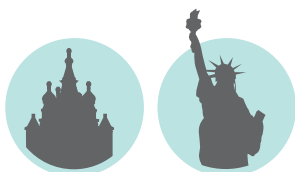
In this report, Ipsos Healthcare has used both primary and secondary research to compare the infrastructure of the healthcare systems in both Russia and the USA to understand the differences in the epidemic and how this influences the treatment management of patients.

1. <http://www.hivruusia.org/stat/2011>

2. http://aids.about.com/od/clinicaltrials/a/russia_3.htm

3. Ipsos Healthcare HIV US Therapy Monitor data Q3 2012

4. <http://aidsinfo.nih.gov/guidelines>, Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents



2. Epidemiology of HIV in Russia and USA

2.1 Prevalence

The Russian Ministry of Health and Social Development indicates that 650,100 people were recorded as living with HIV in 2011⁵, which equates to approximately 0.4% of the population. The USA reports a similar HIV prevalence rate in comparison to its population with an estimated 1.2 million⁶ people living with HIV, although almost 1 in 5 (18.1%) are not aware of their infection.⁷

2.2 Recent HIV infections

New HIV infection rates continue to increase in Russia. Within a 3-year period, from 2008 to 2011, there was a 13% increase in new HIV infections (55,475 to 62,385)⁸. Similarly, HIV-associated mortality rates in Russia also continue to rise; between 2010 and 2011 there was a 16% increase in HIV-associated deaths (15,888 to 18,473)⁹. In comparison, the overall number of new HIV infections in the USA has remained stable since 2006 at the peak of the epidemic (approximately 50,000 new infections in 2011), and HIV-associated mortality rates have decreased. HIV related deaths are estimated to be approximately 10,000 in 2011.¹⁰

2.3. Route of infection

During the socioeconomic crisis that followed the break-up of the Soviet Union in the 1990s, the main route of HIV infection in Russia was the use of non-sterile instruments amongst intravenous drug injectors, and this still accounts for about 1 in 2 HIV infections in Russia.¹¹ The majority of HIV cases in Russia are amongst males (67.6%)¹², although the proportion of females infected with HIV is believed to have increased since 2002.

This has also coincided with an increase in the proportion of HIV infections contracted through heterosexual contact. At the end of 2011, 43.7% of HIV infections were believed to have been contracted through heterosexual contact and 2 in 3 patients in this group were female. HIV infections through homosexual contact remain stable and as low as 1.3%.¹³

In the USA, the main route of infection is by homosexual contact (57%), followed by heterosexual contact (33%), with Center of Disease Control (CDC) data indicating that gay and bisexual men, as well as African Americans and Hispanics/Latinos, are the groups most heavily affected by HIV. Infection via the use of non-sterile instruments amongst intravenous drug injectors only accounted for 17% of total HIV infections in 2008 (and only 9% of new HIV infections in 2009) – much lower than the rate reported in Russia. In more recent years in the USA, there has been significant growth (21%) in the incidence of HIV amongst young individuals aged between 13-29 years, a significant proportion of which are black/African American homosexual males (MSM). As a result, 61% of all new infections recorded in 2009 were amongst MSM¹⁴ - a group which accounts for just 2% of the total USA population.

2.4 Age

When examining the age of newly infected patients, 66% of patients in Russia are under 30 years, which is a unique situation compared to other countries affected by HIV¹⁵ and correlated with high proportion of infections via IVDU. The HIV-infected population is, on average, much older in the USA where 70% of HIV patients in care are aged 36 or older.¹⁶

5. <http://www.hivrussia.org/stat/2011>

6. Center of Disease Control, <http://www.cdc.gov/hiv/resources/factsheets/geographic.htm>

7. Center of Disease Control, <http://www.cdc.gov/hiv/resources/factsheets/geographic.htm>

8. 2012 report Russian Federal HIV Center, <http://www.hivrussia.org/stat/2012.shtml>.

9. Ministry of Health and Social Development, in: 2012 report of the Russian Federal HIV Center,

10. Center of Disease Control, <http://www.cdc.gov/hiv/resources/factsheets/geographic.htm>

11. Ipsos Healthcare, Russia HIV Therapy Monitor 2012Q4

12. Country Progress Report of the Russian Federation on the Implementation of the Declaration of Commitment on HIV/AIDS (2008)

13. 2012 report Russian Federal HIV Center, <http://www.hivrussia.org/stat/2012.shtml>.

14. 2012 report Russian Federal HIV Center, <http://www.hivrussia.org/stat/2012.shtml>

15. <http://www.avert.org/aids-russia.htm>

16. Ipsos Healthcare, US HIV Therapy Monitor 2012Q4



3. Healthcare Funding for HIV in Russia

HIV/AIDS treatment and prevention in Russia are financed by state and regional budgets, as well as local and international charitable donors. Since 2000, positive steps were made by Russia in addressing HIV and, as such, funding towards prevention and treatment has significantly increased in recent years. In 2006, \$140m was allocated to HIV and viral hepatitis, which represented a 20-fold increase in funding compared to 2005. This was doubled again in 2007¹⁷.

In comparison, the Ministry of Health and Human Services in the USA reports that the federal budget available for 2012 included \$28.4 billion for domestic and global HIV/AIDS activities – a 4.7% increase from the level of funding in 2011.¹⁸ Federal funding for AIDS programs falls into five basic categories in the USA:

care and treatment; financial and housing assistance; prevention; research; and global spending, most of which goes out through the USA PEPFAR program. Of these five components, care spending is by far the largest – with a total of \$14.9 billion allocated for care and treatment programs.

The majority of AIDS care funding goes out through the federal Medicare and Medicaid programs for people who do not have private health insurance. The remainder is then principally spent on Ryan White programs that reach more than half a million people each year, improving the quality and availability of care for low-income, uninsured and underinsured individuals and families affected by HIV¹⁹.

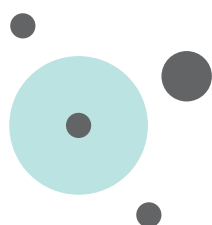
FEDERAL FUNDING FOR HIV/AIDS BY CATEGORY, FY 2007-FY 2012 (US \$BILLIONS)						
CATEGORY	2007	2008	2009	2010	2011	2012 REQUEST
CARE	\$11.0	\$11.7	\$12.4	\$13.2	\$14.1	\$14.9
CASH/ HOUSING	\$2.2	\$2.3	\$2.5	\$2.6	\$2.7	\$2.7
PREVENTION	\$0.9	\$0.9	\$0.9	\$0.9	\$0.9	\$1.0
RESEARCH	\$2.7	\$2.7	\$3.0	\$2.7	\$2.7	\$2.8
GLOBAL	\$4.4	\$5.9	\$6.5	\$6.6	\$6.6	\$6.9
TOTAL	\$21.2	\$23.4	\$25.3	\$26.2	\$27.1	\$28.4

FIGURE 3: FEDERAL FUNDING FOR HIV/AIDS BY CATEGORY. SOURCE: KAISER'S FAMILY USA BUDGET FOR 2012, 2013

17. <http://www.avert.org/aids-russia.htm>

18. 14. Kaiser Family Foundation (March, 2011) 'U.S. Federal Funding for HIV/AIDS: The President's FY 2012 Budget Request

19. 15. Center of Disease Control, <http://www.cdc.gov/hiv/resources/factsheets>



4. Infrastructure of Healthcare system related to management of HIV in Russia

The management and treatment of HIV is located within specific HIV centers in Russia, which can either be part of Infectious Disease hospitals or function alone as separate entities. By law, each federal constituent unit has to have at least one specialized HIV center in order to provide treatment to people living with HIV. Russian HIV centers typically monitor patients, provide the necessary laboratory testing, (including the determination of CD4 and viral load), carry out clinical research, prescription and monitoring of HAART, and offer counseling.²⁰ All patients who attend government-funded clinics are registered, allowing the Federal HIV center that is responsible for monitoring and carrying out statistical research to collect and accumulate accurate information on the epidemic, similar to the role of the Center of Disease Control (CDC) in the USA. Interviews with HIV patients in Russia have indicated that the requirement to join a federal register in order to receive ARV treatment does act as a deterrent to patients seeking treatment. Many patients prefer their HIV diagnosis to remain anonymous, even amongst close family members, and therefore will not seek medical advice if the anonymity of their diagnosis is at risk.

Also similar to the USA, HIV testing in Russia can be done anonymously at any medical institution or at any of the 1,200 specialized HIV testing offices located in the larger metropolitan centers. However, due to a perceived lack

of access to treatment amongst the public as well as the pervasive stigma associated with HIV and the lack of testing centers in the regions with the highest HIV infection rates, patients are often hindered from being tested.^{21, 22} HIV testing in Russia therefore, most commonly occurs as a result of incarceration or an in-patient medical visit.

Despite perceptions, Russian regulations introduced in 1995 currently outline that life-long HIV treatment is guaranteed to people living with HIV. After an initial appointment to confirm the HIV status of a patient, primary care physicians refer confirmed cases over to specialists who manage the treatment decisions for each patient. Although this patient pathway is similar to that of other Western markets, patients report that the referral pathway and getting access to anti-retroviral treatment (ART) involves a long administrative process associated with other complex bureaucratic systems.²³ In Russia, it is not uncommon for patients also to receive additional psychological assessments in order for the managing physician to decide whether the individual is stable enough to receive and adhere to therapy.

In the USA, HIV diagnostic tests are readily available at most local health department clinics, public health clinics and any doctor's office and, since 2012, it has also been possible for individuals to purchase home diagnostic test kits.

20. http://aids.about.com/od/clinicaltrials/a/russia_3.htm

21. Amirkhanian YA, Kelly JA, Issayev DD. AIDS knowledge, attitudes, and behaviour in Russia: results of a population-based, random-digit telephone survey in St. Petersburg. *Int J STD AIDS*. 2001;12:50–57. doi: 10.1258/0956462011916613

22. Balabanova Y, Coker R, Atun RA, Drobniewski F. Stigma and HIV infection in Russia. *AIDS Care*. 2006;18:846–852. doi: 10.1080/09540120600643641

23. Patient interviews 1 and 2.



5. Treatment management of HIV patients in Russia

5.1 Physician specialty/ workload

In Russia, all physicians who treat HIV are infectious disease specialists; it is estimated that there are 10,000 infectious disease specialists in Russia, but only a small proportion (between 500-700 physicians) of these actually treat HIV patients (across 85 HIV centers).²⁴ As a result, physicians who typically manage HIV patients have considerably higher caseloads in Russia (~1,500pts)²⁵ in comparison to physicians treating HIV in the USA (355 pts).²⁶ Because most patients only register to receive antiretroviral (ARV) therapy at the HIV centers in Russia, the majority of these patients are currently receiving therapy and it is difficult to source conclusive literature to understand what proportion of diagnosed patients are also receiving therapy. Best estimates from independent world health agencies put the number of people who receive treatment at about 30% of the total HIV diagnosed population in Russia,²⁷ which is lower than other markets. Of the 1.2 million people living with HIV in the USA, it is estimated that approximately 68% are receiving the therapy needed to manage the disease and keep the virus under control.²⁸

Physicians in Russia indicated that, during the initial consultation, they spent between 21-45 minutes talking to the patient;²⁹ but further follow-up consultations were shorter in length, lasting approximately 11-30 minutes, which is similar to practices in the USA.³⁰ In Russia, patients are typically diagnosed with high CD4 counts above 400/mm³ but due to the treatment practices and the lengthy bureaucratic system, patients wait around 3 years before initiating onto therapy, by which time their CD4 counts are significantly lower.³¹ In the USA, patients

wait around 1 year between diagnosis and starting first line therapy and, as a result, have healthier CD4 counts at treatment initiation.³²

5.2 Drugs and classes

According to the Ipsos Healthcare HIV Therapy Monitor, Russian physicians are very familiar with using all classes of drugs that are available in other markets, namely NRTIs (nucleoside reverse transcriptase inhibitors), NNRTIs (non-nucleoside reverse transcriptase inhibitors), PIs (protease inhibitors), and IIs (integrase inhibitors) in combination. Combivir alongside Kaletra and Stocrin currently dominate the Russian market and physicians indicate good satisfaction with these brands. The leading regimen currently used in Russia is Combivir+Kaletra, followed by Combivir+Stocrin. Most treatments are prescribed as the branded compounds, but stavudine, lamivudine, nevirapine and zidovudine are available in generic form, the use of which remains low amongst the sample recruited in the Ipsos Therapy Monitor study. Similarly, the use of generics in the US is relatively low. While there are now several drugs that are available as generics (namely, Combivir, Retrovir, Videx, Zerit, Eпивir, Ziagen, Viramune, Hivid and Rescriptor), the majority of physicians write out the brand name when prescribing ARV medication and generic substitution will occur at the pharmacy level. In contrast to the USA, Nikavir (a prodrug of Retrovir - zidovudine) is also used as part of the treatment options for HIV, securing approximately 7%³³ of treated patients in Russia. Nikavir is not available in the US and European markets as further studies are required prior to its approval.

24. Interview Russian Physician

25. Ipsos Healthcare HIV Russia Therapy Monitor data Q4 2012

26. Ipsos Healthcare HIV US Therapy Monitor data Q3 2012

27. http://aids.about.com/od/clinicaltrials/a/russia_3.htm

28. Ipsos Healthcare HIV US Therapy Monitor data Q3 2012

29. Ipsos Healthcare HIV Russia Therapy Monitor data Q4 2012

30. Ipsos Healthcare HIV US Therapy Monitor data Q4 2012

31. Ipsos Healthcare HIV Russia Therapy Monitor data Q4 2012

32. Ipsos Healthcare HIV USA Therapy Monitor data Q4 2012

33. Ipsos Healthcare HIV Russia Therapy Monitor data Q4 2012



5.3 Patient compliance

The Ipsos Healthcare HIV Therapy Monitor data indicates that patients in Russia are typically perceived to be less compliant on their ARV therapy in comparison to those treated patients in USA. Russian physicians reported that 28% of their patients were believed to be \leq 95% compliant compared to 53% of treated patients in USA. Lower compliance rates in Russia coincide with expected behavior of patients involved in IVDU, but this could also be a result of challenges within the infrastructure and the lack of availability of single tablet regimens which reduce dosing burden. Patients with poor compliance, are at a higher risk of experiencing virologic failure and building resistance to their ARV therapy. In such situations, there is a higher probability that patients will eventually need to switch therapy or fall out of care altogether.

5.4 HCV co-infection

In line with the high proportion of intravenous drug users in Russia, Hepatitis C (HCV) co-infection rates are also high. 1 in 2 HIV patients in care are co-infected with HCV in Russia,³⁴ compared to only 1 in 10 patients in the USA.³⁵ HCV co-infection does not affect HIV treatment choice, but HCV co-infected patients do typically initiate therapy with lower CD4 counts and higher viral load levels than non HCV co-infected patients.

5.5 Additional support

In Russia, not every HIV center offers non-medical/auxiliary support services to patients. While it is common to have a psychologist on-site, only federal HIV centers have legal support or support groups for the patients.³⁶ Physicians typically know about the existence of non-governmental organizations and the services they provide, but don't usually work with these institutions – and others don't see any necessity in telling patients about these facilities.³⁷ Only recently have the larger federal HIV centers started to offer non-medical support to patients.³⁸ The most recent data collected by the Ipsos HIV Therapy Monitor indicates that the majority of

physicians in the sample were able to offer their patients access to a number of different support services. 3 in 4 physicians reported offering peer support groups to patients living with HIV and their families – particularly if they were co-infected with HCV, pregnant or required mental health support (from a therapist, psychiatrist or psychologist). There did, however, appear to be a lack of support for patients suffering from addiction or who required rehabilitation. Taking into account that 1 in 2 HIV patients become infected via IVDU in Russia, there is certainly a need to improve access and availability of addiction/drug-related support programs in the future.

Feedback from interviews with HIV patients in Russia also suggested that it is not uncommon for patients without access to the necessary support programs to become proactive and organize support groups themselves, which can be financed through international programs and charities. However, due to changes in the law restricting international donations, these types of support sources are limited.

Depending on the funding available in each regional HIV center, patients also have access to a number of auxiliary services, which offer additional support to both patients and their families. Similar to the USA, typical services offered in treatment centers include dental care, gynecology assessments, peer support groups, professional mental health support, access to social worker services and administration/legal advice. Despite these services being available in some treatment centers, only 1 in 4 physicians in Russia report that their treatment center offers support to patients suffering from addictions (drug/alcohol) and/or rehabilitations needs.³⁹

Although many auxiliary services are available in the HIV treatment centers in Russia, patients do report that some appointments are not available in the same clinic/center and access to these services can be delayed and often need to be financed by the patients themselves. By comparison, patient care in the USA is covered by healthcare insurance, whereby patients typically have better access to additional support services.

34. Ipsos Healthcare HIV Russia Therapy Monitor data Q4 2012

35. Ipsos Healthcare HIV USA Therapy Monitor data Q4 2012

36. Interview Moscow 1

37. Interview Moscow 2

38. Patient interview 1

39. Ipsos Healthcare HIV Russia Therapy Monitor data Q4 2012



6. Limitations of Russian healthcare system and access to ARV treatment

With only 30% of the diagnosed HIV population in Russia currently receiving treatment, there is no doubt that there are a number of obstacles limiting the access of HIV patients to antiretroviral therapy. These barriers are not just related to the infrastructure of the Russian healthcare system but also include discriminatory attitudes towards HIV and intravenous drug users:

- Although there are over 1,200 HIV testing clinics across Russia, there is a limited number of HIV clinics and physicians treating HIV. Physician caseloads are high and waiting times between diagnosis and treatment initiation are long. On average, patients wait up to 3 years between diagnosis and treatment initiation, which is a deterrent to patients initially seeking treatment advice or initial linkage to care.
- Treatment centers are typically located in larger metropolitan cities and, therefore, many HIV patients living outside of these cities find it too difficult – financially and geographically – to travel to these treatment centers.
- Multiple stakeholders and specialists are included in the decision-making process on whether patients can receive government-funded treatments, which creates delays in the decision making.
- Although the federal government guarantees free therapy for those living with HIV, it is evident that the federal healthcare budget is unable to cover ARV treatment for all patients and additional support from international charitable donors is not enough to bridge the gap.
- Many individuals are deterred from seeking government-funded HIV treatment as they are required to add their names to a government register and are therefore unable to keep their HIV diagnosis discreet.
- Low awareness and provision of auxiliary support services for patients, which could assist patients with the demands of taking ARVs, is detrimental to treatment rates.
- 1 in 2 patients contract HIV through intravenous drug use. Poor compliance amongst treated patients in Russia also contributes to the lower treatment rate as patients are more likely to experience difficulties with their treatments and fall out of care.
- Although the epidemic is concentrated among injecting drug users, there has been a sharp increase in the number of cases attributed to heterosexual transmission and women. Longstanding stigmas associated with HIV may prevent some individuals, who are at risk, from being tested for HIV and as such many infected patients remain undiagnosed.



7. Conclusions and Recommendations

HIV/AIDS remains a key public health concern in Russia. Although government funding for ARV treatment and HIV research has increased in the last 10 years, the system is still under-funded and offers basic treatment options in comparison to USA . In addition, discriminatory attitudes also act as barriers leading to low treatment rates and poor management of the disease.

Taking into account some of the limitations and obstacles that restrict patient access to ARV therapy, there are a number of recommendations that could be considered within the current infrastructure, allowing a greater capacity of HIV+ patients to be treated in the future.

- Physician workloads are extremely high in Russia. Only a small proportion of infectious disease specialists are currently managing the treatment of HIV patients. Educating and training more physicians and nurses on how to effectively manage HIV could improve the standard of care for HIV patients in the future and improve treatment rates.
- Improving the referral process by streamlining the administrative workload and reducing the number of stakeholders involved in the decision-making process regarding treatment decision could reduce the time lag between diagnosis and initiation and increase treatment rates.
- Offering support and education to patients likely to struggle to be compliant with their ARV treatment (such as drug, alcohol and substance users) can help increase treatment rates. These more difficult-to-treat patient groups should have access to support groups and education programs which promote messages about the benefits of antiretroviral therapy and the importance of compliance; this would assist them in staying on therapy for longer. Physicians should also be given support and education on how to treat these patient groups, and could be supported in this by the pharmaceutical manufacturers.
- Different stakeholders should continue to work with local/national charities to increase awareness of HIV and remove stigma associated with the disease and this will encourage those patients at risk to take an HIV test and increase diagnosis rates.
- Improvements need to be made for patients living outside of large metropolitan cities to gain easier access to HIV-treating clinics – either through setting up new or mobile clinics and/or screening sites in high HIV infection areas, or by providing better transport connections which can support patients in travelling to the nearest HIV clinics on a regular basis.
- More patients would be motivated to seek treatment if their identity could remain anonymous and clinics could ensure that their HIV status stayed confidential.

For more details on the Global HIV Therapy Monitor please contact:

**Victoria Allan
Ayse Levent
Nicola Brookbank**

victoria.allan@ipsos.com
ayse.levent@ipsos.com
nicola.brookbank@ipsos.com

+44 (0)20 3059 4607
+1 646 313 7725

Other contributors include:
Xenia Jung-Davidov