



**HEALTH
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PROJECT**

HIV Policy Assessment:

Ukraine

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- Roman Boyko, consultant on stigma and discrimination and medication-assisted treatment
- Lilia Duma, consultant on social issues related to children and adolescents and HIV
- Zoryan Kis, consultant on men who have sex with men
- Olena Maksymenok, consultant on counseling and testing and procurement of laboratory and other commodities
- Olena Nechosina, consultant on injecting drug users and medication-assisted treatment
- Sergiy Rudyi, consultant on medication-assisted treatment and procurement of HIV/AIDS medications
- Oleksandr Savenok, consultant on gender and gender-based violence
- Marina Shevchenko, consultant on access to high-quality, low-cost drugs and procurement and supply management of HIV/AIDS drugs and commodities
- Olena Zaglada, Lead Consultant and consultant on TB/HIV co-infection
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EXECUTIVE SUMMARY

Background

Ukraine has one of the fastest growing HIV epidemics in the world, and the number of HIV cases diagnosed in the country has doubled since 2001 (UNAIDS, 2010). Ukraine's epidemic remains concentrated among most-at-risk populations (MARPs)—primarily injecting drug users (IDUs), sex workers, most-at-risk adolescents, and men who have sex with men—with over 80 percent of reported HIV cases occurring in these groups (PEPFAR, 2010).

The Government of Ukraine has recognized the importance of the HIV epidemic, and the country has demonstrated a progressive approach toward creating an enabling policy environment. The government's increased commitment to the national HIV response is evident in the increase in government funding for the HIV response. In 2008, the state provided 45 percent of total HIV funding—up from 38 percent the year before.

The 2009 Comprehensive External Evaluation identified presidential leadership (under the former President) and a strong legal foundation as important strengths of Ukraine's national HIV response. The main shortcomings noted in the area of policy reform included inconsistent implementation of national laws and legislation, exacerbated by bureaucratic regulation that hinders responsiveness to policy and changing epidemic patterns (UNAIDS, 2009). Since that time, Ukraine's legal and regulatory framework has continued to evolve. Important progress has been made, including the adoption of a new National AIDS Program and a new HIV/AIDS law.

Objectives and Methodology

The purpose of this assessment is to evaluate the degree to which an enabling policy framework for HIV exists in Ukraine, with an emphasis on HIV prevention among MARPs. USAID/Ukraine asked the Health Policy Project (HPP) to conduct this assessment to provide baseline data for measuring progress toward policy reform over the five-year implementation period of the Partnership Framework, which was signed on February 15, 2011.

Beginning in January 2011, 10 HPP consultants conducted a document review and assessment. The consultants collected and reviewed existing policy analyses and gathered an inventory of source policy documents. Following the document review, the HPP team conducted 72 key informant interviews regarding the policy environment and dissemination and implementation of policies at the national and subnational levels.

Assessment Findings

The legal and regulatory review demonstrated and key informant interviews confirmed that Ukraine has developed a strong foundation for protecting the rights of people living with HIV and providing HIV-related medical and social services to the population of Ukraine—particularly IDUs—with the support of international organizations and donor-funded projects. Key informants at the national and regional levels pointed out that many of the laws and regulations in place were developed with the support of donor-funded projects and with advocacy by international organizations.

The key findings are detailed in each section of this report ranging from stigma and discrimination to gender-based violence to policies related to IDUs and medication-assisted treatment. Gaps and barriers remain, however, including a lack of detailed mechanisms, such as operational guidelines or standards, to support implementation of many of these laws and regulations. As nearly every key informant pointed

out, at both the national and local levels “implementation, coordination, and collaboration are often left to individual personalities and interests of those involved.”

Table 1 provides an overview of the current HIV policy environment in Ukraine. Please note that the check marks do not indicate 100 percent achievement in the relevant categories, rather they are an indication of progress. Areas where progress has been particularly weak or absent have been noted.

Table 1. Snapshot of Current HIV Policy Environment in Ukraine

Policy Category	Number of relevant policies examined	Evidence of engagement of stakeholders in policy development	Evidence of ongoing data collection related to policies	Government endorsement of policy	Implementation mechanism outlined	Policy implementation	Evaluation of policy implementation
Stigma and discrimination	11	√	Weak data	√	√	Limited	None
Gender and gender-based violence	31	√	Weak data	√	Limited	Limited	None
Multisectoral response and linkages	75	√	Weak data	√	√	√	None
Injection drug users	30	√	Weak data	√	Limited	√	None
Medication-assisted treatment	13	√	Collection ongoing	√	√	√	Limited
Children and adolescents—medical services	75	√	Collection ongoing	√	√	√	Limited
Children and adolescents—social services	134	√	Weak data	√	√	√	Limited
Counseling and testing	15	√	Collection ongoing	New policies being reviewed	√	√	None
Access to high-quality, low-cost medications	91	Limited	Weak data	√	Limited	√	Limited
Procurement and supply management	91	Limited	Collection ongoing	√	√	√	Limited
TB/HIV co-infection	47	√	Weak data	New policies being reviewed	√	√	Limited

Specific barriers identified through this assessment include the following:

- MAT services have been highly controversial in Ukraine, both politically and at the service delivery level. There is a lack of guidance on the storage and dispensation of liquid methadone (which many see as a potential solution to concerns about methadone and the illegal drug trade) and significant bureaucratic burdens on MAT providers that make the service inefficient and unappealing to providers.
- While Ukrainian law protects patient confidentiality and specifies penalties for disclosure of HIV status and discrimination against PLHIV, effectively implementing and enforcing these laws to reduce stigma and discrimination remains a challenge.
- The inclusion of sexual partners of IDUs in the Partnership Framework may serve as a significant step toward reducing sexual transmission of HIV. Key informants reported that there are virtually no programs to specifically address the needs of sexual partners of IDUs.
- Centralized procurement policies and supply management systems were highlighted as a significant barrier to high-quality, cost-effective HIV services. Many key informants expressed grave concern that drugs remain too expensive and current need for ART cannot be met without reducing the cost of ART and streamlining drug distribution processes.

The new HIV law, signed by the President of Ukraine in January 2011, and the Partnership Framework signed by the USG and CMU in February 2011 are the first steps in harmonizing Ukrainian policies around HIV. USAID, through the HIV/AIDS Service Capacity Project, intends to continue supporting development of the plans and mechanisms required to implement the new HIV law. These documents open up new possibilities for developing effective mechanisms to support the implementation and enforcement of HIV-related regulations. The Partnership Framework, in particular, underscores several focus areas that will require country ownership of the national response to HIV in Ukraine.

ABBREVIATIONS

AIDS	acquired immune deficiency syndrome
Alliance	International HIV/AIDS Alliance in Ukraine
ART	antiretroviral therapy
ARV	antiretroviral drug
CD4	cluster of differentiation 4 (cell count)
CDPC	children deprived of parental care
CEDAW	Convention on the Elimination of Discrimination Against Women
CMU	Cabinet of Ministers of Ukraine
CSO	civil society organization
FP	family planning
FSW	female sex worker
GBV	gender-based violence
Global Fund	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GOU	Government of Ukraine
HCT	HIV counseling and testing
HIV	human immunodeficiency virus
HPP	Health Policy Project
IDU	injecting drug user
LGBT	lesbian, gay, bisexual, and transgender
MARA	most-at-risk adolescent
MARP	most-at-risk population
MAT	medication-assisted treatment
MOE	Ministry of Economy
MOES	Ministry of Education and Science
MOF	Ministry of Finance
MOFYS	Ministry of Family, Youth and Sports
MOH	Ministry of Health
MOIA	Ministry of Internal Affairs
MOL	Ministry of Labor
MSM	men having sex with men
NAP	National AIDS Program
NGO	nongovernmental organization
OC	orphaned children
OI	opportunistic infection
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PICT	provider-initiated counseling and testing
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission
PSM	Procurement and Supply Management
S&D	stigma and discrimination
SSCFY	Social Services Center for Family, Children, and Youth
STI	sexually transmitted infection
SW	sex worker
TB	tuberculosis
UNAIDS	Joint United Nations Program on HIV/AIDS
UNCRC	United Nations Convention on the Rights of the Child

UNDP	United Nations Development Program
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
USG	United States Government
USAID	United States Agency for International Development
VCT	voluntary counseling and testing
WHO	World Health Organization

INTRODUCTION

Ukraine's HIV Epidemic

Ukraine has one of the fastest growing HIV epidemics in the world, and the number of HIV cases diagnosed in the country has doubled since 2001 (UNAIDS, 2010). Ukraine has the highest adult HIV prevalence (1.1%) and one of the highest HIV incidence rates in Europe and Central Asia (UNAIDS, n.d.)—which, in 2009, itself had the largest increase in HIV prevalence of any region in the world. Together, the Russian Federation and Ukraine account for almost 90 percent of newly reported HIV cases in the region (UNAIDS, 2010).

In 2010, 20,489 new cases of HIV were diagnosed in Ukraine (44.6 per 100,000 population)—a 15.8 percent increase from the number of new cases reported in 2007. Around 110,000 people living with HIV (PLHIV) were under observation at the end of 2010 (56% male, 44% female) (Data of the State Service on HIV and Other Socially Dangerous Diseases). These data do not accurately demonstrate the extent of Ukraine's HIV epidemic, however, as they only include individuals who have been entered into the official register of HIV cases. The Joint United Nations Program on HIV/AIDS (UNAIDS) estimates that there are closer to 350,000 PLHIV in Ukraine. The disparity between this figure and the number of officially registered HIV cases reveals that only around one in four (28%) HIV-positive individuals in Ukraine is aware of his/her HIV status. This indicates a need to expand utilization of high-quality HIV counseling and testing (HCT) services in Ukraine. The fact that, in 2009, 49 percent of HIV cases had already progressed to AIDS by the time they were diagnosed also points to a need for improved HCT services (Ministry of Health, Ukraine, 2010).

There are significant regional variations in HIV prevalence in Ukraine, with the highest prevalence occurring in the southeast regions of the country: Dnipropetrovsk, Mykolaiv, Odesa, and Kherson oblasts (provinces), Kyiv and Sevastopol, and the Autonomous Republic of Crimea. These seven regions accounted for 70 percent of known infections in 2007. Since that time, HIV prevalence has increased in the western, central, and northern regions of the country. The growth rate of HIV incidence has declined steadily since 2006. However, between 2009 and 2010, significant increases in HIV incidence were recorded in western and central oblasts with low and moderate HIV prevalence rates, as well as in the east. Despite progress in expanding the coverage of prevention of mother-to-child transmission (PMTCT) services, vertical transmission rates remain high (6.2% in 2008), and the total number of HIV-positive children in Ukraine continues to grow (Ministry of Health, Ukraine, 2010).

Ukraine's epidemic remains concentrated among most-at-risk populations (MARPs)—primarily injecting drug users (IDUs), sex workers (SWs), most-at-risk adolescents (MARAs), and men who have sex with men (MSM)—with over 80 percent of reported HIV cases occurring in these groups (PEPFAR, 2010). HIV prevalence is also high among prison populations, and there are an estimated 10,000 HIV-positive prisoners in Ukraine (UNAIDS, 2010). The majority (65%) of males ages 15–19 who are officially registered with HIV contracted it through parenteral transmission (piercing of the skin and membranes), mainly through injecting drug use. Sexual transmission is also playing an increasing role in Ukraine's HIV epidemic. In 2008, for the first time since 1995, sexual transmission surpassed parenteral transmission as the primary source of new HIV infections in Ukraine, and most (89%) HIV-positive females ages 15–19 contracted HIV through unprotected heterosexual contact (Teltschik, 2008, p.10–11). In 2010, heterosexual transmission accounted for 45.0 percent of new HIV infections, while parenteral transmission accounted for only 33.8 percent (Ministry of Health, Ukrainian Centre for Prevention and Fight AIDS, Institute of Epidemiology and Infectious Diseases, Central Sanitary-Epidemiological Station, 2011). The overall HIV epidemic remains concentrated among MARPs (Ministry of Health, Ukraine, 2010).

Based on estimates provided by a sociological survey, there are 230,000–360,000 IDUs living in Ukraine, with approximately 175,000 suffering opiate addiction (Analytical report on the results of sociological survey “Assessment of the population of the groups at high risk of HIV infection in Ukraine” as of 2009, n.d.). IDUs are located primarily in urban areas, and HIV prevalence is significantly higher among IDUs than in any other vulnerable group (39–50%) (Kruglov, 2008). An analysis of 164,000 HIV cases in 2007 found that 41 percent of all HIV-positive adults in Ukraine are IDUs. There are promising signs that prevention programs may be starting to reduce HIV incidence among IDUs. Data from a variety of sources indicate that HIV transmission among IDUs in Ukraine is significantly decreasing (UNAIDS, 2010), and between 2006 and 2009, the number of new HIV cases among IDUs remained steady and the overall percentage of new HIV infections occurring among IDUs declined. Treatment rates for active IDUs remain low, accounting for only 7.5 percent of the total number of patients receiving antiretroviral therapy (ART) in 2009. The United Nations General Assembly Special Session on HIV/AIDS (UNGASS) country progress report attributes low treatment rates to adherence problems related to insufficient availability of substitution maintenance therapy (Ministry of Health, Ukraine, 2010). The link between sex work and injecting drug use is contributing to the growth of the HIV epidemic. Injecting drug use occurs frequently among SWs (Kruglov, 2008), and UNAIDS attributes the high HIV prevalence found among SWs (14–31%) to overlap between these behaviors (UNAIDS, 2010).

Ukraine has a large number of street youth (between 40,000 and 300,000), and little is known about HIV epidemic patterns or risk factors among this population. A community-based, multicity assessment carried out in 2010 found an 18.5 percent prevalence rate among street youth (C.L. Robbins, et al., 2010). Data from a secondary analysis of adolescent IDUs and female sex workers (FSWs) ages 13–19—from sentinel surveillance studies among MARPs carried out in 2006 and 2007—showed that the HIV prevalence among MARAs is probably much higher than the official statistics indicate. Almost 40 percent of adolescent IDU girls, 30 percent of IDU boys, 11 percent of adolescent FSWs, and 4 percent of young MSM tested positive for HIV in these studies (Teltschik, 2008, p.10–11).

Between 2008 and 2009, as a result of large-scale ART implementation, AIDS-related deaths in Ukraine declined slightly—decreasing by 2.6 percent, from 2,710 to 2,591 (Teltschik, 2008, p.10–11). In 2010, however, this trend was reversed, with the number of deaths due to AIDS-related illness rising to 3,096 (6.6 per 100,000 population) (Data of the State Service on HIV and Other Socially Dangerous Diseases).

Ukraine’s failure to achieve significant reductions in AIDS-related mortality is partially attributable to low ART coverage. Since 2004, when large-scale introduction of ART began in six regions with support from the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund), ART coverage has expanded to all 27 regions of Ukraine. In 2004, only 250 PLHIV in Ukraine were receiving lifesaving antiretroviral drugs (ARVs) (Ministry of Health, Ukraine, 2010). As of December 2009, 15,871 PLHIV were receiving treatment—9 percent of those eligible for ART under the new (2010) World Health Organization (WHO) treatment guidelines and 15 percent of those eligible under the 2006 guidelines (UNAIDS, 2010). As of January 1, 2011, 22,697 of Ukraine’s estimated 350,000 PLHIV were receiving ART. Of those on treatment, 52 percent are males and 48 percent are females (Ministry of Health, Ukrainian Centre for Prevention and Fight AIDS, Institute of Epidemiology and Infectious Diseases, Central Sanitary-Epidemiological Station, 2011). Prioritization of HIV-positive children has led to nearly universal coverage of children in need of ART (90% in 2008 and 100% in 2009). While overall ART coverage has expanded from 27 percent in 2006 to 41 percent in 2008, slow scale-up of ART remains a key challenge. Moreover, a large and growing number of PLHIV have no access to care and support services (Ministry of Health, Ukraine, 2010).

Most ART (86.3%) is funded through the state budget, and the balance (13.7%) is supported by a Round 6 grant from the Global Fund, which focuses on clients with HIV and tuberculosis (TB) co-infection and HIV/TB/IDU pathology. Global Fund resources also support ART for 681 prisoners. According to official

government service statistics, as of January 1, 2011, 30,437 PLHIV were in need of ART—of whom 8,421 (27.7%, including 119 children) do not receive ART. These figures include only patients who are under active clinical supervision and are registered in the government system of monitoring and treatment (Ministry of Health, Ukrainian Centre for Prevention and Fight AIDS, Institute of Epidemiology and Infectious Diseases, Central Sanitary-Epidemiological Station, 2011).

The lack of access to treatment is compounded by problems with the HIV drug and commodity procurement and supply management system. AIDS treatment remains expensive, and stockouts and shortages of ARVs negatively impact treatment adherence, reducing the effectiveness of the ART program. Beginning in January 2011, disruptions in the supply of ARVs have further restricted access to ART for PLHIV in Ukraine (Danilova, 2011).

Gender, stigma, and discrimination are important dynamics in Ukraine's HIV epidemic. Women in Ukraine, particularly female IDUs and women with most-at-risk sexual partners, are increasingly becoming infected with HIV, and women now account for 45 percent of new cases. Access to services is considerably restricted by societal norms and healthcare provider attitudes toward many at-risk groups, including IDUs, SWs, MARAs, and MSM. Female IDUs are also less likely to access services because, in Ukraine, the label of drug user holds greater stigma for women than for men.

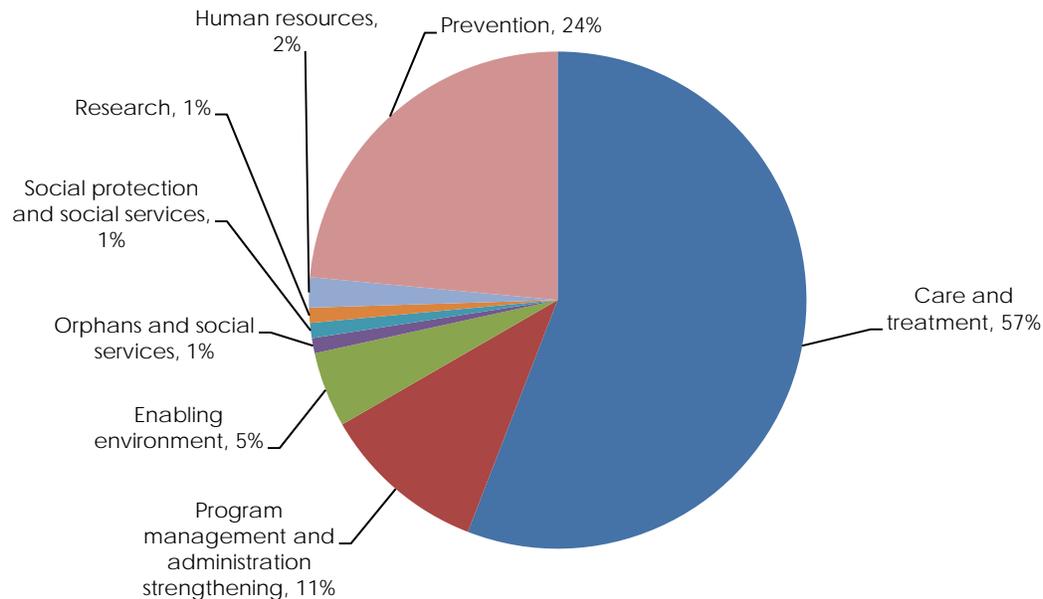
Evolution of Legal, Regulatory, and Policy Environment for HIV/AIDS in Ukraine

Funding

The Government of Ukraine (GOU) has recognized the importance of the HIV epidemic, and the country has demonstrated a progressive approach toward creating an enabling policy environment. The government's increased commitment to the national HIV response is evident in the increase in GOU funding for the HIV response. In 2008, the state provided 45 percent of total HIV funding—up from 38 percent the year before. A considerable proportion of government funding for HIV comes from local budgets (45% and 36% in 2007 and 2008, respectively). Funding for PMTCT other than for purchase of ARVs has also been shifted to the local level. Of all HIV-positive individuals receiving ART in Ukraine, 91.2 percent are being treated at the expense of the state budget. The remaining 8.8 percent of ART is supported by the Global Fund through its round 6 grant (Ministry of Health, Ukraine, 2010).

International organizations provided US\$40.5 million to support Ukraine's HIV response in 2008, accounting for 42 percent of overall HIV funding (see Figure 1). Ukraine's World Bank loan accounted for another 12 percent of funding (down from 21% in 2007). The largest international donors were the Global Fund (US\$26.8 million), the U.S. Agency for International Development (USAID) (US\$6 million), and UN agencies (US\$1.7 million). The Global Fund grant is the primary source of financial support for programs targeting MARPs (US\$8.3 million out of the US\$11.1 million from all funding sources in 2008). The funds are channeled through the two principal recipients: the International HIV/AIDS Alliance in Ukraine (the Alliance) and the All-Ukrainian Network of People Living with HIV/AIDS (Ministry of Health, Ukraine, 2010).

Figure 1. Distribution of National HIV/AIDS Spending by Program Categories, 2008¹



Legal and regulatory framework

The 2009 Comprehensive External Evaluation identified presidential leadership (under the former President) and a strong legal foundation as important strengths of Ukraine’s national HIV response. The main shortcomings noted in the area of policy reform included inconsistent implementation of national laws and legislation, exacerbated by bureaucratic regulation that hinders responsiveness to policy and changing epidemic patterns (UNAIDS, 2009). Since that time, Ukraine’s legal and regulatory framework has continued to evolve. Important progress has been made, including the adoption of a new National AIDS Program (NAP) and a new HIV/AIDS law.

In 2009, Parliament adopted the new NAP for the period 2009–2013.² The program provides for substantial increases in funding to purchase key medical supplies and allows for disbursement of resources to ministries and agencies beyond the health sector. It was developed through a multisectoral consultative process under the leadership of former Head of State, Viktor Yushchenko. Raising the AIDS program’s status to “national” gives it priority budget financing at all levels. UNAIDS and USAID supported the development of regional operational plans and budgets to implement the NAP.

Parliament adopted a revised Law on HIV/AIDS at the end of 2010.³ The law was developed through an inclusive and participatory process, seeking input from various partners at several points in its development. Signed into law by the President in January 2011, the legislation adheres to international best practices and provides clearer and more specific definitions of medical services and the rights and

¹ National Report on Monitoring Progress towards the UNGASS Declaration of Commitment on HIV/AIDS: Reporting Period, January 2008–December 2009. Ministry of Health, Kyiv. 2010.

² Law #1026–VI, February 19, 2009, “On Approval of the National Program for Prevention of HIV Infection, Treatment, Care and Support of HIV Infected People and Those Suffering from AIDS for 2009–2013”
<http://www.aidsalliance.org.ua/ru/library/global/Zakon%20Ukrainu.indd.pdf>

³ Law #2861–VI, December 23, 2010, “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population”

responsibilities of clients and healthcare providers than were included in the previous HIV/AIDS law. It also makes an important change to guidelines on HIV testing, allowing youth between the ages of 14 and 18 to undergo HIV testing without permission from a parent or legal representative.

The impact of the ongoing evolution of Ukraine's policy environment is apparent. As recently as 2005, Ukraine had no harm reduction programs in place to prevent HIV transmission among IDUs, no sexual health education in schools, and no national information dissemination strategy for HIV/AIDS (Diane DeBell, 2005, p.216). In contrast, in 2009, 58.7 percent of schools provided life skills-based HIV education, and harm reduction programs reached 52 percent of IDUs, 36.2 percent of SWs, and 63 percent of MSM (Ministry of Health, Ukraine, 2010, p.13). As discussed above, Ukraine has also made progress in scaling up ART, although there is an ongoing need to expand treatment coverage.

Stakeholder engagement

The administrative reform launched by the GOU in 2010 has the potential to enormously impact the national HIV response. As the reform process is ongoing, its actual effects remain to be seen. As part of this administrative reform, the Ministry of Health's (MOH) committee on HIV and socially dangerous diseases was given the status of a State Service. As of the drafting of this report, the functions of this State Service had not been announced. Other ministries have also undergone a streamlining process. The dissolution of the Ministry of Family, Youth, and Sports (MOFYS) is particularly relevant, as it has been actively involved in Ukraine's HIV response. The functions of the former MOFYS are currently being re-assigned.

Strong and engaged civil society organizations (CSOs) have played an important role in shifting Ukraine's policy environment in a more progressive direction. CSOs have been key advocates for medication-assisted treatment (MAT) and other harm reduction measures targeting MARPs. The GOU has been increasingly open to collaboration with civil society, as demonstrated by the inclusion of the Alliance and the All-Ukrainian Network of PLHIV as co-implementing agencies in the 2009 NAP. National and regional coordinating councils on HIV also require that an HIV-positive individual be elected as one of the deputy chairs.

Gaps and barriers in the enabling environment

While Ukraine has made strong progress in improving the HIV policy environment, major challenges remain. Political instability continues to cause frequent staffing changes at the highest levels of government, making it difficult to maintain policy reform momentum. The 2009 UNGASS report also highlights "insufficiently developed" (Ministry of Health, Ukraine, 2010, p.45) mechanisms of state funding for nongovernmental organizations (NGOs) as a weakness that hinders the sustainability of the national HIV response. It further cautions that the 2009 NAP "fails to establish clear priorities in response to the HIV/AIDS epidemic corresponding to the concentrated epidemic model in Ukraine (Ministry of Health, Ukraine, 2010, p.46)."

There is no distinct national policy and management system for procurement and distribution of HIV-related equipment and services, and quality assurance systems for HIV-related laboratory services and commodities/equipment do not yet meet international standards (Ministry of Health, Ukraine, 2010). An independent quality assessment of HIV test kits remains a key necessity. There is also a pressing need to improve blood donation systems to ensure that all donated blood is screened in a quality-assured manner. Currently, while 100 percent of blood is screened, Ukraine has not established an external quality assurance system for donated blood in accordance with international standards. As a result, in 2008–2009, no blood donated in Ukraine was screened in a quality-assured manner. To address this, in 2009, the MOH designated two laboratories to conduct external quality assurance for laboratory screening of donated blood (the Ukrainian Reference Centre for Clinical Laboratory Diagnostics and Metrology, and

the Reference Laboratory for HIV/AIDS Diagnostics at the MOH AIDS Center) (Ministry of Health, Ukraine, 2010).

Despite increases in GOU funding for HIV, state budget financing remains insufficient to support the full scope of activities outlined in the 2009 NAP. Some areas of the program are entirely reliant on the availability of regional budget funding, including procurement of medications for sexually transmitted infections (STIs), viral hepatitis, and opportunistic infections (OIs); prevention activities among MARPs; and care and support for PLHIV. In 2009, the funding shortfall was 47 percent, which was projected to grow to 48 percent in 2010. The 2008–2009 UNGASS report described the planning, budgeting, and monitoring process for government-funded HIV activities as “extremely complicated and imperfect” (Ministry of Health, Ukraine, 2010, p.45).” There are also regional disparities in coverage and quality of services, particularly voluntary counseling and testing (VCT), as a result of the decentralization of HIV budget support.

Slow implementation of MAT is another weakness in Ukraine’s HIV response. Despite expansion of harm reduction programs, several key barriers hinder effective implementation of the MAT program, including lengthy delays in approval for distributing medications and a lack of specific guidelines for using liquid forms of substitution medications. Unlawful barriers and hindrances to MAT project implementation have also been created—often by local authorities and law enforcement agencies (Ministry of Health, Ukraine, 2010). Doctors dispensing MAT have been harassed by police and forced to disclose confidential patient records (Hurley, 2010) (All-Ukrainian Network of People Living with HIV and International HIV/AIDS Alliance in Ukraine, 2011) (UNAIDS, 2011) (Human Rights Watch, 2011). Changes to regulations on drug possession at the national level have also posed challenges to program implementation, as the new regulations discourage patients from accessing MAT and expose outreach workers to charges of drug possession. The UNGASS report also notes that some narcology professionals are opposed to the MAT program because of a reluctance to assume additional work and/or concern that MAT will reduce demand for traditional narcology services (Ministry of Health, Ukraine, 2010).

Low levels of HIV/AIDS awareness among youth is another area of concern. In 2007, the former President issued a decree that included measures designed to address this issue. The decree assigned relevant ministries, namely the MOH, Ministry of Education and Science (MOES), and MOFYS, in association with the Academy of Medical Sciences and the Academy of Pedagogical Sciences of Ukraine, to do the following:

- Update the curricula of medical and pedagogical institutions of higher learning, as well as medical and pedagogical postgraduate training institutions to improve the training of both medical workers and teaching employees on HIV/AIDS; and
- Take additional measures to ensure that teaching employees and social workers are provided with information and methodological materials on HIV prevention for work with children, youth, and parents.⁴

Despite these actions, in 2009, only 40 percent of young people ages 15–24 were able to both correctly identify ways of preventing sexual transmission of HIV and reject major misconceptions about HIV transmission. Even more worrisome is that this indicator remained unchanged between 2007 and 2009. There continues to be a shortage of trained teachers and comprehensive HIV awareness-raising activities in education institutions. The 2009 UNGASS report notes that “Students of higher and secondary special education institutions, as the most sexually active age group, are currently not reached with any consistent HIV prevention measures at the national level (Ministry of Health, Ukraine, 2010, p.44).”

⁴ Presidential Decree No. 1208/2007, of 12/12/2007 "On Additional High Priority Activities on Prevention of HIV/AIDS in Ukraine" (*Article 5*).

Partnership Framework

Developed in consultation with a wide range of public sector, nongovernmental, and other donor stakeholders, a Partnership Framework between the United States government (USG) and the GOU was signed on February 15, 2011. The Partnership Framework defines goals and activities in the area of HIV programming for the next five years. Over the framework period, partnership between the governments should deepen cooperation and enhance collaboration in implementing a tactical, targeted national response to contain Ukraine's rapidly evolving and growing HIV epidemic (USG and GOU, 2011).

Purpose, Methodology, Sampling, and Steps of the HIV Policy Situation Assessment

The purpose of this assessment was to evaluate the degree to which an enabling policy framework for HIV exists in Ukraine, with an emphasis on HIV prevention among MARPs. USAID/Ukraine asked the Health Policy Project (HPP) to conduct this assessment to provide baseline data for measuring progress toward policy reform over the five-year implementation period of the Partnership Framework, which was signed on February 15, 2011. The assessment

- Documents the current state of implementation of laws, policies, and regulations affecting HIV prevention, care, and treatment access, particularly for IDUs, MSM, SWs, and MARAs;
- Analyzes the extent to which existing laws, policies, and regulations reflect international guidelines; and
- Analyzes gaps and opportunities related to the HIV policy framework, identifying areas where HIV policies could be developed, updated, strengthened, or repealed.

Beginning in January 2011, 10 HPP consultants conducted a document review and assessment. The consultants collected and reviewed existing policy analyses and gathered an inventory of source policy documents.

Following the document review, the HPP team conducted key informant interviews regarding the policy environment and dissemination and implementation of policies at the national and subnational levels. The HPP team used a semi-structured interview guide to collect data from key informants. The tool included general questions about the policy process; the crosscutting issue of legal and human rights; and specific program areas outlined in the scope of work:

- Stigma and discrimination (S&D)
- Multisectoral response and linkages
- Gender-based violence (GBV)
- IDUs and access to MAT
- Children and adolescents
- HIV counseling and testing
- Access to high-quality, low-cost medications
- HIV/AIDS drug and commodity procurement and supply management
- TB/HIV co-infection

The team conducted 72 interviews with key informants in Kyiv (45), Kirovograd oblast (7), and Mykolaiv oblast (20) between February 2 and March 4, 2011. Key informants were identified by the researchers in collaboration with USAID/Ukraine and the consultants conducting the legal and regulatory review. Key informant interviews primarily engaged national-level stakeholders and organizations based in Kyiv. However, to document the process of policy dissemination and implementation at the subnational level,

HPP also consulted key informants in one USAID priority oblast (Mykolaiv) and one non-priority oblast (Kirovograd). Selecting a priority and non-priority oblast will help identify any differences between areas where USAID has and has not been working.

Interview data were analyzed for key themes to relate findings to the legal and regulatory review. In cases of particular legal statements of interest, interview data were reviewed to identify examples of how the laws or regulations are being implemented.

POLICY SITUATION ASSESSMENT IN KEY PROGRAM AREAS

Stigma and Discrimination

The HPP assessment team examined 11 Ukrainian codes, laws, programs, and regulations to identify (1) measures that offer protection against discrimination for PLHIV and different populations most at risk for infection with HIV, (2) consequences for discriminatory practices, and (3) clauses that may exacerbate S&D of PLHIV and MARPs, such as IDUs, MSM, and MARAs.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- New HIV Law defines and protects human rights of PLHIV and vulnerable groups.
 - Protects against inappropriate disclosure in medical settings, but sanctions are unclear
 - Ensures access to services for all
 - Provides for anonymous access to HCT and MAT
- Not all stakeholders are supportive of new disclosure restrictions—providers are concerned the new measures may limit access to social services for PLHIV.
- Vulnerable groups have legal protection, but groups are not specified within the law.
- Some key informants report that discrimination is not widespread, and that instances can be easily resolved.
- Informants also noted that PLHIV and vulnerable groups may not recognize instances of discrimination.
- Data on S&D are piecemeal and unreliable, and there is no ownership of S&D monitoring and information.
- Attitudes of service providers remain poor. Reasons cited include burn out, lack of information about HIV at primary care levels, fear of HIV transmission, and working with a “difficult contingent” or difficulty maintaining productive interpersonal communication with clients.
- Legal recourse is available, but few cases are filed. Few individuals will even complain or document instances with NGOs.

General provisions for human rights of PLHIV

In general, there are significant legal measures to protect PLHIV against discrimination in Ukraine, as well as specific antidiscrimination measures and stigma reduction efforts outlined in labor, healthcare, and education sector regulations. The 2010 HIV/AIDS Law (Law 2861, hereafter referred to as the HIV/AIDS law)⁵ clearly prohibits general discrimination on the grounds of HIV status, as did the previous 1991 HIV/AIDS law.⁶ Article 14 of the HIV/AIDS law guarantees equal rights to legal protection and prohibits discrimination against PLHIV and populations at “high risk of HIV.” This article ensures that PLHIV and MARPs “enjoy all rights and freedoms, envisaged by the Constitution and laws of Ukraine.” While the 2010 law prohibits discrimination against vulnerable groups, these groups are not specified. MARPs are defined in the law as “populations at higher risk of HIV infection, due to their behavior or behavior of their social environment.” The law further specifies that the list of “populations is

⁵ Law #2861-VI, December 23, 2010, “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population.”

⁶ Law #1972-XII, December 12, 1991, “On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Legal and Social Protection of the Population.”

to be made and reviewed by a special authorized healthcare central executive body, based on WHO criteria and guidelines.”

The Criminal Code (Article 161)⁷ assigns criminal liability for actions taken that directly or indirectly limit the rights of a Ukrainian citizen based on race, skin color, political or religious beliefs, sex, ethnicity or social status, place of residence, language, or other characteristics. The new HIV/AIDS law explicitly prohibits discrimination of PLHIV and vulnerable groups. The Constitution and the HIV/AIDS law both guarantee a citizen’s right to bring a case or complaint in a court of law.⁸

One key informant consulted during the assessment noted that “sexual orientation is not currently listed in the Constitution” as a criterion for equal rights protection. The informant noted that, in the absence of rights for lesbian, gay, bisexual, and transgender (LGBT) people assured by the Constitution or by another legal document, the LGBT community has insufficient protection from discrimination. It is important to note that while the Constitution does not list sexual orientation as an explicit criterion for equal rights protection, it does include “and other characteristics” after the list of specific criteria. Health status, age, and disability are also not listed as criteria for equal rights protection. These characteristics, as well as sexual orientation, could be interpreted as “other characteristics.”

Labor sector

The rights of PLHIV have been protected in the labor sector since 1991 under the previous version of the HIV/AIDS Law. Article 16 of the 2010 HIV/AIDS Law prohibits discrimination against PLHIV and their families on the grounds of their HIV status by employers or potential employers. A draft Labor Code, which is currently being reviewed, specifically states that discrimination on the grounds of HIV status is not allowed in the workplace. The 2009 NAP⁹ includes an activity for the development of workplace HIV prevention programs; however, there does not appear to be a legal requirement that employers institute such programs or HIV workplace policies. Unions have been active in the past in developing and implementing workplace policies.

Despite these labor protections, medical workers may be unwilling to report potential exposure or request post-exposure prophylaxis (PEP). One provider reported that a nurse told him informally that she was “stuck with a needle contaminated with HIV.” He advised her to be tested and receive PEP, but she refused, explaining “I don’t want anyone to know. If I do end up with HIV, they will fire me.”

There are restrictions on the employment of people who use opioids on the grounds of drug use. If mandatory treatment is prescribed for a person with drug dependence, this individual may be dismissed from his/her place of employment or expelled from an educational institution or program.¹⁰

Healthcare sector

The 1991 and 2010 HIV/AIDS laws both prohibit “rejection in admission to... medical care facilities” or “denial of health and social services” based on the grounds of HIV status or status of family members of PLHIV. However, these rights were not accorded to MARPs until the revised version of the law was adopted in 2010. The 2010 HIV/AIDS Law also goes a step further than the 1991 law—assuring that PLHIV and MARPs must not be discriminated against in the provision of these medical services and are accorded equal rights in the provision of care.

⁷ Criminal Code of Ukraine: Law #2341–III, May 4, 2001.

⁸ Constitution of Ukraine: Law #254k/96–BP, June 28, 1996.

⁹ Law #1026–VI, February 19, 2009 “On Approval of the National Program for Prevention of HIV Infection, Treatment, Care and Support of HIV Infected People and Those Suffering from AIDS for 2009–2013.”

¹⁰ Law of Ukraine “On Measures to prevent the illicit circulation of drugs, psychotropic substances and precursors and use and abuse thereof.”

Article 132 of the Criminal Code protects the confidentiality of PLHIV from improper disclosure of their HIV status by a medical worker. This article of the Criminal Code is specifically related to HIV and carries with it a harsher penalty than violating the confidentiality of a patient with another disease. Key informants from the All-Ukrainian Network of PLHIV, an organization providing legal support to protect the rights of PLHIV, report that “despite the fact that they know of many violations of PLHIV rights to confidentiality, they do not know of any instance in which a patient filed a grievance against a physician in violation of Article 132 of the Criminal Code.” Patients will complain to the network and their affiliates, but then state, “I still have to continue to receive treatment from that doctor, so I will not bother filing a complaint.”

Key informants at the national and regional levels stressed the importance of training medical workers as well as PLHIV about discrimination in healthcare and social services. USAID-funded projects in Ukraine and Global Fund grant recipients have been training service providers and educators about HIV and the importance of reducing discrimination and adopting a “tolerant attitude to PLHIV.” Several innovative examples were cited, including a project in Mykolaiv that is training primary health doctors to work with IDUs, youth, and PLHIV, so that AIDS Centers are not the only specialists prepared to provide high-quality services to PLHIV and MARPs. As AIDS Centers are only available in oblast capital cities, the project hopes this will provide PLHIV and vulnerable groups with other options for healthcare closer to home. A project in Mykolaiv for HIV-positive women and women at risk of contracting HIV, specifically female IDUs and FSWs, is providing counseling and training to their clients to help reduce S&D in health facilities. They described the services as

- Helping to reduce internal stigma,
- Helping clients to trust medical workers, and
- Building clients’ skills in interpersonal communication with medical workers.

The project explained that this interpersonal communication component was added after they found—through discussions with medical workers—that S&D was being fueled by the perception that clients were “demanding” and poorly communicating their needs. The project is helping women serve as more effective self-advocates for care.

Education sector

The 1991 HIV/AIDS law prohibits “rejection in admission to...educational institutions and social services” based on the grounds of HIV status or status of family members. However, beyond this, it does not include any special prohibitions or guidelines regarding how HIV-positive students are to be treated once they are admitted to an educational institution. A 2008 Presidential Decree to the MOES required the ministry to introduce measures to overcome and prevent stigmatization of HIV-positive children to ensure their ability to exercise their right to education.¹¹ A Joint Order issued by different ministries (2007) stipulates that HIV-positive children attend education facilities “on common terms” with all children.¹² The HIV/AIDS Law also guarantees inclusion of subjects related to S&D and stigma reduction in the curricula of secondary, vocational and technical, and higher education facilities. The development and implementation of these curricula, though, is dependent on financing through the NAP. Some schools and regions, such as Mykolaiv, are already implementing school-based and out-of-school programs to educate students in primary and secondary school about HIV and reduce HIV-related S&D.

¹¹ Presidential Decree #411/2008, May 5, 2008, “On Additional Measures to Ensure Protection of Rights and Legal Interests of Children” (*Paragraph 4*).

¹² Joint Order #740/1030/4154/321/614a of the MOH, MOES, MOFYS, State Department for Enforcement of Sentences, and the MOL, November 23, 2007, “On actions regarding the organization of HIV mother-to-child transmission prevention, medical care and social assistance for HIV-positive children and their families.”

Legal and regulatory measures provoking stigma and discrimination

Recently, the MOH adopted an order that substantially reduces the legal amount of opiates which, if found in an individual's possession, constitutes a criminal offense.¹³ This provision may actively promote discrimination and act as a barrier to services for IDUs. Key informants noted that the provision permits continued criminalization of IDUs and contributes to perceptions of IDUs as criminals—this, in turn, contributes to increased S&D. Key informants also noted that this has discouraged IDUs from accessing needle and syringe exchange programs and may also discourage IDUs from seeking other medical services.

Another regulation that may actively promote discrimination is the provision of increased pay to healthcare workers providing services to PLHIV, clients with TB, and clients at narcology clinics.¹⁴ According to this regulation, employees of AIDS Centers receive an additional 60 percent of base pay as a premium; workers at other health facilities who work directly with PLHIV or HIV-infected materials receive a 60 percent premium for the time they spend on these procedures. Staff at TB dispensaries will now also receive up to an additional 60 percent of base pay as a premium.¹⁵ Narcology staff also receive premiums in the amount of 25 percent of base pay and clinicians in narcology units receive premiums for time spent with PLHIV. These premiums are granted “due to harmful and difficult working conditions.” Medical workers often refer to this additional pay as “hazard pay.”

Addressing stigma and discrimination through the National AIDS Program

The 2009 NAP includes action plans for various ministries, which address S&D to different degrees. For example, the MOES action plan includes a few activities with the goal of reducing S&D in society through efforts in the education sector. These activities include introducing an “optional course” in secondary education on HIV prevention and incorporating a module on “development of tolerant attitudes toward HIV-positive children” into the postgraduate training for teachers and managers in preschools and secondary schools. The action plan does not include any activities addressing the development or implementation of curricula to address S&D of MARPs in secondary, higher education, or postgraduate (medical, teacher, etc.) training. It is important to note that implementation and monitoring of these programs and activities remains limited and, in many cases, unfunded. There is an overall lack of specificity that would increase the protective effect of many of these measures.

The 2009 NAP and the MOH action plan for implementing the program include activities to reduce manifestations of S&D against “risk groups” demonstrated by “associates of the services of healthcare, labor, and social services.” This does not include specific mention of private sector and security forces, nor are there any provisions for including PLHIV as trainers.

Involvement of PLHIV and MARPs in the policy process

While it was not in the mandate of this team to assess the level of meaningful involvement of PLHIV in the policy process, the team did assess legal and regulatory provisions for inclusion of PLHIV, as meaningful involvement of PLHIV and affected communities is considered as a programmatic tool for stigma reduction. Some limited provision for inclusion of PLHIV in the policy process is made through representation on the National Council for HIV and TB. A July 2007 order of the Cabinet of Ministers of Ukraine (CMU)¹⁶ stipulates the inclusion of a Deputy Council Chair as a representative of “CSOs of the people living with TB or HIV (upon consent)” as part of the National Council on HIV and TB. This

¹³ MOH Order #634, July 29, 2010, “On Amending the Order of the Ministry of Healthcare of Ukraine as of 08. 01. 2000 # 188.”

¹⁴ MOLSP and MOH Joint Order #308/519, May 10, 2005, “Terms of payment of employees of health and social care institutions.”

¹⁵ CMU Resolution #123, February 16, 2011 (enters into force on July 1, 2011), “On some measures to increase the prestige of medical staff, who provide medical care for TB patients.”

¹⁶ CMU Act #926, July 11, 2007, “Selected Matters of Response to TB and HIV Infection and AIDS.”

individual is elected by the other council members, which raises questions as to the actual representativeness of this “inclusion,” as it is not clear that PLHIV themselves have a say in naming their representative. As described below,¹⁷ the national council has been a largely ineffectual mechanism, focused mainly on Global Fund business. This brings into question the extent to which PLHIV representation in the council actually enhances overall inclusion of PLHIV in the policy process. At the regional level, the 2007 order stipulates the establishment of regional HIV councils and recommends inclusion of PLHIV as representatives. As described below, the operational of regional councils and the inclusion of PLHIV differs by region. Not all oblasts have active councils, nor do all oblasts facilitate the participation of PLHIV and CSOs in the policy process. No measures are in place to encourage inclusion/involvement of vulnerable groups in the policy process at either the national or regional level.

Implementation and enforcement

The HIV/AIDS Law states that “liability for violating laws protecting the rights of PLHIV entails disciplinary, civil, administrative, or criminal liability, as defined by the laws of Ukraine.”

While there is a mechanism for documentation and accounting of cases of S&D against PLHIV and vulnerable groups, these mechanisms are not governed by the state. Various NGOs and projects have developed and maintained registers of S&D cases (e.g. “Gidnist,” “LIGA,” and the All-Ukrainian Network of PLHIV). These registers have primarily been used for advocacy rather than to prove liability. Some CSOs provide legal counseling and services to PLHIV and MARPs, but these organizations report that clients often do not want to proceed with filing a formal complaint or lawsuit. Often, these clients see no alternative to continuing to interact with the doctor or other official that violated their rights and do not want to “make the situation worse.” Additionally, no measures provide for assessment of stigmatization of either vulnerable groups or PLHIV. There are also no indicators to measure implementation or enforcement or even success in reducing S&D in the NAP.

Multisectoral Response and Linkages with Other Health and Development Programs

The HPP team reviewed 75 Ukrainian laws, codes, regulations, standards, protocols, and guidelines to assess whether policies, mechanisms, and coordinating bodies at the national and subnational levels support linkage of HIV/AIDS programs with other health programs, including maternal and child health, safe motherhood, TB, STI, and narcology programs; and whether HIV/AIDS programs in the health sector link to other sectors, such as social services and education.¹⁸ The team also assessed policies that facilitate participation of the private sector and civil society, including faith- and community-based organizations and women, PLHIV, IDUs, MSM, SWs, and MARAs, in the development and implementation of HIV/AIDS programs.

Summary

National- and regional-level coordination

There are mechanisms for national and regional coordination on HIV/AIDS and TB in Ukraine with broad multisectoral representation.

¹⁷ See this report’s section titled “Multisectoral Response and Linkages with Other Health and Development Programs.”

¹⁸ The review of linkages between TB and HIV programs is presented in the “TB/HIV Co-Infection” section of this report on page 52. A review of linkages between narcology and HIV programs is presented in the “Injecting Drug Users” section on page 22. A review of linkages between CT sites and AIDS Centers is presented in the “HIV Counseling and Testing” section on page 40.

- National Council on HIV/AIDS and other socially dangerous diseases under the CMU
 - Deputy Chair is from the PLHIV community
 - Questionable participation from other ministries
 - Primarily focused on Global Fund business
 - Currently not seen as a forum to “discuss and resolve problems”
- Regional coordination councils
 - Deputy Chair is typically from a CSO or PLHIV community
 - Activity and success varies by region—many at the national and regional levels cited USAID assistance to coordination councils as critical
 - Success varies by strength of NGO presence in the region and at the council meetings, as well as the leadership of government participants

Multidisciplinary coordination

- Coordination is dependent on individuals involved at the political and service delivery levels.
- Key informants noted that it seems other ministries do not perceive a need or requirement to implement MOH decrees, even those that are approved by the Ministry of Justice.
- National-level participation of most ministries other than the MOH is weak, with the exception of the MOFYS.
- The Ministry of Internal Affairs (MOIA) sees itself playing a drug control role in relation to HIV/AIDS, rather than acting as a partner in public health.
- Coordination in providing care and support to PLHIV has improved.
- Referral and information sharing still requires attention—particularly in relation to diagnosis, case management, and infection control for HIV/TB coinfection.
- There is no routine in-service clinical training on HIV/AIDS.

Procurement of NGO services by government

- A legal and regulatory base for procurement of NGO services exists.
- Political will is critical at the national and regional levels—some key informants questioned whether NGOs are actually doing any work; other key informants from the public sector state that NGO services are integral to a national and regional response to HIV.
- The Mykolaiv Oblast’s department of Social Services is currently pilot testing a procurement of NGO services through a small grants program.

Legal provision for multisectoral linkages

Ukrainian legislation is guided by international conventions and legal instruments recognizing the effectiveness of multisectoral approaches in the areas of HIV prevention, treatment, care, and support and protection of the rights of PLHIV. Multisectoral collaboration in the area of HIV/AIDS in Ukraine is regulated at the legislative, intersectoral, and regional levels.

The 1991 HIV/AIDS Law of Ukraine¹⁹ envisaged collaboration between different sectors at the national and subnational levels. Article 5 of this law established the authority of executive bodies, local governments, institutions, and organizations to implement HIV activities. It assigned responsibility for coordination to a specially established central executive body in the area of healthcare. In 2006, the Ukrainian AIDS Center at the MOH was assigned to perform the management, coordination, and monitoring of HIV/AIDS prevention and response activities.²⁰ The 2009 NAP envisages the continued strengthening of multisectoral approaches to address HIV/AIDS.

¹⁹ Law #1972–XII, December 1991.

²⁰ MOH Order #225, April 14, 2006.

The current 2010 HIV/AIDS Law²¹ establishes the government's guarantee to provide more effective services by working through different sectors. This law focuses particularly on the provision of services through the involvement of organizations of different forms of ownership, including civil society, charity, faith-based organizations, and trade unions. The 2009 NAP and 2010 HIV/AIDS law demonstrate high-level commitment to mitigating the impact of HIV on Ukrainian society. According to key informants, however, there is still much to be done to engage high-level political leaders and other influential people and sustain their involvement to address HIV challenges.

National coordination

The National Coordination Council on HIV/AIDS under the CMU was established in 2005. This strategic decision was originally intended to create a high-level national coordinating body to encourage partnership between the government, civil society, PLHIV, and international organizations. However, the CMU determined that the National Coordination Council would play only an advisory and consultative role, without authority to implement its coordination decisions. The name of the council was changed to reflect this lack of a coordination role. The national council has broad multisectoral representation from a variety of ministries, as well as NGOs, academia, religious organizations, and the PLHIV community. Several key informants noted that other ministries, such as the Ministry of Internal Affairs and the MOES, send different representatives every time and that the representatives are not actively engaged in proceedings. With the exception of the former MOFYS, the participation of other ministries was characterized by key informants as "sporadic, ineffective, and low-level." For example, one key informant explained that most ministries do not feel obligated to implement or enforce decrees or orders issued by the MOH, even if they are approved by the Ministry of Justice.

A variety of ministries, such as the MOIA and Ministry of Finance (MOF), can have a tremendous impact on HIV policy and policy implementation. For instance, the MOIA has sent its staff to audit NGOs and government facilities providing services to IDUs, and many key informants at all levels noted that it is important to ensure adequate engagement and ownership of the national response to HIV across ministries. The United Nations Development Program (UNDP), UNAIDS, USAID, and others have led HIV policy and governance initiatives across sectors.

The Deputy Chair of the national council represents the PLHIV community; however, the Deputy Chair is elected by the entire council rather than being selected by the PLHIV community alone. According to key informants (as well as the minutes of council meetings), the council is primarily focused on Global Fund business, such as approving quarterly reports and grant proposals. Several key informants representing both the government and nongovernmental sectors noted that the council is "currently not a forum to discuss and resolve problems."

Regional coordination councils

Regional and local coordination councils have been established in the oblasts and raions (districts) of Ukraine. They include representatives of different organizations involved in the HIV/AIDS response in each region, including religious organizations and service providers. The Deputy Chair typically represents the CSO or PLHIV community. The oblast and raion councils function with little to no support from the National Council, but some oblasts have been actively supported by donor-funded projects. In regions with this support, such as in Mykolaiv, the coordination council can be a highly effective mechanism despite a lack of additional resources to operate or participate in the council. Key informants also noted that success of the coordination council varies according to the strength of the NGO presence and the leadership of government participants. A government representative in Mykolaiv explained that

²¹ Law #2861-VI, December 2010.

“The regional coordination council is a very useful, helpful mechanism for collaboration and coordination as well as for addressing problems. Collaboration is something that hasn’t been stressed in our system in general. We are very thankful to the NGO sector—they know about the issues and help design solutions.”

In contrast, the Kirovograd Oblast Coordination Council had not met in the six months prior to this assessment, and some representatives from the NGO sector did not consider their voices to be adequately considered during the council meetings. They noted that “you can’t advocate or really bring questions of importance to the council for discussion.” Kirovograd does not receive international donor investment in the area of HIV.

At the regional level, NGOs fulfill a vital role as watchdogs to monitor the oblast government’s role in addressing HIV, implementing integral HIV programs, as well as advocating for patients whose rights may have been violated. In some regions, NGOs have built strong relationships with the government and with health facilities. In other regions, these relationships are strained, and NGOs face obstacles to providing services or protecting the rights of PLHIV.

Planning and financing

According to our key informants, although the MOH is responsible for the development and implementation of the NAP and its respective budget, the MOF refuses to fund certain activities or funding amounts that it considers unnecessary or something that should not be supported by the national budget. These decisions are apparently made in the absence of sufficient technical expertise to evaluate different program interventions. This was also well documented by the 2009 Comprehensive External Evaluation (UNAIDS, 2009).

There is often a disconnect between national laws and policies and the budget allocations to implement them. This can result in direct contradiction with Ukrainian laws guaranteeing free access to HIV prevention, HCT, treatment, and care and support services. At the same time, the MOH lacks the financial authority to establish broader collaboration with other ministries. These factors complicate the MOH’s ability to plan for the future and develop concrete strategies to mitigate the effects of HIV/AIDS.

Referral and coordination between the medical and social sectors

Collaboration between social and medical services has been facilitated by strong participation in HIV/AIDS service delivery by the MOH, the former MOFYS, and the Social Services, which is a part of the MOFYS. Key informants described a great deal of initiative from the MOFYS and Social Services in developing their own detailed guidelines and regulations for providing services. Regional representatives of this ministry also described their active participation in the development of these policies and guidelines. One representative stated that the region “notices gaps and works to fill them. We send comments to the MOFYS about our problems and needs, and the ministry helps to solve them.” This representative also noted that, when there are issues around collaboration between the medical and social sectors, these issues can and have been resolved through joint orders by the MOH and MOFYS.

The MOFYS has issued extensive policies and regulations that help organize social services provided to PLHIV and MARPs, but more work is needed to ensure continuum of care. Additionally, gaps remain in collaboration with the Penitentiary Services. For example, key informants noted that homeless shelters do not routinely ensure that their clients go to health facilities to receive TB treatment. One NGO in Mykolaiv reported that 80 percent of homeless in the region are former prisoners, who may have been exposed to TB and other infectious diseases. Social support and medical support for people leaving penitentiary services and for the homeless is important to ensure that they access adequate health services.

Referral and coordination between vertical health programs

Referral mechanisms and coordination protocols are clear between some vertical health programs but are less clear or less specific for other programs. Legislation around medical and social support for mothers and children is one of the more detailed and developed set of HIV-related laws in Ukraine. Key informants pointed out, however, that there is a need to update the legal and regulatory base related to PMTCT. A joint order approving the National Program on PMTCT and Support to Affected Children 2006–2008 outlined a strategy for the prevention of vertical transmission of HIV and established a system of medical and social follow-up for HIV positive women, children born to them, and their families, which includes the provision of artificial formula feeding for infants under one year of age. This order established multidisciplinary teams to provide health and social services to HIV-positive and -affected families. The successful strategy described in the Order has continued to be implemented by order of current legislation through the 2009 NAP.²²

The current NAP does not contain a distinct section about HIV prevention among women specifically, nor on the accessibility and quality of reproductive health services for women living with HIV (including, gynecological services, prevention of unwanted pregnancies, and application of supplementary reproductive technologies for HIV-positive women).

Public contracting of social services—procurement of NGO services by government

During interviews at the national and subnational level, informants repeatedly stressed the importance of effectively using a mechanism for government procurement of NGO services. There is a limited legal and regulatory base for public contracting of social services or “sots-zakaz,” and while it was cited as an insufficient regulatory mechanism, the barrier is more often a lack of political will to procure NGO services.²³ During a visit to Mykolaiv oblast, the Deputy Governor and the head of the department on youth for Oblast Social Services described a small pilot program they had established for small grants to NGOs. The Social Services representative noted that “even small amounts of funding can be used successfully.” The representatives suggested that they “would be proud to share their experience with providing small grants” and plan to continue this practice.

Gender and Gender-based Violence

*“We don’t know what gender means.”
—NGO leader in Mykolaiv*

The HPP team reviewed 31 international conventions, Ukrainian laws, programs, guidelines, and regulations to assess (1) how the HIV policy environment reflects and treats gender; (2) to what degree these laws and regulations place some individuals at greater risk for HIV infection or present barriers to seeking and/or accessing services; and (3) the current legal and regulatory framework for attention to GBV and sexual violence within national HIV/AIDS policies, the government’s capacity to prevent and respond to GBV, and policies and laws that may perpetuate GBV.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

²² Law #1026–VI, February 2009.

²³ CMU Act #178-p, April 13, 2007, “On adoption of the Concept for reform of the social services system”; and CMU Act #1052-p, July 30, 2007, “On adoption of the action plan in implementation of the Concept for reform of the social service system for the period through 2012.”

Women and Girls

- The Ukrainian legal and regulatory framework guarantees equal rights for males and females but does not define equal rights for transgenders or sexual minorities.
- Female sexual partners of IDUs are not noted as a “risk group” and many fall through the cracks in terms of receiving HIV services.
- Social norms can put women and girls at an increased risk for HIV—females are subject to sexual coercion, and female IDUs are often last to use shared syringes.
- Many support services are targeted to men, such as rehabilitation for drug dependency.
- Awareness of gender issues and understanding of how to design gender supportive programs is low among both NGOs and the government.

Men who have sex with men

- There is no official agreement on of the estimated size of the MSM population or the rate of HIV prevalence among MSM.
- Ukraine’s Constitution does not specifically note sexual orientation in its equal rights clause.
- MSM, other sexual minorities, and transgenders are not clearly defined as a vulnerable group in the new HIV law or the NAP.
- MSM are defined as a vulnerable group in the partnership framework.
- MSM are listed in Ukraine’s HCT protocol as a key target group.
- Mykolaiv LGBT NGO noted that the organization has been subject to several human rights violations by local authorities.

Gender-based violence

- Ukrainian laws and regulations define GBV and grant survivors of sexual violence the right to PEP.
- Comprehensive healthcare services for survivors of sexual violence are not detailed in HIV-related legislation, and there are no clinical management guidelines for providing services to GBV survivors.
- MSM and other sexual minorities are not clearly defined as groups vulnerable to GBV.
- There is low awareness of the need for GBV programming.
- Links between social and medical services around GBV are poor.
- Those reporting GBV are stigmatized in Ukrainian society.
- Extensive documentation and investigation are required to officially report sexual violence and receive PEP, and NGOs report that many women do not want to put themselves through that level of scrutiny.

When questioned about gender equality and providing gender-sensitive services, key informants generally feel there is a “lack of understanding of what gender means” and that “gender is a western concept that does not fit into Ukrainian society.” While gender inequality often refers to a negative impact on women, gender is not just a women’s issue. Gender refers to the economic, social, political, and cultural attributes and opportunities associated with being male or female (USAID, 2007). Gender inequality can also refer to the rights of LGBT populations and MSM. The President’s Emergency Plan for AIDS Relief recognizes that social and economic inequalities between women and men, as well as harmful gender-based cultural norms and practices, perpetuate women’s and men’s vulnerability to HIV.

Article 24 of the Constitution of Ukraine states that “Citizens have equal constitutional rights and freedoms, and are equal before the law. There can be no privileges or restrictions based on race....sex,

ethnic or social origin, property status, place of residence, linguistic or other characteristics.”²⁴ The overall legal and regulatory framework of Ukraine accords men and women equal rights; however, laws and regulations are not the only factor in determining the level of equality in society.

Girls and women

Service providers and advocates noted that many HIV treatment and support services are targeted to men, since HIV services are “focused on meeting the needs of IDUs in general” and it is generally believed that most IDUs are men. It is important to note, though, that there are no clear estimates of population size of female IDUs or female sexual partners of IDUs. Because IDUs are predominantly considered to be male, and because some services, such as inpatient rehabilitation centers and shelters, do not have the resources to provide appropriate living conditions for men and women in the same facility, women are not included as a target group. As a representative of a NGO in Mykolaiv oblast pointed out

“Some vulnerable women and girls only reach formal services when they become pregnant or even are coming to deliver their child. Female IDUs, female SWs, and pregnant women at least may have programs specifically to meet their needs, but female sexual partners of IDUs fall through the cracks.”

Key informants stressed that laws and regulations are not able to address some aspects of gender inequity and inequality. For instance, social norms and constructs increase the vulnerability of girls and women to HIV. Informants highlighted that Ukraine is a “patriarchal society” and that harmful practices are still prevalent among women. For example, women are at risk of coercion to engage in unprotected sex, and three informants noted the practice and social order among IDUs that women use the syringe for injection only after it has been used by the men.

NGO and PLHIV leaders in Mykolaiv oblast also reported that women are not as effectively reached by HIV testing, care, and support programs for a variety of reasons. For instance, women in small towns or rural settings are concerned about the stigma associated with disclosure of their status. HIV-positive women with infants and young children are hesitant to use formula provided by the government or NGOs, as this will provoke questions from their neighbors, families, and friends about breastfeeding.

Men sometimes convince their female partners that they do not need to seek services; they may prevent them from seeking services under threat of violence or may refuse to give permission. Women with children also face economic barriers to seeking services. If a woman is not working outside the home, she may face childcare barriers to participating in peer support groups or receiving other services. In Mykolaiv oblast, a progressive program is trying to address these barriers by working with male partners/husbands to encourage them to bring in their partners for testing and counseling and provide them with essential HIV prevention and support services.

Men who have sex with men

While Article 14 of the HIV/AIDS Law assures equal rights to legal protection for and prohibits discrimination against PLHIV and populations at “high risk of HIV,”²⁵ MSM are not clearly defined as a vulnerable group in the HIV/AIDS Law, nor are they mentioned in the text of the NAP.²⁶ MSM are

²⁴ Constitution of Ukraine: Law #254k/96–BP, June 28, 1996, (*Article 24*).

²⁵ Law #2861–VI, December 2010.

²⁶ Law #1026–VI, February 19, 2009, “On Approval of the National Program for Prevention of HIV Infection, Treatment, Care and Support of HIV Infected People and Those Suffering from AIDS for 2009–2013”
<http://www.aidsalliance.org.ua/ru/library/global/Zakon%20Ukrainu.indd.pdf>.

mentioned once along with estimated targets in the addendum to the law, which outlines the NAP. Funding for these activities comes exclusively from the Global Fund grant.

Based on the legal and regulatory review, MSM are mentioned as a vulnerable group in only two other documents related to HIV/AIDS services: (1) the Counseling and Testing Protocol includes specific procedures for providing HCT to MSM, prisoners, and other specific population groups²⁷; and (2) a joint ministerial order detailing standards for providing social services to MARPs identifies MSM as a key target group covered by the standards.²⁸ To make informed decisions and plan effectively for service provision to different MARPs, accurate estimates of population size and prevalence are required. As stated earlier, there is currently insufficient agreement on the estimates of population size and HIV prevalence among MSM in Ukraine.

As described above,²⁹ one key informant expressed concern that the absence of constitutionally and legally-assured equal rights for the LGBT community provides insufficient protection from discrimination. This NGO leader noted that “things would be easier for our organization and the LGBT community if we had a basis on which to work and an active role in implementing the NAP.”

Human rights abuses, constitutional rights violations, and harassment of MSM have been documented by NGOs and community groups. A LGBT NGO in Ukraine described their experiences of being harassed and accused of “promoting homosexuality.” The head of this NGO stressed that

“When the MSM community receives some threats or violations, they can’t ask for help from the police or legal bodies. Police are often the ones that harass our community...If MSM are not existent in the legal and regulatory base, then they don’t have a status and their rights are not protected.”

In Mykolaiv, a local NGO brought forward civil action against local authorities for prohibiting a LGBT sports and entertainment event. The court ruled that local authorities had no right to prohibit the event. Following the ruling, the city sent the local NGO a letter—signed by the Mayor—noting that, despite the court’s ruling, the city will continue to prohibit such events to “prevent wrongdoings, crimes, and mass riots.”³⁰

The Mykolaiv NGO actively documents individual situations and often registers complaints, which are left unanswered. The NGO reports that its discotheque has been threatened, its photography exhibit blocked and pictures stolen, and that many of its staff have received personal threats. The head of the organization noted that when someone was severely beaten in the city, the police rounded up all staff of their organization and interrogated them without clear cause. The police services have also interfered with the organization’s outreach work by threatening clients.

The inclusion of MSM as a MARP in the Partnership Framework between the USG and CMU is a significant step forward in ensuring greater focus on providing gender-sensitive medical and social services to MSM (USG and GOU, 2011).

²⁷ MOH Order #415, August 19, 2005, “On improvement of voluntary HIV counseling and testing.”

²⁸ MOFYS, MOLSP, and MoH Joint Order #3123/275/770, September 13 2010, “On approval of standards of social services provision to risk group representatives.”

²⁹ See page 9.

³⁰ Letter from Mykolaiv City Mayor to Mykolaiv Association for Gays, Lesbians and Bisexuals “LIGA.” 17.01.2011 Ref. No 14397/510-14-15.

Sex workers

Sex workers are included as a MARP in the NAP without specification of male or female. Several NGOs are providing counseling and medical services to sex workers, particularly FSWs. It was evident through key informant interviews that sex workers are typically considered to be female. Considering the level of discrimination against the LGBT community, there was no mention of programs specific to SWs who are also MSM. Two of the NGOs providing services to this population noted that they do face limitations in providing services to SWs who are not yet legal adults. These organizations are hesitant to provide services due to complaints that they would be “promoting prostitution.” Key informants noted that the decriminalization of sex work (which was changed to an administrative offense)³¹ many years ago has resulted in less contact with the police and reduced opportunities for violence or abuse by the police.

Gender-based violence

GBV is “any harmful act that is perpetrated against a person’s will and that is based on socially-ascribed (gender) differences between males and females (Inter-Agency Steering Committee (IASC), 2005).” There are strong national laws prohibiting sexual violence and domestic or family violence in Ukraine, especially among children, but there is almost no attention to GBV within national HIV/AIDS policies and programs. What little mention there is of GBV focuses only on women. There is no specific reference to sexual minorities, transgenders, and violence in laws and regulations, nor is there reference to GBV among men. The only reference to sexual violence in the HIV legal and regulatory framework appears in Article 4 of the HIV/AIDS Law, which assures “free access to post-exposure HIV prophylaxis for individuals who have been exposed to HIV as a result of sexual abuse, performance of professional duties, or other incidents, including appropriate counseling, in line with the procedure approved by a special authorized healthcare central executive body.”³² Comprehensive healthcare services for survivors of sexual violence are not described in detail in HIV-related legislation, and there are no clinical management guidelines for providing services to GBV survivors.

The capacity of government ministries, institutions, service providers, and civil society is insufficient to prevent and respond to GBV. Concluding observations of the Committee on the Elimination of Discrimination against Women (CEDAW)’s periodic report for Ukraine in 2010³³ referenced a continued concern that there is insufficient evidence of effective implementation of Ukraine’s Prevention of Domestic Violence Act.³⁴ The report also noted a concern that penalties imposed by the courts for individuals convicted of domestic violence were predominantly monetary fines. CEDAW noted this penalty as “largely ineffective...because it does not impact specifically on the offenders but on the family as a whole.”³⁵ Additionally, the report noted that the extent of violence against different genders is not documented. Recommendations in the report included a significant need for sex-disaggregated statistical data around GBV, monitoring information on implementation of the law, training for public officials on violence, ensuring of access of rural and other marginalized families to services, and ensuring of effective penalties in the cases of domestic violence.

Despite the existence of national programs led by the former MOFYS, there is low awareness among medical service providers and some NGOs of the need for GBV programming. One service provider noted that “there is no need for rape crisis services in our small territory.” Rather than openly discussing

³¹ Law of the Verkhovna Rada of the USSR of 07.12.1984 № 8073-X Code of Ukraine on Administrative Offences; Code is supplemented by the article 181-1 according to the Presidium of the Verkhovna Rada of the USSR of 12.06.1987, as amended by the Law of 07.02.1997 N 55/97-VR.

³² Law #2861-VI, December 2010.

³³ Committee on Elimination of all types of discrimination against women. “Final comments of the Committee on Elimination of all types of discrimination against women to the 6th and 7th regular reports of Ukraine.” January 18 – February 5, 2010.

³⁴ Law of Ukraine of 15.11.2001 № 2789-III [On Prevention of Family Violence](#).

³⁵ Concluding observations of the Committee on the Elimination of Discrimination against Women expressed to the 6th and 7th periodic reports of Ukraine at the 45th Session; January 18–February 5, 2010.

and admitting the need for GBV prevention services in vulnerable families, some key informants joked about the issue and stated that there is “more abuse of husbands than of women.” One NGO in Mykolaiv providing progressive solutions for families noted that although they focus on services for women, they often reach women through their husbands/partners. During this initial outreach through men, they provide counseling to men and discuss issues such as domestic violence and intimate partner violence. Generally, our team witnessed gaps in the linkages between social and medical services, including those related to GBV.

Some key informants noted that existing guidelines detail extensive documentation and investigation required to officially report sexual violence and to provide PEP—and these requirements are a significant obstacle to providing survivors of rape with treatment and support services. These informants noted that the extensive legal requirements to seek justice for GBV may actually perpetuate GBV. Survivors of sexual violence are often unwilling to report GBV due to the “stigma associated with being a victim.” NGO representatives explained that women fear being called a sex worker or being treated poorly by the police. An NGO representative in Mykolaiv noted that sexual minorities and transgenders fear reporting GBV to the police, as the police have also been instigators of physical and sexual violence. When asked about whether they offer PEP to individuals reporting sexual violence, providers noted that many survivors of GBV would not agree to take, or would not continue to take, the full course of PEP due to toxicity and side effects, so there is “really no need to counsel about it.”

Injecting Drug Users (IDUs)

The HPP team assessed 30 Ukrainian laws, policies, programs, protocols, and standards that affect IDUs’ ability to access needle and syringe programs and MAT. The assessment also reviewed relevant ministries’ involvement with MAT to better understand their influence on public health prevention policy around drug use and MAT implementation. The policy review included laws on drug use and possession of drug paraphernalia. The assessment also examined the legal and regulatory framework for any requirements for accessing drug addiction treatment or ART that limit or negatively affect IDUs’ ability to access services.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- IDUs are clearly noted as a primary “risk group” in legal and regulatory documents and service provision.
- Legal and regulatory frameworks have included a definition of harm reduction for 15 years, but there are no comprehensive standards for providing harm reduction services.
- Programming focused on female IDUs and sexual partners of IDUs is limited.
- A case management approach has been emphasized in NGO programs, but there is a need to integrate this approach into public health facilities to provide streamlined care.
- Disposal of used syringes collected by NGOs remains a problem.
- There are protocols for vaccination and treatment of Hepatitis B and C, but no national program.
- Regulations do not require Hepatitis B vaccination—even for medical providers.
- Limited diagnostic testing for hepatitis is conducted, and there is no funding for hepatitis treatment.

Medication-assisted treatment

- The MOH initiated a new working group on MAT.
- The legal and regulatory framework provides a strong foundation for MAT but lacks sufficient detail and is interpreted in different ways.
- Clear guidance on storage and security is lacking. There is a need to develop concrete regulations on the storage and dispensation of oral solutions of methadone, which many see as a solution for the concerns about methadone security and the illegal drug trade. Methadone in oral solution form is legal, but not procured by the government.
- Both the public and private sectors are authorized to provide MAT; however, MAT service sites are limited due to complicated licensing requirements.
- Healthcare workers are often unwilling to implement MAT due to extensive documentation requirements and perceived security risks.

General IDU policy environment

Although, over the last three years, sexual transmission has been reported as the predominant route of HIV transmission, IDUs continue to be a driver of Ukraine's concentrated epidemic. Based on estimates provided by a sociological survey, the population of IDUs in Ukraine is between 230,000 and 360,000 people—approximately 175,000 of whom suffer opiate addiction. Given this population size, the recommended HIV program coverage for IDUs is 290,000 individuals (Analytical report on the results of sociological survey "Assessment of the population of the groups at high risk of HIV infection in Ukraine" as of 2009, n.d.). To ensure universal access to prevention, treatment, care and support for IDUs, a comprehensive approach to providing the medical and social services is required.

According to international recommendations by the WHO, the United Nations Office on Drugs and Crime, UNAIDS, and other global agencies, comprehensive programs targeting the needs of IDUs should provide the following components:

1. Programs for the needle and syringe distribution and exchange
2. Opiate substitution treatment and other types of drug addiction treatment
3. HCT
4. ART
5. Prevention and treatment of STIs
6. Programs for distribution of condoms to IDUs and their sexual partners
7. Target programs in the field of information, awareness building, and communication, specifically targeting IDUs and their sexual partners
8. Vaccination, diagnosis, and treatment of viral hepatitis
9. Prevention, diagnosis, and treatment of TB

Analysis of the legal and regulatory framework was conducted in relation to the above components, some of which are included below.

Overall, HIV programs focused on IDUs are declared as national policy priorities. IDUs are recognized in the NAP as one of the groups at high risk of HIV infection, and there is a focus on providing them with medical and social services. The program aims to provide services to 60 percent of the IDU population. Standards and guidelines have been developed for providing HIV-related medical and social services to IDUs.

It is important to note, though, that it is not clear which central executive government authority is responsible for implementing programs for IDUs. The NAP declares that this responsibility should be assigned to the MOFYS, as well as to the State Social Service, which is subordinated to the MOFYS. However, this ministry has been disassembled, and its functions are currently being reallocated as a part

of the administrative reform process.^{36,37} Ukraine also lacks adequate documents describing a full package of harm reduction services and guidelines on providing these services. Key informants noted that draft guidelines on providing harm reduction services have been in circulation for over a year but have been pushed aside several times. One key informant based at an NGO anticipates that these will be reviewed and approved sometime in this calendar year.

Although sociological surveys have been conducted to estimate the population of different risk groups, including IDUs, these surveys were not formally contracted by the government and, as a result, the data received has not been formally recognized by the GOU.³⁸ These data are not considered in the process of identifying the NAP targets and determining funding allocations from public budget sources.

The process of providing medical services to IDUs is outlined by clinical protocols and standards of care that are adopted through an MOH order.³⁹ These documents outline the course of action for different types of medical practitioners but do not adequately reflect the mechanisms for organizational cooperation between different healthcare facilities (specifically, AIDS Centers, drug addiction clinics, TB services, primary healthcare facilities, and others). Establishment of integrated service centers, which is declared as an objective in the NAP, has not yet been accomplished. Several key informants noted that these issues should be addressed as a part of the general strategy for healthcare sector reform.

Needle and syringe distribution and exchange programs

The program for exchange and distribution of needles and syringes is an indispensable component of core HIV prevention services or harm reduction for IDUs. This program is formally permitted and encouraged in the new HIV/AIDS law, as well as in the 2009 NAP. The list of services provided by needle and syringe exchange points, staff descriptions, and terms of providing such services are described in the standards of social services. Protection of client confidentiality and compliance with ethical norms are essential requirements in providing social services to IDUs and are assured in the standards of treatment and social services.⁴⁰

By law, government, private sector, and CSOs are allowed to implement programs for exchange and distribution of needles and syringes for IDUs.⁴¹ Programs for pharmacy-based distribution and exchange of syringes used by IDUs, however, are still in the experimental stage.⁴² The Alliance has been trying to implement a needle and syringe exchange program with pharmacies. While pharmacies can dispense syringes, they cannot collect used syringes because the government sanitary-epidemiological service dictates that needle and syringe exchange is too dangerous in a “public place.”

Currently, there is no clear strategy for disposal and disinfection or destruction of used syringes and needles. While medical facilities have clear protocols and guidance on disposing of them, there are no requirements for medical facilities to accept used syringes from NGOs. Instead, NGOs must establish an

³⁶ Presidential Decree #1085/2010, December 9, 2010, “On optimizing the central executive government authority system.”

³⁷ Delegation of the MOFYS capacity and functions to other newly established government authorities is not yet effective or clear.

³⁸ The current practice in Ukraine for establishing agreement on an estimated population for groups at risk of HIV infection involves discussions at stakeholders’ meetings and at meetings of the National Council. Despite that they have established some agreement on the estimated population size, this is not sufficient to recognize such data as official data.

³⁹ MOH Order #476 of August 19, 2008, “On the approval of the standard treatment for HIV-positive people are injecting drug users”; MOH Order #276 of May 28, 2008, “On the approval of clinical protocol of care to patients with combined diseases—tuberculosis and HIV infection”; and MOH Order #551, July 2010, “On the approval of clinical protocol antiretroviral therapy of HIV infection in adults and adolescents.”

⁴⁰ Joint MOFYS, MOL, and MOH Order #3123/275/770, September 13, 2010, “Standards of social services to patients with triple diagnosis (HIV infection, tuberculosis, drug dependence)”; and MOH Order #476 of August 2008 (*see above*).

⁴¹ Law #1972–XII of December 1991, amended by Law o#2861–VI of December 2010.

⁴² MOH Order #56, February 3, 2009, “About the pilot project to exchange used syringes.”

agreement with medical facilities, they must purchase appropriate supplies to destroy or clean the syringes, or they must contract with commercial disposal services.⁴³

There is growing concern among NGOs about the new MOH drug circulation law, in which the legal threshold for possession of opiates has been lowered to the point that the amount of opiates left in a syringe after injection is sufficient to warrant a criminal offense.⁴⁴ Key informants at NGOs, as well as service providers in government medical facilities, explained that this impedes harm reduction programs because some clients are afraid to turn in their used syringes. IDUs may come to get clean syringes but do not want to be caught with used ones. Transportation of used syringes by harm reduction workers may also prove dangerous based on this law. Workers on needle and syringe programs carry special certificates showing that they work with these services to avoid harassment.

Medication-assisted treatment (opioid substitution therapy)

MAT is not a separate initiative but a key element in overcoming HIV/AIDS in Ukraine. Without the involvement of IDUs in health and social services, it would be impossible to curb the spread of HIV. Information, support, and treatment provided within MAT programs are essential to reducing the impact of IDUs on the epidemic in Ukraine. Additionally, provision of MAT can reduce needle use and needle-sharing, a high-risk behavior that is a common route of HIV transmission.

As of February 1, 2011, the MOH reports that there are 6,044 drug-dependent patients receiving MAT—of whom 2,722 (45%) are HIV positive, 3,147 (52%) have viral hepatitis (B and/or C), and 1,024 (16.9%) have TB. The MAT program is implemented in 127 treatment facilities (drug treatment clinics, AIDS Centers, and TB treatment clinics) (Ministry of Health, Ukraine, 2011).

MAT was initiated in Ukraine through a Presidential Order⁴⁵ and two MOH Orders⁴⁶ authorizing the provision of methadone and buprenorphine in government and nongovernmental facilities for opioid dependence. The titles of these orders themselves demonstrate the complex, bureaucratic obstacles that the idea of MAT and the draft variants of these orders had overcome. While the distribution of MAT is performed by the MOH, law enforcement bodies are involved in approving these orders. These are milestone documents, as they represented understanding and actual recognition by the government authorities of the advantages of the harm reduction strategy. Although MAT has received attention and support within the government, funding from the state budget has never been allocated, and the MAT program is still exclusively reliant on the financing provided within the Global Fund grant. With the initiation of a new working group by the MOH as well as a MOH statement that MAT is a part of the national response to HIV, the government continues to demonstrate interest and some level of commitment to MAT.

Sufficient legal provisions exist to implement a national MAT program, but these regulations are inconsistent across ministries and at various levels, lack some elements of detail, and are being interpreted in different ways. One example of inconsistent and potentially unclear restrictions on MAT clientele is among MAT for IDUs under age 18. Regulations at the national level do not establish any restrictions on

⁴³ MOH Order #223 of October 22, 1993, “On the collection, disinfection and delivery of medical devices used for single use made of plastic.”

⁴⁴ MOH Order #634, July 29, 2010, “On Amending the Order of the Ministry of Healthcare of Ukraine as of 08. 01. 2000 # 188.”

⁴⁵ Presidential Order #1208, December 12, 2007, “On Additional Urgent Measures Aimed at HIV/AIDS Prevention in Ukraine” (*Article 3, Paragraph 2*).

⁴⁶ MOH Order #827, December 13, 2006, “On Approval of the Schedule for Distribution of Addnok Drug to Health Care Facilities that Perform Substitution Maintenance Therapy”; and MOH Order #295, June 4, 2007, “On Approval of the Schedule for Distribution of Addnok (buprenorphine hydrochloride) and Metadol (methadone hydrochloride) Drugs.”

MAT clientele;⁴⁷ however, regulations at the municipal and regional levels may stipulate that access to MAT is restricted for persons under age 18. The City of Kyiv's Department of Health does not allow MAT services for drug-dependent individuals under age 18.⁴⁸

Methadone and buprenorphine are explicitly registered in Ukraine for use in opioid dependence treatment programs.⁴⁹ One potentially crippling barrier to MAT is related to the engagement and understanding of different ministries, including the MOIA, in the regulation and provision of MAT services. There is concern that medications used in the provision of MAT will enter the illicit drug market or will not be safely and properly administered. Despite that client medical records and medical information must be maintained in confidentiality by the MAT facilities,⁵⁰ there were numerous reports from around the country that MOIA representatives demanded information about MAT clientele in January 2011. An additional example of the need for collaboration across ministries is the lack of provisions allowing patients receiving MAT prior to imprisonment to continue treatment for the duration of incarceration or to start MAT while in prison.⁵¹

Security of handling methadone

Guidance on storage, dosing, and security is neither sufficiently widespread nor is it yet part of routine training for medical workers. This has resulted in some confusion about the prevalence of drug trafficking among medical providers and clients. There are regulations providing for proper storage and distribution of methadone in pill form, but the use of oral solutions of methadone is not adequately described in current guidelines and standards.⁵² Key informants expressed interest in using an oral solution of methadone ("liquid methadone") to prevent theft and misappropriation. Although liquid methadone is legally registered for use in Ukraine, it is not actively procured. Liquid methadone cannot be as easily stolen and circulated as methadone pills. Barriers to using liquid methadone include a lack of guidelines for using and prescribing liquid methadone, a lack of guidelines for disposing of or destroying liquid methadone that has expired, and a lack of adequate pumps and bottles to store and prepare doses of liquid methadone.

Client access

While initial regulations around MAT allowed anonymous involvement in the program (clients did not have to be registered), current regulations require that clients be registered in the MAT clinic. Clinical guidelines for providing MAT specify that in order for a client to receive MAT, they must have participated in a rehabilitation program or other sort of treatment no less than three times. One key informant reported that this part of the guidelines is not actively monitored and that it is "not uncommon for a client to receive MAT without ever attempting another form of therapy or treatment."

An additional barrier is the number and geographic coverage of facilities providing MAT. If a client requires home-based treatment or is not able to leave his/her home, the client is deprived of the

⁴⁷ Order #645, November 10, 2008, "On Approving the Methodological Guidelines 'Medication Assisted Therapy for Persons with Opioid Dependence Syndrome.'"

⁴⁸ Kyiv City Main Department of Health and MOH Order #593, November 9, 2005 "On Implementing Medication-Assisted Therapy for People with Opioid Dependence and Concomitant HIV in Kyiv City Clinical Hospital No. 5."

⁴⁹ CMU Resolution #333, March 25, 2009, "On Approving the National List of Essential Drugs and Medical Projects"; MOH Order #631, July 29, 2010, "On Approving the Amendments to the List of Essential Drugs of Domestic or Foreign Manufacture Available for Purchase by Health Care Organizations Financed via the State Budget or Local Budgets in Full or in Part"; and MOH Order #645, November 10, 2008, "On Approving the Methodological Guidelines 'Medication Assisted Therapy for Persons with Opioid Dependence Syndrome.'"

⁵⁰ Civil Code of Ukraine, Chapter 21, Article 286, "The Right to Secrets about the State of Health."

⁵¹ Order #645, November 2008.

⁵² CMU Resolution #689, June 3, 2009, "On Approving the Procedure for Business Activities Associated with the Circulation of Drugs, Psychotropic substances and Precursors and Control over their circulation"; and MOH Order #11, January 21, 2010, "On Approving the Procedure for Circulation of Drugs, Psychotropic Substances and Precursors in Health Care Institutions of Ukraine" (registered with the Ministry of Justice on May 27, 2010 as #347/17642).

opportunity to obtain MAT. In a few rare instances, facilities have provided a dose to family members or have sent it to the home through a health worker and a security guard from the facility. In addition, if a client is hospitalized in another healthcare facility that does not provide MAT services, the ability to obtain MAT drugs will depend on the license that authorizes the facility or the client's ability to move between facilities.

MAT providers

Although, by law, public and private sectors are allowed to provide MAT, there are complicated licensing requirements that make many facilities and medical providers reluctant to be involved in providing MAT. In addition to narcology clinics, some TB clinics are providing MAT. For instance, in Mykolaiv, informants noted that MAT is provided in both the TB dispensary and the narcology clinic. Narcologists also face barriers to providing attentive, high-quality services. Key informants noted that narcologists "have to spend more time on paperwork and documentation than with patients." Also, they noted that narcologists face restrictions to practicing medicine. For instance, in order to adjust a client's dose of methadone and/or buprenorphine, the narcologist must complete large amounts of paperwork that can interfere with the quality of patient care.

Key informants asserted that conflicts between medical services, the Prosecutor's office, police, and the MOIA continue around MAT services. It is becoming more difficult to provide MAT in situations where facilities are inspected at will. The presence of authorities during inspections and the interrogation of clients hinders treatment.

Antiretroviral treatment among IDUs

Current ART protocols and standards in Ukraine include a specific treatment protocol for IDUs. These protocols also clearly state that injecting drug use does not constitute grounds for excluding a client from access to ART and that MAT may strengthen ART adherence.⁵³ Non-medical care and support services are typically provided by the NGO community. This was evident from our key informant interviews, as well as in the new HIV/AIDS law and NAP. There is no clear identification of a central executive government authority responsible for organizing and providing social services (care and support) for HIV-positive IDUs.

Prevention and treatment of STIs among IDUs

Prevention, diagnosis, and treatment of STIs among risk groups (including IDUs) are included in the NAP section on HIV prevention activities. Funding for these activities is available predominantly from the Global Fund grant. While STI treatment protocols are in place for the general population, STI syndromic management as an approach to meet the needs of risk groups has not been adopted by the MOH. Protocols had been drafted for implementing syndromic management of STIs, but they have been repeatedly set aside.

Programs for distribution of condoms to IDUs and their sexual partners

While the distribution of condoms is included in the list of social and medical HIV prevention services for IDUs, there are no specific programs focused on the sexual partners of IDUs listed in the NAP or among the NGO representatives with whom we spoke.

Vaccination, diagnosis, and treatment of viral hepatitis

Despite that all hepatitis epidemic response activities are regulated by an order issued by the MOH of the USSR in 1989,⁵⁴ there was no active process for registering cases of hepatitis prior to 2008.⁵⁵ Even now,

⁵³ MOH Order #476 of August 2008 and MOH Order #551 of July 2010.

⁵⁴ Order of the MOH of the USSR #408, December 7, 1989, "On efforts to reduce the viral hepatitis incidence in the country."

only acute cases are registered, while chronic cases are not monitored. While there are current protocols for the diagnosis and treatment of Hepatitis B and C among IDUs, there is no established system for the prevention, diagnosis, and treatment of viral hepatitis.

While the standards for treatment of HIV-positive IDUs specify “medical assistance in the event of hepatitis,”⁵⁶ there is no national program for viral hepatitis, nor is there government funding for treatment. A key informant in the government in Mykolaiv suggested, “We need to collect data about Hepatitis B and C at the regional level to inform development of the national program.” The high cost of treatment is prohibitive, and our key informants noted that Hepatitis C is seen as a “death sentence.” Regulations do not mandate vaccination among medical workers or IDUs, although key informants described that some NGOs and health facilities in Mykolaiv are operating donor-funded pilot projects to provide diagnostics and Hepatitis B vaccination.

Children and Adolescents—Medical Services

The HPP assessment team examined 75 laws and regulations impacting HIV-positive and affected children, including policies addressing (1) children’s access to care and treatment; and (2) integration of HIV prevention, care, and treatment for children into both existing ART sites focused on adult care and into maternal, newborn, and child health services.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- National AIDS Program 2009–2013 guarantees
 - PMTCT services fully funded from the national budget
 - Availability and funding for ART for children
 - Youth as a priority group for prevention activities
- The 2010 HIV Law allows CT for youth ages 14–18 years without legal representative present; however, service providers report confusion about the approach to post-test counseling.
- The current system for diagnosing and monitoring HIV-positive children distorts epidemiological data for Ukraine. All children born to HIV-positive mothers are listed as HIV-positive until a confirmatory diagnosis, and there are delays in removing children from this register.
- Guidelines for treatment of HIV and AIDS in children and adolescents are outdated.

The 2009 NAP includes youth as a priority target group for prevention activities. The program also includes street children and children from families “that experience enormous suffering and require assistance” as a high-risk group. In June 2009, the MOH issued orders establishing interim standards of medical care for adolescents and youth, including HCT⁵⁷ and “youth-friendly clinics,” with HIV prevention as a major objective.⁵⁸ Prior to 2004, pediatricians, gynecologists, and others providing care to HIV-positive women and children had no guidelines or protocols for providing PMTCT and other related services.

⁵⁵ MOH Order #476 of August 2008.

⁵⁶ MOH Order #476 of August 2008.

⁵⁷ MOH Order #382, June 2, 2009, “On Approving the Interim Standards of Medical Care for Adolescents and Youth.”

⁵⁸ MOH Order #383, June 2, 2009, “On the Center/Division for medical care services for adolescents and young people of the Ministry of Health of Ukraine “On Improving Medical Care Services for Adolescents and Youth.”

HIV testing and diagnosis

The 1991 AIDS law⁵⁹ outlined procedures for HIV testing for youth. Under the 1991 law, minors under the age of 18 could be tested for HIV at the request or with the consent of their parent/guardian or legal representative, who remained present during testing. Provision of HIV testing for youth ages 14–18 was a gray area, as the 1991 law contradicted the Civil Code of Ukraine,⁶⁰ which states that from the age of 14, medical care may be provided with a youth's consent, without requiring consent of the youth's legal representative. The revised AIDS law passed in 2010 changed the regulations surrounding HIV testing for youth by clearly allowing the testing of youth age 14 and above without the consent or presence of a parent or legal representative.⁶¹ It is important to note that the law provides for testing without consent or presence but strongly recommends the presence of a parent or legal representative when communicating HIV-positive results to a young person

Mandatory HIV testing of minors is prohibited under the laws of Ukraine (specifically, the AIDS Law). However, current procedures for providing medical care to children placed in homes for minors and centers for social and psychological rehabilitation include language that allows for mandatory HIV testing, and testing children in reception centers without their consent or permission from a legal representative remains a common practice. There is also a lack of regulation of HIV testing in temporary placement settings, which is compounded by a lack of training among the staff of residential institutions and a corresponding lack of respect for children's right to confidentiality (Bordunis, Unpublished).

Prevention of mother-to-child transmission

Ukraine's PMTCT program has enjoyed great success in comparison to other HIV prevention efforts. Since 2004, PMTCT coverage has increased to 95 percent of pregnant women (Ministry of Health, Ukraine, 2010). In 2010, 92 percent of infants born to HIV-positive women in Ukraine received a polymerase chain reaction (PCR) test by two months of age (Ministry of Health, Ukrainian AIDS Center, 2010). In Mykolaiv, the rate of PMTCT has reduced dramatically over the past six years. In 2004, 20 percent of children born to HIV-positive mothers were diagnosed with HIV,⁶² compared with only 3.9 percent in 2010. Nevertheless, obstacles remain. The most significant is lack of a reliable supply of ARVs, which reduces the efficiency of PMTCT efforts. While procedures for managing and distributing the supply of ARVs for PMTCT are included in a 2007 joint order and an updated 2009 order outlining methods for calculating the need for ARVs,⁶³ the procedures have significant flaws and are rarely followed by regional AIDS centers.⁶⁴ The Comprehensive External Evaluation also noted an urgent need to improve early diagnosis of newborns and improve overall coordination and monitoring (UNAIDS, 2009). The legal and regulatory review revealed two significant flaws in the monitoring system: first, current monitoring forms do not correspond with current clinical protocols, and second, the PMTCT monitoring data gathered by the National AIDS Center differ significantly from those gathered by the MOH's Department for Motherhood and Childhood. These gaps indicate a need for unified monitoring procedures with improved technology and an interdisciplinary approach.

The GOU has demonstrated commitment to the PMTCT program, which has contributed to its success. A 2008 CMU resolution included improvement of the PMTCT program as a strategic prevention priority,⁶⁵ and improving PMTCT is a major objective of the 2009 NAP, which aims to achieve a 5 percent

⁵⁹ Law #1972-XII, December 1991.

⁶⁰ Civil Code of Ukraine (*Section 3, Article 284*).

⁶¹ Law #2861-VI, December 2010.

⁶² Key informant interviews in Mykolaiv, February 2011.

⁶³ MOH Order #936, December 16, 2009, "On Approving the Method for Needs Assessment for Supply of Antiretroviral Drugs"

⁶⁴ This issue is discussed further in the section on HIV/AIDS drug and commodity procurement and supply.

⁶⁵ CMU Resolution #728p, May 21, 2008, "On Approving the Concept of the National Target Program to Ensure HIV Prevention, Treatment, Care, and Support for HIV-infected People and People with AIDS for 2009–2013."

reduction in vertical HIV transmission. The 2010 AIDS law guarantees free access to PMTCT for all HIV-positive women. The government has also taken steps to improve training in PMTCT for service providers. In 2009, the MOH approved an undergraduate training program for doctors, which includes PMTCT, as well as a curriculum on PMTCT for HIV for students of postgraduate education institutions and postgraduate education faculties of medical institutions of higher learning.⁶⁶

PMTCT services are provided on a decentralized basis. In 2006, the MOH delegated authority to provide VCT services, including those related to PMTCT, to regional health authorities.⁶⁷ PMTCT is financed via the national budget, relying heavily on the contributions of external donors, particularly the Global Fund. HIV testing of pregnant women is performed with patient consent during registration or before delivery. Testing of umbilical cords is compulsory to ensure timely treatment to prevent HIV in newborns.⁶⁸ The 2004–2008 NAP guaranteed free access to VCT for pregnant women.⁶⁹

In November 2007, the MOH adopted a clinical protocol on obstetrics care related to PMTCT, which includes all WHO-recommended techniques.⁷⁰ The joint order⁷¹ of the same month outlines procedural guidelines for PMTCT, including the provision of PMTCT in correctional facilities. The order guarantees access to PMTCT services for all HIV-positive women, as well as ART adherence support during pregnancy. It guarantees a regular supply of ARVs to AIDS Centers and maternity hospitals to enable them to provide PMTCT services. The order also requires training of both medical and non-medical personnel in the provision of PMTCT and social support services for HIV-positive women, their infants, and families. The joint order assigns doctors responsibility for assessing treatment adherence among pregnant women. If adherence is inadequate, the doctor (with the patient’s informed consent) notifies a specialist in the relevant Social Services Center for Family, Children, and Youth (SSFCY) to initiate psychological and social support services.

Family planning (FP) services are the second component of the PMTCT system and prevention of HIV among children and adolescents is a major objective of FP services in Ukraine. The MOH has approved guidelines for the provision of FP services to PLHIV. Several MOH orders outline clinical protocols and integration of FP measures with HIV prevention services. The 2007 joint order outlines clear tasks for developers and implementers of FP services for HIV-positive individuals in a section on “FP Services for HIV-infected People.”⁷² Despite the inclusion of family planning in legal and regulatory documents related to HIV, key informants uniformly reported that FP services are inadequate for the population as a whole, and vulnerable groups particularly have insufficient access to FP counseling, services, and methods.

⁶⁶ MOH Order #313, May 8, 2009, “On Optimizing Training for Specialists on HIV and Prevention of Mother-to-Child Transmission of HIV.”

⁶⁷ MOH Order #421, June 27, 2006, “On Approving the Model Regulations on *Dovira* Units (Trust Centers).”

⁶⁸ CMU Resolution #2026, December 18, 1998, “Matters of HIV/AIDS Prevention and Population Protection Efforts.”

⁶⁹ CMU Resolution #264, March 4, 2004, “On Approving the ‘Concept of Government Actions Targeted at Prevention of the Transmission of HIV/AIDS Until 2011’ and ‘The National Program to Ensure HIV Prevention, Treatment, Care, and Support to HIV-infected People and People with AIDS for 2004–2008.’”

⁷⁰ MOH Order #716, November 14, 2007, “On approving the Clinical Protocol on Obstetrics Care ‘Prevention of Mother-to-Child Transmission of HIV.’”

⁷¹ MOH, MOFYS, Ministry of Labor and Social Policy, MOES, and State Committee on Enforcement of Sentences Joint Order #740/1030/4154/321/614a, November 23, 2007, “On Activities to Prevent Mother-to-Child Transmission of HIV, Medical Care and Social Services for HIV-infected Children and their Families.”

⁷² *Ibid.*

Early diagnosis of HIV in children

A 2007 joint order⁷³ outlines procedures for early diagnosis of HIV in infants under the age of 18 months using PCR⁷⁴ testing. Unfortunately, the current system for diagnosing and monitoring HIV-positive children distorts epidemiological data for Ukraine. Key informants noted that currently all children born to HIV-positive mothers are included on the list of HIV-positive individuals, regardless of the fact that only 9 percent of such children are ultimately confirmed as HIV positive. The inclusion of children whose HIV status is not yet confirmed makes statistical data inaccurate and misleading.

Access to care and treatment

Several regulatory documents provide guidelines for the treatment of HIV in children and adolescents, and the GOU reports 100 percent coverage of children with ART (Ministry of Health, Ukraine, 2010). Clinical protocols for ART and medical management of HIV-positive children are outlined in MOH Order 182 of April 2007.⁷⁵ A 2007 joint order includes regulations on the integration of pediatric ART with the primary care system.⁷⁶ In Mykolaiv oblast, service providers, government officials, and NGOs alike reported that providing treatment, care, and support for children is the first priority. In Mykolaiv, 550 children are registered as born to HIV-positive mothers, 138 have a confirmed HIV diagnosis, and 12 are living with AIDS. Currently, 102 children are on ART in Mykolaiv.

A key informant providing services in a national pediatric AIDS center reported that despite the diligent work of experts in developing these guidelines, they are already outdated, and that there is a need to reconsider the bureaucracy associated with updating and revising regulatory documents that directly impact service delivery. She noted that the main policy barriers in the area of pediatric HIV services are

“Insufficient dissemination of policy documents...there is no training on how to implement new standards and protocols...limited communication between providers and government...a lack of a pediatrician at the Ukrainian National AIDS Center...and the bureaucracy involved in updating these policy documents is unacceptable.”

Specifically, the key informant stated that annual training is required to participate in policy development working groups and noted that there is a lengthy and in-depth approval process required for service delivery-oriented policy documents by individuals that are not knowledgeable about the issues described in the document. This physician pointed out that “only people with access to the Internet and with English language skills can read and use international best practices and updates.”

There appears to be a gap in Ukraine’s legal and regulatory framework related to certification of caregivers in the health sector and beyond. In the health sector, certification of health personnel providing services to HIV-positive children is governed by regulations for the general population. There is no special certification for providing care to HIV-positive children. In institutions governed by the MOFYS, certification related to serving HIV-positive children is governed by Order 1695 of April 1998.⁷⁷

⁷³ MOH, MOFYS, Ministry of Labor and Social Policy, MOES, and State Committee on Enforcement of Sentences Joint Order #740/1030/4154/321/614a, November 23, 2007, “On Activities to Prevent Mother-to-Child Transmission of HIV, Medical Care and Social Services for HIV-infected Children and their Families.”

⁷⁴ Polymerase chain reaction.

⁷⁵ MOH Order #182, April 13, 2007, “On Approving Clinical Protocols.”

⁷⁶ MOH, MOFYS, Ministry of Labor and Social Policy, MOES, and State Committee on Enforcement of Sentences Joint Order #740/1030/4154/321/614a, November 2007.

⁷⁷ MOFYS Order #1695, April 22, 1998, “On Approving the Procedures for Certification of Workers of Centers for HIV-infected Children and Young People.”

Children and Adolescents—Social Protection and Social Services

HPP examined 134 policies, regulations, and guidelines providing protection for orphans and vulnerable children in the areas of inheritance rights; protection against violence; and access to education, shelter, food, and social support.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- There is concern and confusion about the dissolution of the MOFYS—the primary executive body responsible for regulating and administering programs for the protection of children and adolescents—without clear guidance on the reassignment of the functions of this ministry. Some key informants view this as an opportunity for needed change.
- Ukraine has made strides toward developing a strong legal and regulatory framework related to children and adolescents, but the UN Committee on the Rights of the Child report that legislation remains “inadequate.”
- Inadequate data are available on populations of children and adolescents in need of social services.
- Children living and working on the street are not clearly defined in the legal and regulatory framework, thus providing services to this important group is challenging.

Overall policy environment and protections for children

Ukraine is a signatory to the United Nations Convention on the Rights of the Child (UNCRC), which lays out the fundamental civil, political, economic, social, health and cultural rights of children (United Nations General Assembly, 1989). In March 2009, Ukraine adopted an implementation plan to increase its compliance with the convention and strengthen legal protections for the rights and well-being of children. The implementation plan aims to reduce the spread of HIV, TB, and drug use among children and to protect the rights of HIV-positive children.⁷⁸ The government also adopted several additional measures related to rights and social protection for children:

- Law to Combat Child Pornography (January 2010)
- Law on Social Protection for Orphans and Children Deprived of Parental Care (2005)
- National Plan of Action for Children 2010–2016 in March 2009 as a Law on the National Plan of Action for Children
- National Strategic Action Plan for HIV prevention among children and youth of risk groups and HIV vulnerable people (May 2010)
- National Program against Children’s Homelessness and Neglect (2006–2010)

Despite this progress, in 2011, the Committee on the Rights of the Child—responsible for monitoring compliance with the UNCRC—noted persistent shortcomings in Ukraine’s legal environment relating to children and adolescents. The committee described domestic legislation on the rights of the child as “inadequate” (United Nations Committee on the Rights of the Child, 2011, p.2). Specific concerns noted by the committee include the following:

- “High rates of children deprived of their family environment at birth and in later stages of childhood” (United Nations Committee on the Rights of the Child, 2011, p.10)

⁷⁸ Law #1065-VI, of March 5, 2009, “National Action Plan to Implement the UN Convention on the Rights of the Child for the Period until 2016”; and Bordunis, unpublished.

- Limited amount and quality of state services to protect and assist families with children
- Sustainability of child policies in the context of the administrative reforms launched in 2010, particularly dissolution of the MOFYS
- Failure to include families and children as a prominent component of the national poverty reduction strategy for 2010–2015
- Lack of national database with comprehensive and disaggregated data on children
- Inadequate training of professional groups dealing with children—specifically limited training on children’s rights for law enforcement officers, health professionals, social workers, teachers, immigration officials, members of the judiciary, and representatives of the media
- Failure to fully implement the principle of nondiscrimination with respect to children with disabilities, children in street situations, children living with HIV/AIDS, and refugee children (United Nations Committee on the Rights of the Child, 2011)

Children living with HIV in Ukraine are guaranteed social protection and free medical and social services,⁷⁹ and those under the age of 16 years are provided with monthly state assistance.⁸⁰ When an HIV-positive child under the age of 18 years is assigned disability status, a government disability allowance is granted to the child and the parents are given a wage increase to support care for the child.⁸¹ Children living with HIV are guaranteed the right to receive social support from the SSCFCY.⁸² The list of free social services for HIV-positive children has been specified and includes social and medical, psychological, social and economic, social and pedagogical, legal, social welfare, and information services.⁸³

In 2006, the CMU issued a directive on the creation of centers for HIV-positive children and youth. The centers are designed to provide a variety of free social services. They operate on a daytime basis and are funded through local budgets.⁸⁴ Several key informants noted that creating a parallel structure for providing social services to children with HIV is not an effective use of resources and can be stigmatizing. For instance, one key informant described that the “Daycare Centers for HIV-positive children are often on a city’s edges promoting stigma by separating the child from mainstream centers as well as institutionalizing geographic discrimination by placing the center in difficult to reach locations.”

⁷⁹ Law #1972–XII of 12/12/1991, “On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Legal and Social Protection of the Population” (*Section I, Article 4*); Law #1645 of 4/6/2000, “On Protection of the Population against Infectious Diseases” (*Article 19*); CMU Resolution #2026 of December 18, 1998; and CMU Resolution #264 of 3/4/2004, “On Approval of the Concept of the Government Strategy of Actions Aimed at Prevention of HIV/AIDS for the Period till 2011 and of the National Program for the Prevention of HIV Infection, Support, and Treatment for HIV-infected People and AIDS Patients for 2004–2008.”

⁸⁰ Law #1972–XII, December 12 1991, “On Response to the Transmission of Diseases Caused by Human Immunodeficiency Virus (HIV) and Legal and Social Security of People Living with HIV” (*Section III, Article 19.1*); Law #2402–III of 4/26/2001, “On Protection of Childhood” (*Article 29*); CMU Resolution #1051 of 7/10/1998, “On the Amount of a Monthly State Allowance to Children Under 16 Years Living with HIV or AIDS”; MOH Order #265 of 8/31/98, “On Procedures to Pay the Monthly State Allowance to Children Under 16 Years Living with HIV or AIDS”; and Joint MOH, Ministry of Labor and Social Policy, MOF Order #454/471/516 of 11/8/2001, “On Approval of the List of Medical Indications that Entitle to Receive State Social Benefits for Disabled Children Under 16 Years of Age.”

⁸¹ Law #2109–III of 11/16/2000, “On State Social Allowance to Persons Disabled from Childhood and to Disabled Children” (*Article 3*).

⁸² Joint MOH, MOES, MOFYS, Ministry of Labor and Social Policy, and State Penitentiary Department Order #740/1030/4154/321/614a of 11/23/2007 (*Paragraph 9.2*).

⁸³ Standards of Minimum Social Service Package for Children Living with HIV and Children Born to HIV-infected Mothers, Members of their Family (approved by MOFYS Order #4941 of 12/18/2008); CMU Resolution #1126 of 8/27/2004 (in edition of 11/20/2009), “On Measures to Improve the Social Work with Families, Children, and Youth.”

⁸⁴ CMU Resolution #148, February 15, 2006, “On Approval of Standard Provision on the Center for HIV-Infected Children and Young People.”

Instructions on procedures for the provision of health and social services to HIV-positive children specify the need to take into account the different needs of children, but a needs assessment tool for this purpose (beyond the standard SSCFCY social inspection certificate) has not been legally designated. NGOs have developed and applied different assessment tools, which have been adopted by some municipal authorities. Various regulations encourage NGO participation in the provision of social services to HIV-positive children and children who are vulnerable to HIV infection.⁸⁵

Parental support for HIV-positive children

Legal provisions have also been made to enable parents (or those acting on their behalf) to provide care and support to HIV-positive children. Parents of HIV-positive children under the age of 16 are legally entitled to leave from employment and disability support to enable them to care for their sick child. The AIDS laws of 1991 and 2010 also guarantee parents of HIV-positive children the right to stay in the hospital with children under the age of 14.⁸⁶ In cases of inpatient treatment for children up to the age of six years (as well as seriously ill children of an older age), the mother or another member of the family is also provided with free food and accommodation at the health facility where the child is being treated.⁸⁷

State guardianship and different forms of custody

Orphans and children deprived of parental care (OC and CDPC) are guaranteed guardianship by the Ukrainian state. The Ukrainian legal and regulatory framework outlines several forms of government support, including guardianship or trusteeship; adoption; and placement in family-based children's homes or state institutions for these children.⁸⁸ There are also social hostels, which are temporary (up to three years) residences for OC and CDPC ages 15–23 years, which are designed to help residents prepare for independent life.⁸⁹

HIV-positive children are placed in children's institutions in accordance with general practices, but are provided with high-calorie nutrition to support their health.⁹⁰ The regulations about adoptive families clearly indicate that OC and CDPC living with HIV can be reared in adoptive families. However, the

⁸⁵ Law #996–IV of 6/29/2003 (12/30/2009 edition), “On Social Services” (*Article 13*); Presidential Decree #1086/2005, “On Priority Measures to Protect the Rights of Children” (*Paragraph 7*); MOFYS Order #4414 of 11/4/2008, “On Approval of the Strategy to Develop the System of Social Services for Families, Children and Youth for 2009–2014” (*Paragraph 5.5.1*); Law #2402–III of 4/26/2001, “On Protection of Childhood” (*Article 5*); Joint MOH, MOES, MOFYS, Ministry of Labor and Social Policy, and State Penitentiary Department Order #740/1030/4154/321/614a of 11/23/2007, “On Measures to Organize PMTCT of HIV, Healthcare and Social Support to HIV-positive Children and their Families” (*Paragraph 4.7*); MOFYS Order #4569 of 12/29/2009, “Sample Sectoral Standard for the Provision of Social Services to Families with Children in Hard Living Conditions”; Law #2558–III of 6/21/2001, “On Social Work with Families, Children, and Youth” (*Article 3*); Law #2623–IV of 6/2/2005, “On Basics of Social Protection of Homeless Individuals and Homeless Children” (*Article 29.2*); and CMU Resolution #1062 of 7/25/2002, “On Approval of Procedures to Tender on the Draft Programs Developed by Youth and Children's Civil Organizations and their Unions for Children, Youth, Women, and Families.”

⁸⁶ Law #1972–XII, December 12, 1991 (*Section 4, Article 21*); and Law #2861–VI, December 23, 2010, “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population.”

⁸⁷ Law #2081 of 11/19/1992 (as amended on 10/13/2010), “On Basic Principles of Ukrainian Legislation on Health Care.”

⁸⁸ Constitution of Ukraine 6/28/1996 *Article 52*; Law #2342–IV of 1/13/2005, “On Ensuring Organizational and Legal Conditions for Social Protection of Orphaned Children and Children Deprived of Parental Care” (*Article 1*); Law #2402–III of 4/26/2001, “On Protection of Childhood” (*Article 24*); Law #2947–III “The Family Code of Ukraine” (*Article 245*); MOES/MOFYS Joint Order #747/460 of 9/21/2004, “On Approval of Provisions about Children's Homes and Secondary Education Boarding Schools for Orphaned Children and Children Deprived of Parental Care” (*Paragraphs 1.1 and 3.4*); MOH Order #123 of 5/18/1998, “On Approval of the Standard Provisions about Children's Homes.”

⁸⁹ CMU Resolution #878 of 9/8/2005, “On Approval of Standard Provisions on Social Hostel for OC and CDPC.”

⁹⁰ Joint MOH, MOES, MOFYS, Ministry of Labor and Social Policy, and State Penitentiary Department Order #740/1030/4154/321/614a of 11/23/2007 (*Section 7.1*).

regulations on family-based children's homes do not contain a provision for children living with HIV.⁹¹ Provisions are made to train potential adoptive parents and foster parents to raise HIV-positive children.⁹²

While regulations include a list of social services for OC and CDPC, HIV-specific services are not specified. In addition, no document exists to establish standards for the provision of social services for children placed in adoptive families or family-based children's homes or for children in guardianship and trusteeship. The curriculum to prepare graduates of institutions for OC and CDPC for independent living does include HIV prevention topics.⁹³

The GOU has declared a need to reform the system of institutional care for children. In particular, GOU statements have focused on transitioning from an institution-based system of care to a more family- and community-centered model.⁹⁴ To this end, family forms of guardianship for OC and CDPC have been identified as a priority.⁹⁵ Regulations have also introduced the possibility of return to parental care for OC and CDPC. However, no formal mechanism for returning children to the care of biological parents has been adopted.⁹⁶

There are also important gaps in the current system related to temporary custody of homeless and neglected children. Different forms of temporary placement of OC and CDPC have been defined: shelters operated by the service on children's affairs; Centers of Social and Psychological Rehabilitation of

⁹¹ Family code of Ukraine, *Article 5*; Joint Order ##740/1030/4154/321/614a of 11/23/2007 (*Section 7.3*); and CMU Resolution #565 (*Paragraph 2*).

⁹² Presidential Decree #411/2008 of 5/5/2008, "On Measures to Protect the Rights and Legal Interests of Children"; CMU Resolution #565 (*Paragraph 9*); MOFYS Order #3385 of 9/25/2009, "On Approval of Procedures for Cooperation between the CSSFCY and Services on Children's Affairs in the Process of Establishment of Guardianship and Trusteeship, and Development and Ensuring the Activities of Adoptive Families and Family-type Children's Homes" (*Paragraph 2.2*); CMU Resolution #905 of 10/8/2008, "On Approval of Procedures to Implement Adoption and Supervise the Observance of the Rights of Adopted Children" (*Paragraph 25*); MOFYS Order #2668 of 7/25/2007, "On Approval of the Training Curriculum for Candidate Adoptive Parents and Tutors to Upbring HIV-Infected Children."

⁹³ Law #2342-IV (*Article 1*); and Order of the State Social Service #31 of 6/4/2008, "On Approval of Program for CSSFCY for Social Adaptation of OC and CDPC from among Students of Senior and Graduate Classes of Boarding Schools, Social Rehabilitation Schools, and Individuals from among OC and CDPC" (*Topic 2.4*).

⁹⁴ MOES and MOFYS Order #747/460, September 21, 2004, "On Approval of Provisions on Children's Homes and General Educational Boarding Schools for the Orphaned Children and Children, Deprived of Parental Care"; Presidential Decree #1086/2005, July 11, 2005, "On Priority Measures to Protect the Rights of Children"; CMU Instruction #178-r, April 13, 2007, "On Approving Conceptual Approaches to Reform the System of Social Services"; CMU Resolution #1242, October 17, 2007, "On Approval of the State Targeted Social Program to Reform the System of Institutions for Orphaned Children and Children Deprived of Parental Care"; Presidential Decree #411/2008, May 5, 2008, "On Additional Measures to Ensure Protection of Rights and Legal Interests of Children"; CMU Instruction #1052-p, July 30, 2008, "On Approval of Action Plan to Implement the Concept to Reform the System of Social Services for the Period till 2012" (in the edition of 7.30.2008); Law #1065-VI, May 3, 2009 "On the National Program National Action Plan to Implement the UN Convention on the Rights of the Child for the Period till 2016"; and CMU Resolution #1263-r, October 21, 2009, "On Approving the Action Plan to Implement Measures in 2010 under the National Program 'The National Plan of Action to Implement the U.N. Convention on the Rights of the Child' until 2016."

⁹⁵ Law #2342-IV, January 13, 2005, "On Ensuring Organizational and Legal Conditions for Social Protection of Orphans and Children Deprived of Parental Care"(Article 6); Presidential Decree #376/2007, May 4, 2005, "On Additional Measures to Protect the Rights and Legitimate Interests of Children"; CMU Resolution #623, May 11, 2006, "On Approval of the State Program to Overcome Children's Homelessness and Neglect for 2006-2010"; CMU Resolution #1242, October 17, 2007, "On Approval of the State Targeted Social Program to Reform the System of Institutions for Orphaned Children and Children Deprived of Parental Care"; MOFYS Order of #4414, April 11, 2008, "On Approval of the Strategy to Develop the System of Social Services for Families, Children and Youth for 2009 -2014"; Presidential Decree #411/2008, May 5, 2008, "On Additional Measures to Ensure Protection of Rights and Legal Interests of Children"; CMU Instruction #1263-p, October 21, 2009, "On Approval of Action Plan to Implement in 2010 the National Program 'National Plan of Actions to Implement the UN Convention on the Rights of the Child for the Period till 2016.'"

⁹⁶ MOFYS/MOH Order #302/80/49, February 2, 2007, "On Approving the Procedure for Moving Children from Facilities for Orphaned Children and Children Deprived of Parental Care, as well as Programs of Social Protection of Children, to Family-Type Child Care Facilities" (as amended on 9.6.2010); and CMU Resolution #1242, October 17, 2007, "On Approval of the State Targeted Social Program to Reform the System of Institutions for Orphaned Children and Children Deprived of Parental Care."

Children; social and rehabilitation center “Children’s Town”; institutions for OC and CDPC; and families. However, there are no provisions to allow the temporary placement of children without the formal status of “orphaned” or “deprived of parental care.” Current legislation also makes no allowance for temporary custody of children when they have been placed with institutions or individuals on a temporary basis. Without a temporary custody mechanism, there is no legal authorization for caregivers to provide medical care to children. This gap is particularly significant given the high HIV risk and vulnerability of homeless and neglected children.⁹⁷

Legislation regulating temporary stay institutions also does not require employees to respect HIV-positive children’s rights or specify mechanisms to protect their confidentiality. Workers in temporary placement institutions are often unaware of children’s right to healthcare. Children in temporary stay institutions are regularly tested for HIV without the informed consent of the child or his/her legal representatives. Children’s confidentiality is also routinely violated, as workers of temporary placement institutions are generally unaware that disclosure of a child’s health status is prohibited.

Property rights of children and adolescents

The state guarantees the protection of children’s property rights. The right of children, especially OC and CDPC, to housing is established under law.⁹⁸ Parents of an infant do not have the right to enter into agreements on the division or change of their house or apartment, sign any written obligations on behalf of the child, or refuse the child’s property rights without permission of the body for guardianship and trusteeship. A child whose parents have been deprived of parental rights does not forfeit his/her right to inherit their property.⁹⁹ Responsibility for monitoring the rights of OC and CDPC is assigned to the service on children’s affairs. However, monitoring and enforcement mechanisms to protect the rights of children living with HIV or vulnerable to HIV in case of rights violations have not been specified.

Protection against violence

Children also have legal protections against violence. Several government institutions are involved in responding to violence against children, including a police unit on children’s affairs; guardianship and trusteeship bodies; service on children’s affairs; and the SSCFCY. Criminal police unit on children’s affairs has the right to remove children from families if remaining in the family’s care poses a threat to the life or health of a child.¹⁰⁰

⁹⁷ Bordunis, Tetiana. 2010. “Legal and regulatory review on the rights of children and young people living and working on the street, prevention of homelessness and neglect in Ukraine.” USAID HIV/AIDS Service Capacity Project in Ukraine.

⁹⁸ Presidential Decree #1086/2005 of 7/11/2005, “On Priority Measures to Protect the Rights of Children” (*Paragraph 7*); Law #1065–VI of 3/5/2009, “On the National Program National Action Plan to Implement the UNCRC for the Period till 2016” (*Article 4.3*); Family Code of Ukraine, *Articles 167 and 248*; Law #2402–IV of 4/26/2001 (in the edition of 7/27/2010), “On Protection of Childhood” (*Article 18*); Law #2342–IV of 1/31/2005, “On Ensuring Organizational and Legal Conditions for Social Protection of OC CDPC” (*Articles 32 and 33*); CMU Resolution #565 of 4/26/2002, “On Approval of Provisions on Adoptive Family”; CMU Resolution #564 of 4/26/2002, “On Approval of Provisions on a Family-Type Children’s Home” (*Article 30*); CMU Resolution #226 of 4/5/1994, “On Improvement of Upbringing, Education, Social Protection, and Financial Security of OC CDPC” (*Paragraph 9*); Law #2623–IV of 6/2/2005, “On Basic Principles of Social Protection of Homeless Citizens and Neglected Children” (*Article 11*); and CMU Resolution #310 of 3/15/2006, “On Approval of Standard Provisions on SOS–Children’s Town” (*Paragraph 10*).

⁹⁹ Family Code of Ukraine, *Article 174.1, 177.2*; CMU Resolution #1263–p of 10/21/2009, “On Approval of Action Plan to Implement in 2010 the National Program ‘National Plan of Actions to Implement the UNCRC for the period till 2016’” (*Paragraph 17*); Civil Code of Ukraine, *Article 72.1, 74.1*; Law #2402–III of 4/26/2001, “On Protection of Childhood” (*Article 17*); CMU Resolution #564 of 4/26/2002, “On Approval of Provisions on a Family-Type Children’s Home” (*Paragraph 17*); Law #2623–IV on 6/2/2005, “On Basic Principles of Social Protection of Homeless Citizens and Neglected Children” (*Article 12*); and CMU Resolution #866 of 9/24/2008, “On Activities of Guardianship and Trusteeship Bodies for the Protection of Children’s Rights” (*Paragraphs 55 and 59*).

¹⁰⁰ Law #20/95–VR of 1.24.1995, “On Juvenile Agencies and Juvenile Services and Special Institutions for Children” (*Article 5*); CMU Resolution #502 of 7.8.1995, “On Establishment of the Criminal Juvenile Police” (*Paragraph 4*); Law #2402–III of 4.26.2001, “On Protection of Childhood” (*Article 10*); Law #2789–III of 11.15.2001, “On Prevention of Violence in the

Confidentiality and discrimination

Regulations specify that the staff of government institutions for HIV-positive orphaned children should maintain confidentiality about the HIV status of their clients.¹⁰¹ The regulations specify that managers of government institutions that provide care to HIV-positive orphaned children do not have the right to disclose information about children's HIV status to employees of the institution.¹⁰² However, information about a child's health (including HIV status) may not be concealed from prospective adoptive parents.¹⁰³ Penalties for violating the confidentiality of a patient, which are outlined in Article 132 of the Criminal Code, include fines, community service, correctional labor, and "restraint of liberty" for up to three years.¹⁰⁴

Multiple key informants reported that discrimination against children living with HIV has reduced significantly over the past several years. They reported that there are few instances of children being rejected. The PLHIV Network in Mykolaiv explained that, by law, HIV-positive children must be allowed into schools, camps, and in any other public setting. While there are individual cases during which the PLHIV Network is asked to meet with a teacher or camp counselor to educate them about HIV and the rights of children living with HIV, these children are not rejected participation or entry into services or programs.

Right to education

As described in this report's "Stigma and Discrimination" section (see page 9), all children are guaranteed the right to education, regardless of their health status. A 2008 Presidential Decree to the MOES required the ministry to introduce measures to overcome and prevent stigmatization of HIV-positive children to ensure their ability to exercise their right to education.¹⁰⁵

Families" (in the edition of 01.01.2009) (Article 3.1); CMU Resolution #616, of 4.26.2003, "On Approving the Procedure for Processing Applications and Notifications Filed by Children on Incidents of Domestic Violence or a Real Threat of Committing Domestic Violence" (*Paragraph 10*); Order #5/34/24/11 of 1.16.2004 of MFYS, MOIA, and MOES, "On Approving the Procedure for Processing Applications and Notifications of Incidents of Domestic Violence Against Children or a Real Threat to Commit Domestic Violence" (*Paragraphs 3.7 and 3.9.3*); MOES and MFYS Order #747/460 of 9.21.2004, "On Approval of Provisions on Children's Homes and General Educational Boarding Schools for the Orphaned Children and Children, Deprived of Parental Care" Presidential Decree #411/2008 of 05.05.2008 (*Paragraph 7*); CMU Resolution #866 of 9.24.2008, "On Activities of Guardianship and Trusteeship Bodies for the Protection of Children's Rights" (*Paragraph 8*); CMU Resolution #1263-r of 10.21.2009, "On Approving the Action Plan to Implement Measures in 2010 under the National Program "The National Plan of Action to Implement the U.N. Convention on the Rights of the Child" until 2016" (*Paragraphs 25 and 26*); MFYS Order #4569 of 12.29.2009, "Model Industry Standards for the Practice of Social Work with Families With Children In Difficult Circumstances" (*Paragraph 2.2.3*); and MFYS Order #1480 of 5.27.2010, "On Approval of Procedures for the Centers for Social Services for Families, Children and Youth to Perform Social Inspection of Families, Children and Youth in Hard Living Conditions" (*Paragraph 3.3*).

¹⁰¹ Law #966-IV of 6/19/2003 (as amended 12/30/2009), "On Social Services" (*Article 10*); Law #2801-XII of 11/19/1992 (as amended 10/13/2010), "On the Basic Principles of Ukrainian Legislation on Health Care" (*Article 39.1*); Law #1972-XII of 12/12/1991, "On Prevention of AIDS and Legal and Social Protection of the Population" (*Section III, Article 13*); Joint MOH, MOES, MOFYS, Ministry of Labor and Social Policy, and State Penitentiary Department Order #740/1030/4154/321/614a of 11/23/2007, "On Measures to Organize PMTCT of HIV, Healthcare and Social Support to HIV-positive Children and their Families" (*Paragraph 1.4*).

¹⁰² Joint MOH, MOES, MOFYS, Ministry of Labor and Social Policy, and State Penitentiary Department Order #740/1030/4154/321/614a of 11/23/2007, "On Measures to Organize PMTCT of HIV, Healthcare and Social Support to HIV-positive Children and their Families" (*Paragraph 7.2*).

¹⁰³ CMU Resolution #905 of 10/8/2008, "On Approval of the Procedures to Implement Adoption and Supervise the Observance of Rights of Adopted Children."

¹⁰⁴ Law #2341-III of 5/4/2001 "The Criminal Code of Ukraine" (*Article 132*).

¹⁰⁵ Presidential Decree #411/2008 of 5/5/2008, "On Additional Measures to Ensure Protection of Rights and Legal Interests of Children" (*Paragraph 4*).

Important remaining gaps

While some progress has been made in the area of child protection and social services for children and adolescents, important gaps remain.

- Children living and working on the street are not clearly defined in the legal and regulatory framework, thus providing services to this important group is challenging.
- No clear legal minimum age for sexual consent has been established in Ukraine and the Civil Code allows marriage of children age 14–18 if it is in the best interests of the child. The code also includes a lower legal marriageable age for females (17) than for males (18).¹⁰⁶
- Training programs on HIV prevention for children are implemented in educational institutions. However, there are no standardized protocols and authorities to provide training for the school teachers, headmasters, teachers, and employees of orphanages and other social welfare institutions involved in HIV prevention for children and adolescents.

Children living and working on the street

High-risk behaviors, such as injecting drug use, are on the rise among children in Ukraine—particularly incarcerated children, children left alone by migrating parents, and children living on the street. Legal and attitudinal barriers continue to limit the access of at-risk children to vital services. For example, the new regulations lowering the threshold for criminal possession of drugs may result in more children entering the juvenile justice system. The UNCRC Committee expressed concern that the drug strategy for 2010–2015 fails to take such issues adequately into account (United Nations Committee on the Rights of the Child, 2011). There is also a continuing lack of specialized, youth-friendly services targeting at-risk children for treatment and rehabilitation. The coverage, scope, and quality of HIV prevention programs among MARAs remain low. At the same time, MARAs have elevated HIV risk and vulnerability. This is partly due to low levels of HIV-related knowledge and skills coupled with low risk perception.

A recent legal review on the rights of children and young people living and working on the street noted a lack of official statistics on the number of children and young people living and working on the street (Bordunis, Unpublished). This lack of data is a barrier to effectively addressing HIV among MARAs.

The Family Code of Ukraine condones abandonment of “children born with physical or mental disabilities and under other circumstances of importance.”¹⁰⁷ This may increase the likelihood of a child being abandoned, being sent to an institution, or eventually living on the street. The UNCRC Committee expressed concern about the provision on child abandonment in its February 2011 report (United Nations Committee on the Rights of the Child, 2011, p.10).

While estimates vary, street children are a large and growing population. Many youth living on the street have high vulnerability to HIV infection and engage in behaviors—such as injecting drug use and sex work—that increase the risk of HIV transmission. Street children often engage in high-risk behaviors to avoid returning to home environments in which they have experienced neglect and abuse. Poverty encourages youth to engage in transactional sex. Children are often placed in institutions that lack the capacity to provide adequate care, preventing them from developing necessary life skills and increasing the likelihood that they will escape to the street. Youth incarceration also increases HIV risk, as prison environments often expose youth to sexual abuse and drug use, and HIV prevention and treatment services are limited. Children and young people living and working on the street in Ukraine have poor awareness and knowledge of HIV and low risk perception. They also have limited access to services due to S&D and poverty. Healthcare providers often demand payment for health services from homeless children and youth.

¹⁰⁶ Civil Code, Ukraine.

¹⁰⁷ Family Code (article 143, paragraph 3).

The vulnerability of children and young people living and working on the street is increased by several gaps in Ukraine’s legal and regulatory framework. While national legislation defines the concept of a homeless child, it does not contain a definition of a “neglected child,” nor does it regulate the rights of homeless and neglected children. There are no mechanisms in place to enable homeless and neglected children to exercise their rights, nor is there a mechanism in place for CDPC to receive benefits.¹⁰⁸

Government institutions that provide social protection for homeless children include Service on Children’s Affairs shelters; centers for the social and psychological rehabilitation of children; and social and rehabilitation centers (“Children’s Town”). Children with substance addictions can only be admitted to the Centers for Medical and Social Rehabilitation for Minors.¹⁰⁹ It is important to note that the regulations do not specify that children living on the street must be placed in an institution; however, key informants report that these children are regularly “rounded up and put into a shelter by police services.” Once in those temporary shelters, service providers do not always provide a full spectrum of required services, and many children escape—not wanting to be placed back in their homes or in previous institutional settings. One NGO representative suggested that these police services “should be better prepared to approach the children and convince them to come in for services. Shelters should be open for children to come and go to get access to services rather than feeling imprisoned.”

No limitations for HIV-positive children to stay at institutions for homeless children have been specified.¹¹⁰ However, HIV is not mentioned in the National Program to Overcome Children’s Homelessness and Neglect for 2006–2010. Nor are HIV-related services included in the list of services for children to be provided in social and rehabilitation centers (“Children’s Town”).¹¹¹ Standards for provision of social support and social services to homeless children have not been adopted, nor are there procedures and tools to assess the needs of and create a social support plan for such children.

A 2004 MOH/MOFYS joint order outlines procedures for the interaction between social service centers for youth and healthcare institutions with respect to the prevention of early social abandonment.¹¹² However, these procedures have not been effectively implemented. In December 2009, the MOFYS

¹⁰⁸ Bordunis, Tetiana. 2010. “Legal and regulatory review on the rights of children and young people living and working on the street, prevention of homelessness and neglect in Ukraine.” USAID HIV/AIDS Service Capacity Project in Ukraine.

¹⁰⁹ Law #20/95-VR of 1.24.1995, “On Juvenile Agencies and Juvenile Services and Special Institutions for Children” (*Article 7*); CMU Resolution #1072 of 9.6.1996, “On Approval of Standard Provisions on Center for Medical and Social Rehabilitation of the Minors”; Law #2402–III of 4.26.2001, “On Protection of Childhood” (*Article 24*); CMU Resolution #565 of 4.26.2002, “On Approval of the Provisions on Adoptive Family” (*Paragraphs 1 and 15*); CMU Resolution of 1.28.2004, “On Approving the Model Regulations on the Center for Social and Psychological Rehabilitation of Children” (*Paragraphs 1 and 17*); Law #2623–IV of 6.2.2005, “On Basic Principles of Social Protection for Homeless Individuals and Neglected Children” (*Articles 2.3, 23, 24, and 25*); CMU Resolution #1291 of 12.17.2005, “On Approval of Standard Provisions on Social and Rehabilitation Center – Children’s Town” (*Paragraphs 1 and 3*); CMU Resolution #1421 of 12.29.2009, “On Approving the Model Regulations on the Center for Social Protection of Children ‘Our Children’” (*Paragraphs 1, 4, and 19*).

¹¹⁰ *Ibid.*

¹¹¹ Law #2402–III of 4.26.2001, “On Protection of Childhood” and Law #2623–IV of 6.2.2005, “On Basic Principles of Social Protection for Homeless Individuals and Neglected Children” (*Article 2*); CMU Resolution #565 of 4.26.2002, “On Approval of the Provisions on Adoptive Family” (*Paragraph 21*); Verkhovna Rada Resolution #1428–IV of 2.3.2004, “On the Recommendations of the Parliament Hearings ‘On the Problem of Homeless People and Street Children and Ways of Overcoming the Problem’” (*Paragraph 1*); Joint Ministry of Labor and Social Policy, MFYS, MOH, MOIA, State Committee for Nationalities and Religion, and State Department for Enforcement of Sentences Order #70/411/101/65/19/32 of 2.19.2009, “On Approving The Information Exchange Procedure for Entities Providing Social Services for Homeless People” (as amended on February 19, 2009); MFYS Order #4568 of 12.29.2009, “On Approving of the Model Regulations on the Multidisciplinary Street Social Work Team Providing Social Services for Risk Groups among Children and Youth”; CMU Resolution of 1.28.2004, “On Approving the Model Regulations on the Center for Social and Psychological Rehabilitation of Children.”

¹¹² MOH, MOFYS Joint Order #625/510, October 22, 2004, “On Approving the Procedures for Interaction between Social Services Centers for Young People and Healthcare Institutions to Prevent Early Social Abandonment.”

issued an order¹¹³ establishing a multidisciplinary team of specialists to provide social and prevention services to most-at-risk children and youth. This is the first time that such a team has been created to prevent HIV among homeless and neglected children.¹¹⁴

HIV Counseling and testing (HCT)

“Current legislation is not allowing us to provide HCT to MARPs without violating the legislation”—about the uncertain status of mobile clinics and the requirement to take doctors from the AIDS center to outreach services.

The HPP team examined 15 Ukrainian laws, regulations, and guidelines and spoke with key informants about the implementation of these laws and regulations as well as potential gaps or barriers that may influence access to and quality of HCT services.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- Clinical guidelines for HCT are detailed for every population group, but are outdated.
- Current legislation for HCT is oriented to the client coming voluntarily rather than to provider-initiated CT.
- The new HCT protocol, including provider-initiated counseling and testing (PICT), is currently in draft form and has been submitted to the MOH for review and approval.
- HCT can be offered by any organization with a license and accreditation, but supervision of HCT services is not consistent.
- HCT services are available through mobile clinics with medical providers, but the legal status of mobile clinics is uncertain.
- Rapid testing is limited to maternity hospitals in the government sector and through donor and grant support for other populations. Protocols for wider use of rapid testing are in draft form but will still only be dependent on the availability of local funding.
- There is insufficient involvement of *Dovira* cabinets, TB, narcology, and STI centers in HCT.
- Trainings for HCT specialists is scarce, but an USAID-funded project is currently working with the post-graduate Medical Academy in Kyiv to initiate an in-service training in HCT.

Access to HIV counseling and testing services

Legislation provides for free of charge access to HCT by any healthcare facility regardless of its ownership (private, non-profit, or government), as long as it holds an appropriate license and is formally accredited.¹¹⁵ Some NGO leaders that served as key informants for this assessment expressed concern that

¹¹³ Order of the MOFYS #4568 of December 29, 2009, “Standard Regulations on the Multidisciplinary Street Team on Social Work with Most-at-Risk Children and Adolescents.”

¹¹⁴ Bordunis, Tetiana. 2010. “Legal and regulatory review on the rights of children and young people living and working on the street, prevention of homelessness and neglect in Ukraine.” USAID HIV/AIDS Service Capacity Project in Ukraine.

¹¹⁵ Both the HIV/AIDS law (Law 2861, Dec. 2010) and the National HIV/AIDS Program 2009–2013 (Law 1026, Feb. 2009) enable access to HIV counseling and testing services.

this licensing and accreditation system has not actually been developed or implemented yet. They fear that their services could be closed by the government once the law is implemented.

Despite legislative assurances that HCT is provided free of charge, the national budget only includes funding for tests for blood donors and pregnant women. Oblast budgets are expected to pay for tests for 5 percent of their population, and these 5 percent are to be reserved for MARPs. Implementation of this requirement varies depending on funding availability in regions. Mykolaiv reported paying for tests for 6.4 percent of the population (70,000–80,000 individuals), but Kirovograd reported paying for testing for only 3.5 percent of the population last year during the economic crisis. They stated that this year's financing would be the obligatory 5 percent.

The guidelines for providing HCT are defined but are out-of-date and currently are being updated.¹¹⁶ Although current regulations have specific emphasis on informing potential clients, and in particular MARPs, about HCT services, a strategy for targeted offering of HCT services to MARPs does not exist.¹¹⁷ Instead, NGOs have primarily cooperated with international organizations to provide more information to clients about HCT.

While HCT is primarily offered by *Dovira* cabinets, which are AIDS center sub-branches in each raion center, these regulations also emphasize the importance of providing HCT in TB dispensaries, STI, and narcology clinics.¹¹⁸ Unfortunately, key informants report that the public is not informed about *Dovira* cabinets as the main HCT sites. The sites are not promoted properly or properly labeled within facilities. The client may not see the cabinet mentioned on the directory and may have to ask someone where it is located. Additionally, other medical workers may not be aware of the *Dovira* cabinets and the services available.

A number of regulatory documents aimed at improving HCT services are currently being reviewed and approved by the MOH. These draft regulations include guidance on PICT, regulations on providing HCT in mobile clinics, and a MOH regulation on quality assurance of laboratory testing. These documents were developed by an active MOH VCT Working Group supported by USAID.

Testing and counseling among youth ages 14–18 years

As described above,¹¹⁹ the 2010 HIV/AIDS Law permits counseling and testing of youth ages 14–18 years without parental consent or legal representation. Several key informants considered this a groundbreaking change in legislation to provide greater access to young people. There are some areas of confusion for stakeholders, including among service providers, in the interpretation of how to provide post-test counseling, particularly in the case of a HIV-positive result. While the HIV/AIDS law notes that it is *recommended* to provide test results in the presence of parents/guardians/legal representation, some of the key informants we interviewed have interpreted this as a *requirement*. The recommendation also specifies that HCT service providers consider the emotional and physical well-being of the child when providing test results. This is a point of confusion for many service providers. One key informant noted that “any child or young person would require emotional support when receiving an HIV-positive diagnosis.”

¹¹⁶ The guidelines for providing CT are defined in the MOH Order #415, August 2005, which standardizes the procedure.

¹¹⁷ MOH Order #236, April 2006 and MOH Order #446, July 2006.

¹¹⁸ MOH Order #102, February 2008.

¹¹⁹ See page 5.

Mobile clinics providing HCT

Mobile clinics operating out of healthcare facilities as well as NGO mobile clinics are permitted to provide HCT services.¹²⁰ Specific regulations on the status and scope of mobile clinics in providing HCT services are currently being reviewed and approved by the MOH. Currently, according to key informants, the vast majority of mobile clinics offering HCT are operated by NGOs. Key informants in the regions consider the mobile clinics to be an excellent resource for reaching raions, villages, and vulnerable populations that may not have access to HCT services near their homes.

One key consideration and concern of NGOs providing mobile clinic services is that current regulations require HCT post-test counseling be provided by a physician. Mobile clinics must have a physician with them in order to communicate the test results, and official results of the HIV test in the form of a certificate (*spravka*) cannot be provided by NGOs—only by facilities with a licensed and accredited laboratory. Key informants in Kirovograd and Mykolaiv noted the importance of adequate training and task-shifting to allow others to provide post-test counseling.

Post-test counseling regulations

In addition to the regulatory requirement that physicians provide post-test counseling and guidelines on providing that service,¹²¹ there are also new regulations that specify how a provider should counsel their client and guidance that the provider should provide to the client about informing partners. Although HCT services can be provided anonymously, if a client tests positive for HIV, the provider encourages the client to register at the AIDS Center in order to enter care and provides information about NGOs that can provide support. Diagnostic testing, care, and ART can only be provided once a client chooses to register. Registration at the AIDS Center is confidential, and medical providers must not disclose a client's HIV status to anyone, according to the new HIV/AIDS Law.¹²² Service providers and NGO representatives that were interviewed reported that many clients choose not to register and some are lost to care and treatment.

Informing partners and partner counseling

The HIV/AIDS Law specifies that a provider should first ask the client to inform his/her partners. The client can give his/her partners to the doctor and ask the doctor to inform partners for him/her; however, there is no clear mechanism or procedure for informing partners.

As described in the law, if the client refuses and, after repeated counseling sessions, the provider believes that the client is continuing to engage in high-risk behaviors, the provider must take responsibility for informing the client's partners without disclosing the identity of the client. This requirement may provide opportunities for abuse. Key informants, including service providers, expressed concern about the difficulty in implementing this new requirement. They expressed concern that there are no criteria for deciding that the client will not change his/her behavior, nor are there clear criteria for identifying high-risk behavior. There is also no mechanism described to identify the client's partners unless the client provides that information.¹²³

Implementation and promotion of provider-initiated opt-out counseling and testing

Current legislation for HCT is oriented toward the client seeking services voluntarily (VCT) and not toward PICT. However, awareness among the public about the availability of HCT services is still low, and initiation of HCT for vulnerable groups is mostly provided by NGOs.

¹²⁰ MOH Order #415, August 2005.

¹²¹ *Ibid.*

¹²² Law# 2861-VI, December 2010.

¹²³ Law of Ukraine # 2861-VI as of 12.23.2010.

PICT can become a substantial complement to the existing HCT practices, but currently only donor blood and pregnant women are tested through a provider’s initiation. PICT is currently being considered by the MOH for wider implementation in Ukraine.

Key informants, including international NGOs and service providers, are interested in implementing PICT to help address the problem of loss of clients referred by NGOs to the AIDS Center. These key informants noted that the introduction of PICT will require significant pre- and in-service training for healthcare providers at all levels of care.

Policies allowing appropriately trained and supervised lay workers to provide counseling and testing services

Current legislation allows for both state- and NGO-owned mobile clinics, outreach teams, and private and NGO clinics to provide HCT services. As described above, regulations require that physicians provide post-test counseling. Training of HCT providers is defined in legislation,¹²⁴ but the capacity of state programs is low. Government-sponsored training is only available in the National Academy of Post-graduate Education in Kyiv, which offers only two courses per year. The majority of trainings for medical and social workers is performed by international organizations or NGOs. The newly adopted HIV/AIDS law requires that specialized training for HCT workers be provided by a licensed and accredited training site.

Point-of-care rapid HIV testing

Centralized supply and use of rapid tests in health facilities is limited only to “maternity houses” (labor and delivery facilities) and donor blood testing in urgent cases.¹²⁵ In 2009, a temporary provision was issued by the MOH allowing rapid tests to be used for express diagnostics in TB, STI, and narcology clinics; however, their procurement is reliant on local will, and funding and is rarely fulfilled.¹²⁶ In 2010, the supply of HIV rapid tests was mainly provided by the Clinton Foundation and the Alliance.

According to current legislation, the use of rapid tests across health facilities and in mobile clinics for regular HCT services is not permitted. A new MOH Order on laboratory diagnostics of HIV infection “Procedure of identification of serological markers of HIV, and quality assurance of testing,” currently being registered in the Ministry of Justice, will formally regulate the use of rapid tests more widely. This protocol will allow for the use of rapid tests in any facility if it can afford the cost of the test system. Key informants noted that individual laboratories and epidemiologists sometimes do not register cases of HIV because they do not believe that rapid testing is accurate and do not agree with the approach of using two different rapid tests to confirm HIV.

Access to High-Quality, Low-Cost Medications

“We cannot provide treatment according to those [international] guidelines because we don’t have a reliable supply [of drugs].”

The HPP team assessed the GOU’s commitment to provide access to high-quality, low-cost medications to PLHIV, including ART, OI prophylaxis and treatment, and other drugs through the review of 91 Ukrainian laws, regulations, standards, protocols, and guidelines.

¹²⁴ Law 1026, Feb. 2009 (National AIDS Program) an MOH order 415 provide for trainings of physicians on CT.

¹²⁵ Law 2861, Dec. 2010, MOH Order 255, June 2003.

¹²⁶ MOH Order 639, August 2009.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- The NAP declares that the government will provide 80 percent of ART drugs and aims to prevent resistance to ART.
- The NAP declares the government-defined need for ART; however, these estimates are not consistent with international guidelines.
- Ukrainian laws and regulations promote domestic production of ART and medical products and ensure highly-effective, safe medications.
- The State guarantees availability of essential drugs according to a formulary.
- The registration of new drugs is well defined and valid for 5 years. The process for registering new drugs is reported to be cumbersome.
- Ukraine is party to the TRIPS Plus agreement and does not allow generic versions of drugs currently under patent. The MOH could file a request with the World Trade Organization for exceptions to this agreement in the case of an epidemic but has not yet made this request.
- The MOH Order and the NAP (2010) establishes a joint working group on intellectual property and access to medicines.

Policy on access to high-quality, low-cost medications by different populations

The GOU declared its commitment to provide HIV/AIDS drugs to PLHIV in the 2009 NAP. The national program aims to achieve 80 percent coverage of the specified need for ART and prevention ART resistance through the provision of ART according to standards and clinical protocols. Ukraine's standards and clinical protocols were revised in 2010 to reflect changes in international standards that call for treating PLHIV earlier than previous guidelines. The 2010 ART guidelines issued by the WHO recommend initiating ART in patients with CD4¹²⁷ counts of 350 and below, regardless of symptoms, whereas the previous guidelines recommended initiating ART in patients with advanced clinical disease and/or a CD4 count of 200 or below (WHO, 2010). The targets for ART in Ukraine were not adjusted in the NAP to reflect these changes. There is also a lack of a clear strategy for scaling up access to ART.

During key informant interviews, the team asked service providers whether they are implementing the new MOH-approved clinical guidelines recommending initiating ART at CD4 counts of 350. Service providers responded that "there's no way we can implement that guideline with the current funding. We struggle to take new patients on fast enough at their current practice of 150 CD4." One service provider noted new patients often have to wait for therapy and may only begin treatment at very low CD4 counts—even as low as a CD4 count of five.

The 2009 NAP also guarantees funding for the PMTCT program from the state budget to purchase components such as HIV tests kits, rapid tests, CD4 and viral load tests, ARVs, PCR tests for early diagnosis among newborns, supplies, and adapted infant formula for infants born to HIV-infected mothers. The NAP also guarantees availability of pediatric ARVs and registering and monitoring of drug side effects.

PLHIV and their partners living in rural areas face significant barriers to receiving high-quality, comprehensive medical services. In regions such as Mykolaiv, the AIDS Center hosts regular lectures, trainings, and informational sessions for infectionists and primary care physicians working outside the

¹²⁷ Cluster of differentiation 4 (cell count).

city of Mykolaiv. Not all regions have the resources or initiative to provide this level of support to physicians treating PLHIV outside the AIDS Center. In some regions receiving lower levels of funding and external donor support, key informants reported that “there is little communication and data sharing between the AIDS Center and physicians at the district level or in rural areas.” This results in inadequate and uncoordinated care for PLHIV living outside the oblast center.

Access to medications

Ukrainian laws guarantee free ART and treatment of OIs, as well as the accessibility and appropriate quality of HCT services (including anonymous testing, the provision of preliminary and follow-up consulting services, and ensuring of the safety of testing for client and provider).¹²⁸

Pediatric clients are a specific priority group for care and treatment services. Based on consistent responses during key informant interviews with service providers, government officials, and NGOs, it was clear that OI drugs—with the exception of TB drugs—are only being partially covered by regional budgets. The remaining cost is paid for through humanitarian assistance or by the client. Two respondents noted that providers may provide the first half of the OI treatment for free from their pharmacy and then expect the client to purchase the other half of the treatment. As a result, the client often takes only the first half of the treatment. National budgets fund TB treatment in full for clients, although key informants stipulated that sometimes the full course of drugs are not available. In some cases, the full range of required drugs were not delivered to the facility.

Although the state has committed to providing free ART, the needs of all adult patients cannot be met due to the high price of medications. While the government and Global Fund are providing significant funding for ART, clinicians do not have sufficient amounts of ARVs available to begin ART in accordance with the new clinical protocols and international standards. Many clients are waiting for access to ART. In one facility we visited, the head doctor noted that the facility has 20 clients with CD4 counts below 150 who must wait for the next shipment of drugs to arrive, as currently they do not have sufficient stocks of ARVs to meet their needs. The drugs are not likely to arrive before the fall—at least seven months from now. The head doctor at another AIDS Center noted that 70 percent of the center’s clients have a CD4 count of 100 or below.

Inconsistent central procurement of ARVs and other medications has led to stockouts and threatened stockouts in Ukraine. AIDS Centers generally follow guidance to “cover patient need for 12 months”; however, the timing of the delivery of the next year’s procurement is unpredictable. The Main Control and Auditing Department of Ukraine (known as KRU) is responsible for investigating how funds are used and if they are allocated and used properly. The agency can penalize institutions for overestimating their need or for underutilizing existing inventory. Facilities across the country must find ways to amass enough drugs to avoid stockouts and maintain treatment adherence until the next shipment of medications arrives. One method for building up extra stock is to adopt a more conservative approach to initiating clients on ART. One service provider interviewed noted that

“No patient of mine currently on ART will suffer from stockouts. It is the new patients who are waiting to receive drugs who will suffer. For instance, in the first quarter of the year, I should have accepted 10 individuals on treatment through the Global Fund program and 40

¹²⁸ Law 1972-XII of 12/12/1991, “On the response to the transmission of diseases, caused by the human immunodeficiency virus (HIV), as well as legal and social security of people living with HIV”; Law # 2861-VI of 12/23/2010, “On the amendments to the Law of Ukraine ‘On the prevention of acquired immune deficiency syndrome (AIDS) and social security of population’”; Law # 2801-XII of 11/19/1992, “Fundamental principles of healthcare legislation of Ukraine”; Law # 1026-VI of 02/19/2009, “On the approval of National Program for HIV prevention, treatment, care and support to HIV-positive and people with AIDS for 2009–2013.”

individuals through the government funded treatment program. I was able to take on all 10 clients using Global Fund resources, but only 20 clients on the government-funded program. I couldn't put the clients on ART at risk of a stockout and break in treatment.”

When asked about how the facilities prevent stockouts, one head doctor reported that they keep an extra six-month supply of drugs on hand. Another head doctor reported maintaining a supply buffer of three months. These providers freely admitted that this is not permitted by auditing authorities, but that they cannot trust the government's procurement and supply chain processes. More information about procurement and supply chain management can be found in the section “HIV/AIDS Drug and Commodity Procurement and Supply” (see page 48).

Resistance and access to second and third-line ART

Ukraine does not currently use government funds for research and testing on drug resistance (Ministry of Health, Ukraine, 2010). One facility noted during key informant interviews that they were able to test for drug resistance when they participated in an internationally-funded project in the past. Most funding for ART is used for first-line drugs. Second- and third-line drugs are simply too expensive for the government to provide more widely.

Government provisions on pricing

Final pricing for a medication is determined by taking into account several factors. One of the most influential factors is the presence or absence of patent protection. Patent owners can choose to control and limit the development, distribution, and use of other medications (generics) on the basis of their invention. Patent and intellectual property rights are addressed below.

Two CMU resolutions issued in 2008 and 2009 govern drug pricing. These resolutions specify that the premium for a Ukrainian firm trading in these medications (“middleman”) should not be higher than 12 percent of wholesale prices and that the trading (retail) premium for a pharmacy should be no higher than 25 percent of the purchase price for drugs included in the Essential Drug List. Also, the resolutions specify that pharmaceuticals and medical products (except narcotics, psychotropic drugs, precursors and medical gases), procured wholly or partially with government budget resources, should have a premium no higher than 10 percent. ARVs that are approved for distribution and use are published in the drug formulary for Ukraine.¹²⁹

Timely registration of ART, OI drugs, and drugs for care and treatment

On the legislative level, the issue of registering medications used in the field of HIV/AIDS is regulated by Article 9 of the 1996 law “On medications.”¹³⁰ Medications are approved for use in Ukraine only after their registration. The government body that grants registration approves the quality control methods and production technologies for the medication and assigns it a registration number, which is entered into the National Medications Register. Medications can be used in Ukraine for up to five years after their state registration.

The period of time for the drug's approved use in Ukraine can be shortened at the request of the individual or organization applying for registration. This may happen if previously unknown dangerous side effects of the medication occur or for some other reason. The MOH, or a body authorized by it, can

¹²⁹ MOH Order No. 226, of May 24, 2005, “On Approving the Regulations on the National List of Essential Drugs and Medical Products and the Regulations on the Expert Committee on Drawing Up, Making Changes In the List of Essential Drugs and Medical Products.”

¹³⁰ Article 9 of Law of Ukraine # 123/96-BP of 04/04/1996, “On medications” (*latest edition of 06/05/2010 on the basis of the Law of Ukraine #2165-VI of 05/11/2010*).

make a decision for a full or temporary ban of the medication. The decision to refuse to register a medication is made on the basis of verified conclusions regarding its effectiveness and safety.

Compulsory licensing and intellectual property rights

Registration may also be refused if granting it will infringe on effective patent-protected intellectual property rights through the production, distribution, or use of the medication. The patent owner can, for an established period of time, limit competitors' ability to use the formula/innovation used in developing the drug. This hinders the access of patients to cheaper generic drugs. Through key informants, the team learned that in cases of an epidemic, the MOH can apply flexibilities or exclusivities to ignore the intellectual property rights of an individual or corporation in the interest of the public good. This right has not been applied by the MOH in the case of HIV drugs.

Additionally, for five years after a medication is registered, it is prohibited (irrespective of the validity term of any patent related to the medication) to use the registration information in applying for registration of another medication, except for cases in which the right to refer to or use such information was obtained or purchased from patent owner. This could be a significant barrier delaying access to lower-cost drug options.

One other important issue jeopardizes prospects for lowering medication prices in the near future—legal protection for pre-clinical and clinical trial data. By law, patent owners are allowed to prevent the use of pre-clinical and clinical trial data by others attempting to register a generic medication. This can negatively influence access to treatment by keeping the price of available drugs higher than they could be if the generic version were registered for use in Ukraine.

The MOH and the National Academy of Sciences of Ukraine established a joint working group on intellectual property and access to medicines in 2010.¹³¹ This working group is tasked with improving Ukrainian legislation regulating registration of medications and protection of intellectual property rights.

Regulations on quality control and stock management

The quality control of medications (including ARVs) imported into Ukraine is also regulated by the 1996 medication law. Article 17 stipulates medications registered in Ukraine can be imported if there is a quality certificate issued by the manufacturer. At the end of 2008, the State Inspectorate on the Quality Control of Medications was granted the authority to execute state control over the quality of medications imported to Ukraine.¹³²

If an imported medication already has a Good Manufacturing Practices (GMP) certificate provided by an agency, such as the U.S. Food and Drug Administration, it passes only visual quality control. On its own, the certificate already indicates an adequate level of quality. If the certificate is absent, the medication goes through double control—visual and laboratory quality control. The procedures for laboratory control of medications are now under development. Executing laboratory control for each shipment of medication requires considerable resources (time, money, and specialists).

A decree issued by the President of Ukraine in 2005 prevents the circulation of counterfeit and sub-standard medical products.¹³³ Additionally, the CMU has passed resolutions that help implement this decree. In 2008, the CMU issued an action plan to improve state control over the trafficking of drugs and

¹³¹ Order # 787/130 of the MOH of Ukraine of 09/16/2010.

¹³² Cabinet of Ministers Decree # 902 of 09/14/2005, "On the approval of the Procedure for state quality control of medications imported to Ukraine."

¹³³ *Ibid.*

medical devices. Then, in 2010, the CMU issued a mechanism to prevent the circulation of counterfeit, substandard, and unregistered drugs.¹³⁴

The MOH has issued its own series of orders to control drug quality:

- Instructions on how to control drug quality at wholesale and retail trade (2001)¹³⁵
- Regulation of storage and quality control of medicines in healthcare settings (2003)¹³⁶
- Procedure for clinical trials of medicines and expertise of clinical trials (2009)¹³⁷
- Concept of the pharmaceutical sector in the health of Ukraine for 2011–2020 (2010)¹³⁸

Despite the efforts of the MOH and CMU to continually regulate the quality and pricing of medications available in Ukraine, key informants maintain that there are still significant problems with gaining access to ARVs and other drugs used in providing treatment and care to PLHIV.

HIV/AIDS Drug and Commodity Procurement and Supply

“If the law was clear, everything was planned out and programmed, of course, there would be no disruption to the supply chain.”

The HPP team assessed the Ukrainian government’s Procurement and Supply Management (PSM) system for HIV drugs and commodities through the review of 91 Ukrainian laws, regulations, and guidelines. The assessment focused on the status of the general supply chain, procurement, and forecasting systems in Ukraine, as well the PSM system for medications and supplies specifically related to HIV/AIDS, such as ARVs and CD4 and other lab tests to monitor ART.

Summary

While progress has been made in the PSM system, significant shortfalls and challenges remain. The main challenges identified by the team include the following:

- Lack of effective coordination and cooperation among the MOH, MOF, and the Ministry of Economy (MOE).
- Insufficient transparency and limited civil society participation in the MOH permanent tender committee.
- Barriers to participation of foreign-based organizations and foreign manufacturers in the tendering process.
- Dependence of regions on central procurement process for ARVs and other essential HIV-related drugs and commodities.

¹³⁴ Decree # 260 of the Cabinet of Ministers of Ukraine of 02/03/2010 (amended according to the Decree #902 of the COM of 10/04/2010), “Selected issues of state control over the medications quality.”

¹³⁵ Order # 436 of the MOH of Ukraine of 10/30/ 2001, “On the approval of the Instruction on the regulations for quality control of medications in retail and wholesale distribution” (registered at the Ministry of Justice of Ukraine of 02/05/2002 as # 107/6395).

¹³⁶ Order # 584 of the MOH of Ukraine of 12/16/2003, “On the approval of the Regulations for storage and quality control of medications in healthcare facilities” (registered at the Ministry of Justice as # 275/8874 of 03/03/2004).

¹³⁷ Order # 690 of the MOH of Ukraine of 09/23/2009, “On the approval of the Procedure for conducting clinical trials of medications and for expert assessment of clinical trials’ materials, as well as Standard provisions on the Ethical Issues Commissions” (registered at the Ministry of Justice of Ukraine of 10/29/2009 as # 1010/17026).

¹³⁸ Order # 769 of the MOH of Ukraine of 09/13/2010, “On the approval of the Development concept of the pharmaceutical sector of healthcare industry of Ukraine for 2011–2020.”

- Unclear and inconvenient supply and distribution system for HIV-related drugs and consumables, including a system for forecasting needs that creates opportunity for significant errors; unreliable distribution of commodities from the central level; and lack of a buffer supply system to prevent shortages and stockouts.
- Continuing gaps and shortfalls in quality assurance.
- Laboratory quality assurance compromised by the requirement that reagents used as control samples may only be procured if passed through the full government registration system.

Public procurement of healthcare commodities

Procurement of medical drugs and commodities, including those related to HIV/AIDS, is subject to Ukraine's general public procurement regulations.¹³⁹ All ARVs, as well as many other drugs and commodities used to provide HIV services, are centrally procured. The essential drug list¹⁴⁰ regulates which drugs may be procured by healthcare facilities and institutions through government budgets. ARVs, STI drugs, and drugs for the treatment of OIs are included on the essential drug list. The MOH, MOF, and MOEC are jointly responsible for the procurement of medical commodities. The MOEC is also responsible for the national pricing monitoring system for essential drugs and medical products.¹⁴¹ Annual funding for TB, HIV/AIDS, and oncology is usually regulated by joint orders of the MOH and MOF (e.g., 576/720, July 2010). Lack of effective coordination and cooperation between these ministries often delays procurements significantly and leads to difficulty securing necessary funding.

Within the MOH, procurement is managed by a permanent tender committee comprising representatives of MOH departments. The committee can invite the non-voting participation of technical experts or NGOs. In practice, however, this rarely happens, and there are many complaints about a lack of transparency in the committee's work.

Ukrainian law¹⁴² includes a principle of non-discrimination toward trade participants and stipulates that domestic and foreign participants shall participate in procurement procedures on equal terms. Nevertheless, several factors continue to limit participation of foreign-based organizations in bidding and restrict direct contact with foreign manufacturers. Tender information is usually available only in Ukrainian. The law only requires publication of English versions if the expected value for the purchase of goods is above 200,000 Euro. In addition, goods and services may only be procured from companies that are formally registered and licensed to operate in Ukraine.

Between 2008 and 2010, the Ukrainian government launched several legal and regulatory initiatives to improve the HIV-related procurement system. In March 2008, the MOH adopted a methodology for estimating the needs and collecting applications from regions for centralized procurement of drugs, medical products (including test kits), and equipment to provide medical care to PLHIV.¹⁴³ In December 2008, the MOH established an inter-ministerial working group to improve the procurement system for HIV/AIDS-related goods, works, and services.¹⁴⁴ The 2009 NAP included the establishment of a commission at the MOH on developing nomenclature for HIV-related drugs and commodities.¹⁴⁵

¹³⁹ Laws 493/95-VR (December 1995) and 2289-IV (June 2010).

¹⁴⁰ CMU Resolution 1071 (September 1996).

¹⁴¹ CMU Resolution 1247-p (September 2008)—*On Approving the Plan of Activities for Improvement of Circulation of Medicines and Medical Products*.

¹⁴² Law 2289-V (January 6, 2010)—*On Execution of Public Procurement*.

¹⁴³ MOH Order 102-Adm (March 2008).

¹⁴⁴ MOH Order 827 (December 2008).

¹⁴⁵ MOH Order 1057 (December 2010).

In February 2010, the MOH took several steps to strengthen the PSM system for HIV-related commodities, but challenges still remain:

- Established internal working groups¹⁴⁶ on (1) procurement of test kits, reagents, and medical products for HIV programs; and (2) procurement of drugs and medical products to ensure HIV prevention, treatment, care and support for PLHIV.
- Adopted a new regulation for tender documents, which prohibits contract prices from exceeding established ceiling prices for drugs and medical products.¹⁴⁷
- Outlined measures to prevent and combat acts of corruption in the procurement of medical drugs, commodities, and services.¹⁴⁸
- Set up the MOH Permanent Working Group for specialized management of public procurement.¹⁴⁹

Availability of ARVs and HIV-related drugs

The new 2010 AIDS law¹⁵⁰ guarantees free access to ARVs and laboratory monitoring for all PLHIV. Availability of ART and drugs for the treatment of STIs and OIs is guaranteed through their inclusion in the National List of Essential Drugs and Medical Products.¹⁵¹ Inclusion in the essential drug list means that they should be available at all times in adequate amounts, appropriate dosage forms, with guaranteed quality, with adequate information, and at a price affordable for any individual and for the society as a whole.

Despite these guarantees, the 2009 NAP's ultimate target for the fifth and final year of its implementation (2013) is to reach 80 percent of adult patients and 100 percent of pediatric patients in need with ARVs.¹⁵² The government reports and key informants verify that pediatric client needs for ART or OIs are met completely. The methodology used to estimate overall need for ARVs is not transparent and no reassessment of need was conducted after the new ARV treatment protocol was adopted in 2010.¹⁵³ Government and international estimates of ART coverage differ, and service providers verified during key informant interviews that they are unable to implement Ukrainian and international standards for starting ART. Additionally, budget support and procurement of medications to treat STIs and OIs is delegated to the local level. This makes the availability of such medications dependent on the commitment of the local authorities and the level of budget fulfillment, which, according to informants is rarely implemented in full.

Participation in procurement and supply planning

The MOH approved a methodology for estimating the need for ARVs in 2009.¹⁵⁴ The methodology was implemented for the first time in 2010. It states that regional healthcare authorities and the National AIDS Center are authorized to make arrangements for implementation and ensuring compliance of subordinate healthcare facilities during the process of estimating need for ARV drugs. The estimation system as currently defined involves a one-time annual centralized procurement of ARVs. Therefore, regional authorities are asked to project the ART needs for each patient for 12 months, including the expected number of new patients. While no official timeline for submission of planned needs is provided, oblasts

¹⁴⁶ MOH Order 104 (February 2010).

¹⁴⁷ MOH Order 73 (February 2010) .

¹⁴⁸ MOH Order 94 (February 2010).

¹⁴⁹ MOH Order 61 (February 2009).

¹⁵⁰ Law 2861-VI (December 2010).

¹⁵¹ CMU Resolution 333 (March 2009).

¹⁵² National AIDS Program, Law 1026-VI (February 2009).

¹⁵³ MOH Order of № 551 of July 2010, "On approval of clinical protocol antiretroviral therapy of HIV infection in adults and adolescents."

¹⁵⁴ MOH Order 936 (December 2009).

have to send their requests for ARVs to the National AIDS Center in the first half of the preceding year. The large time lag between estimating need and the delivery of drugs introduces high potential for errors in estimating need.

Key informant interviews revealed a prevalent opinion that the planning mechanism is ineffective and that often the drugs received are not the drugs requested. In addition, as described in this report's section "Access to High-Quality, Low-Cost Medications," there is no provision for keeping a buffer stock of ARVs to ensure continuity of treatment in case of delays in the procurement and distribution at the national level. According to informants, a variety of shadow measures, such as overplanning and redistribution of drugs among facilities, are employed by providers in an attempt to prevent shortages and stockouts.

Quality assurance

Responsibility for quality control rests with the State Inspectorate for Quality Control of medical goods,¹⁵⁵ which is the central body of executive power. The actions of this body are directed and coordinated by the CMU through the MOH.

Current regulations¹⁵⁶ define cases when state registration of a certain medical product may be cancelled, suspended for a defined period, or withdrawn from the market and its circulation limited or prohibited. They also outline procedures for handling cases in which a product adversely affects or poses risks to human health—whether detected during manufacturing or during use. The regulations also address inconsistency in marking and low quality and effectiveness of a product in comparison with that declared by the State Inspection for Quality Control of Medical Products. From interviews, the team observed that, while the procedure for notification of adverse effects is established, it does not always work effectively due to a lack of training, fear of receiving reduced supplies of medications in the next period, and unwillingness to do the necessary paperwork.

A CMU resolution for HIV test kits,¹⁵⁷ in accordance with a European Parliament and European Council Directive,¹⁵⁸ was issued in November 2004. The resolution stipulates that, "In the event that medical goods for in vitro diagnostic, cause risks to human health and/or safety of patients, users and other persons, the manufacturer or its authorized representative are required to take all reasonable measures to withdraw such devices from circulation or prohibit or restrict putting such devices into service." The resolution, however, is not legally binding until a corresponding law is passed. The current regulations also do not contain the procedures and amounts of clinical testing for such medical devices provided in European Union (EU) documents.

Registration of medical devices and medical commodities

Procedures for registering medical equipment and medical products are outlined in CMU resolutions.¹⁵⁹ In the case of laboratory testing, international standards call for routine implementation of quality control/assurance procedures and tests to ensure that equipment and test kits are producing accurate, high-quality test results. In Ukraine, private laboratories are able to implement internal and external quality assurance procedures, as necessary reagents are available commercially; however, government laboratories are unable to purchase the control reagents required for control testing due to requirements of the government procurement system.

¹⁵⁵ CMU Resolution of 20 December 2008 № 1121.

¹⁵⁶ CMU Regulation 1497 (November 2004).

¹⁵⁷ CMU Resolution 641 (July 2008).

¹⁵⁸ European Parliament and European Council Directive 98/79/EC, dated October 27, 1998.

¹⁵⁹ CMU Resolution 1497 (September 2004) and Order 51 (May 2010) of the State Inspectorate for Quality Control.

Reagents for quality assurance (control samples) are defined in the regulatory documents as medical products, not as technical samples. This means that the reagents must be passed through the full government registration system. The volume of the reagents used for quality control purposes is so small that it is not financially feasible or beneficial for corporations to register the substances in Ukraine. This limits laboratories' ability to monitor their own quality and participate in external quality assurance programs.

Supply management of HIV-related drugs and consumables

The National AIDS Center is responsible for monitoring use of ARVs at the regional level. Supply, storage, and transportation of HIV drugs, test kits, and consumables are organized according to the Schedule of Distribution. Supplies and commodities are supplied directly to regional AIDS Centers.¹⁶⁰ The Reference Laboratory is responsible for distributing test kits and equipment procured via the state budget to HIV/AIDS reference laboratories.¹⁶¹ “Ukrvaktsyna” State Enterprise is responsible for the delivery of test kits, and “Ukrmedpostach” State Enterprise is responsible for the delivery of ARVs.

Interviews revealed a prevailing opinion among providers that the existing system of HIV-related drugs and consumables supply is unclear and inconvenient. State procurements and distribution of products are not clearly defined in terms of delivery. In 2009–2010, the MOH issued a variety of orders defining distribution of HIV-related drugs and consumables procured through the state budget. These additional regulations were adopted in an emergency response to delays and shortcomings in the distribution system. These orders covered the distribution of the following drugs and commodities:

- HIV test kits¹⁶²
- Test kits and consumables to determine the level of viral loads¹⁶³
- Distribution of the ARV drug Kaletra for treatment of children with HIV/AIDS (provided as a charity)¹⁶⁴
- ARVs for treatment and prevention¹⁶⁵
- Reagents and consumables to determine CD4 count¹⁶⁶

TB/HIV Co-Infection

“TB doctors are not interested to know about AIDS treatment and which drugs are used. They do not even know how TB and ARV drugs interact.”—Infectionist (practicing physician specializing in HIV/AIDS)

The HPP team reviewed 47 international conventions and Ukrainian laws, guidelines, and regulations to assess (1) how the HIV policy environment reflects and supports HIV/TB coordination and (2) to what degree these laws and regulations allow available, effective, and high-quality care for people affected by TB and HIV. In addition, the team reviewed these documents to assess the current legal and regulatory framework for attention to the TB epidemic and its consequences for the national HIV/AIDS response,

¹⁶⁰ MOH order 704 (August 2010).

¹⁶¹ MOH Order N 230, of April 17, 2006, “On Setting Up a HIV/AIDS Reference Laboratory Under the National AIDS Center of the MOH”

¹⁶² MOH Order 893 (October 2010), Order 103 (February 2010).

¹⁶³ MOH Order 615 (August 2009).

¹⁶⁴ MOH Orders 666 and 726 (August 2010).

¹⁶⁵ MOH Orders 795 (September 2010) and 1008 (November 2010).

¹⁶⁶ MOH Order 1050 (November 2010).

the capacity of the government to prevent and respond to TB among PLHIV, and policies and laws that may support or hinder prevention and detection of HIV among people with TB.

Summary

Key findings from the legal and regulatory review and key informant interviews include the following:

- Importance of coordination on TB/HIV acknowledged in HIV and TB laws, National HIV and TB programs
- Good progress in coordinating care for individuals with TB/HIV co-infection:
 - Joint orders between the MOH, former MOYSF, and Ministry of Labor (MOL) — standards of social care for people with TB/HIV, TB/HIV/IDU
 - Joint orders on coordination of efforts between the MOH and penitentiary service
 - MOH order on integrated case management of patients with TB/HIV and IDU was developed. Draft order soon to be posted for public discussion.
- Registration of TB/HIV deaths not handled uniformly throughout the country. In January 2011, National AIDS center sent recommendations to all AIDS Centers providing guidance on the inspection and registration of death among PLHIV.
- TB screening recommended in AIDS centers, but official diagnosis and treatment of TB cases only in TB dispensaries.
- TB doctors often not aware that TB in a PLHIV is a precondition to start ART. TB doctors reported to be unaware of drug interactions (TB drugs and ART).
- Violations of infection control standards frequent. New standard of infectious control defined in the MOH order (2010).

Coordination on TB/HIV

The importance of coordination on TB/HIV is acknowledged in both HIV and TB laws, and the current law on TB¹⁶⁷ and law on HIV/AIDS¹⁶⁸ contain references to each other. Activities related to TB and HIV co-infection are included into both the 2009 NAP and National TB Program (2007–2011).¹⁶⁹ Since 2007, the National Council on HIV/AIDS has also included TB.¹⁷⁰ All regions also include TB in the scope of regional coordination councils. At the MOH, there is a separate agency to coordinate all government activities for HIV/AIDS, TB, and other socially dangerous diseases.¹⁷¹ Recently, through the administrative reform process, the MOH’s Committee on HIV and Socially Dangerous Diseases was changed to the status of a State Service, and it is anticipated that it will maintain its coordinating role.

In addition to MOH actions on TB and HIV, other ministries have issued joint orders and recommendations. For example, recognizing the need for coordination in the provision of social services, joint orders between the MOH, former MOFYS, and MOL were adopted in September 2010 to prescribe standards of social care for people with TB/HIV co-infection and IDUs with TB/HIV co-infection.¹⁷²

Considering the prevalence of TB and HIV in the penitentiary system, the GOU recognized that coordination between the penitentiary service and medical and social sectors are vital. A July 2009 CMU

¹⁶⁷ Law of 05.07.2001 № 2586-III, “On Fighting Tuberculosis.”

¹⁶⁸ Law of 12.12.1991 № 1972-XII, “On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and social protection” as amended by Law from 23.12.2010 № 2861-VI.

¹⁶⁹ Law of 08.02.2007 № 648-V approving the National Program against TB in 2007–2011.

¹⁷⁰ Resolution of the CMU of 11.07.2007 № 926, “Some aspects of the TB and HIV/AIDS control.”

¹⁷¹ CMU Resolution of 31.05.2006 № 759, “On establishment of the Committee for HIV/AIDS and other socially dangerous diseases.”

¹⁷² Joint Order MOFYS, MOL, MOH from 13.09.2010 № 3123/275/770.

resolution approved an implementation plan for providing assistance in the social re-adaptation of prisoners.¹⁷³ This was followed by a joint order issued in October 2010 on the coordination of efforts between the MOH, MOIA, MOFYS, MOL, and penitentiary service for effective TB case management of individuals who are released from prisons.¹⁷⁴

TB/HIV surveillance system

The TB surveillance system, particularly for TB/HIV co-infection, is still weak. Development and implementation of a computerized TB register for maintaining health information records was declared in the National TB Program for 2007–2011. Introduction of the TB register is also envisaged in a new TB Law, which passed the first reading at the Verkhovna Rada (Ukrainian Parliament). However, as of March 2011, the register has only been piloted in three oblasts (Kherson, Dnipropetrovsk, and Donetsk). The newly launched Global Fund Round 9 Grant on TB in Ukraine will further the implementation of this register.

Several key informants pointed to significant problems with understanding the procedure of registering deaths among individuals with TB/HIV co-infection. In the forms used as a part of the health information system¹⁷⁵ and HIV/AIDS reporting forms,¹⁷⁶ there is no clear instruction on how to register deaths of patients with TB/HIV. Deaths among patients with TB/HIV are often registered as deaths due to AIDS rather than deaths due to TB. This results in an apparent increase of AIDS-related deaths, while TB deaths remain hidden. In January 2011, the National AIDS Center sent an information letter with recommendations for inspection and registration of death among PLHIV. According to this information letter, these cases of co-infection now have to be considered at a meeting of a clinical expert commission before a decision is made on the cause of death.¹⁷⁷

Detection of TB among PLHIV

TB screening is obligatory for patients who are newly registered in AIDS Centers; however, the procedure for routine TB screening among those who are already registered is limited to one examination per year or the presence of TB symptoms.¹⁷⁸ According to an MOH order related to health facility staffing, AIDS Centers should have a TB doctor present on staff.¹⁷⁹ The majority of AIDS Centers have a TB doctor on staff and can provide TB screening routinely. For those AIDS Centers without a TB doctor on staff, such as in Kirovograd oblast, centers must refer patients to the oblast TB dispensary. Key informants expressed concern about this approach, as clients may choose not to go to the TB dispensary or may even be put at risk of infection while visiting the TB dispensary. Even for those clients that are screened for TB in the AIDS Center, confirmatory diagnosis is only available in TB dispensaries, which again risks clients choosing not to go to the TB dispensary or being exposed to TB infection. Although clients are supposed to be actively tracked to ensure that they appear at the TB dispensary if they had a positive TB screening, the reality described to the team during the key informant interviews is that clients cannot be forced to come and this can result in a loss to follow-up.

¹⁷³ CMU Resolution of July 2009 № 740, “On approval of a plan of implementation of the Concept of social adaptation of persons serving sentences of imprisonment for a term up to 2015.”

¹⁷⁴ Joint Order of the MOH, State Department for Punishment Executions, MOIA, MOL, MOFYS of 04.10.2010 № 834/365/474/304/3466, “On approval of the interaction between health care institutions, penal institutions and detention prisons, territorial agencies of internal affairs, labor and social protection, centers of employment, social centers for families, children and youth on case management of tuberculosis in the event of TB patients release from penal institutions, detention prisons, and continuation of treatment in specialized health care settings.”

¹⁷⁵ MOH forms N 502-1/o, N 502-2/o.

¹⁷⁶ MOH forms N 1 – HIV/AIDS and N2 – HIV/AIDS.

¹⁷⁷ Letter of the Ukrainian Center for Prevention of AIDS of 13.01.2011 #41.

¹⁷⁸ MOH Order of № 551 of July 2010, “On approval of clinical protocol antiretroviral therapy of HIV infection in adults and adolescents.”

¹⁷⁹ MOH Order N 122 of 12.03.2008 about modification in MOH order of 23.02.2000 N 33.

Service providers interviewed noted that not all patients testing positive for HIV will choose to be registered at AIDS Centers. These clients may not undergo routine physicals or routine TB screening, and their TB/HIV history is not monitored.

HIV testing and counseling among TB patients

TB hospitals are obliged to provide HIV screening among TB patients on a voluntary basis.¹⁸⁰ Since 2009, a temporary regulatory document defines the procedure for using rapid tests for HCT services in TB, STI, and narcology clinics.¹⁸¹ However, rapid tests are not supplied through centralized procurement, and availability of test kits depends on local procurement or Global Fund programs. If a client tests positive for HIV in one of these medical settings, the client is formally referred to the AIDS Center for confirmation of the diagnosis. Quarterly reports with the number and results of tests are sent by the TB, STI, and narcology clinics, and there is no responsibility to effectively refer and follow up with clients to ensure that they went to the AIDS Center for further care.

As of the date of submission of this report, a draft MOH Order “On the referral services for diagnosis, treatment and support of patients with concurrent disease, HIV, TB, viral hepatitis,” which outlines a clear referral system and a protocol for PICT for HIV, had been finalized and was expected to be made available soon for public discussion on the MOH website.

Treatment of patients with TB/HIV co-infection

The MOH has a protocol for treatment of clients with TB/HIV co-infection.¹⁸² The protocol contains a note that it should be updated in May 2010; however, it was not and has not yet been updated. The protocol does not cover issues on TB/HIV treatment among children, nor does it include specifics or link to guidelines on adherence counseling for TB and ARV drugs. Patients are often sporadically counseled depending on doctors’ availability and/or the presence on NGOs. The lack of systematic adherence counseling for clients with TB/HIV co-infection sometimes results in interruption of treatment and may result in development of resistance to TB and ARV drugs.

Key informants remarked that TB doctors do not receive special training on the interaction of TB and HIV drugs and often believe it is necessary to complete an intensive phase of TB treatment before administration of ARVs. This may result in delaying initiation of ART until CD4 count has fallen to five or fewer cells. Not all TB doctors are aware of the protocol for immediate cotrimoxazole treatment together with TB treatment for patients TB/HIV co-infection and CD4 counts lower than 200.¹⁸³ A course for TB/HIV is scheduled to be introduced in 2010 for medical students and in post-graduate academies.

Infection control

A new standard on infection control for TB in healthcare settings, the penitentiary system, and residence of patients with TB was recently adopted.¹⁸⁴ Specialists from the Sanitary-Epidemiological Service are responsible for monitoring and assessment of infection control measures for TB in healthcare settings at least once a quarter; however, additional trainings are not provided to meet this new standard. The National TB Program (2007–2011) contains only one infection control activity, which is providing TB

¹⁸⁰ MOH Order No. 399 of August 2005 and in accordance with the MOH instruction of July 2006 No. 446 on VCT in TB, STI and narcology dispensaries.

¹⁸¹ Temporary Instruction of application of rapid tests in TB, STI, and narcology clinics (approved by the MOH Order of August 2009 N 639).

¹⁸² MOH Order of May 2008 № 276 approves the Protocol of treatment of patients with HIV/TB co-infection.

¹⁸³ *Ibid.*

¹⁸⁴ MOH Order of August 2010 N 684.

facilities with local decontamination facilities.¹⁸⁵ In interviews with key informants, violations of infection control were mentioned and lack of infection control was described as one reason why patients with HIV were often lost to follow-up when they were referred to TB clinics.

¹⁸⁵ Law of 08.02.2007 № 648-V approving the National Program against TB in 2007–2011.

CONCLUSION

Ukrainian policy and legislation provides a strong foundation; however, it is evident from key informant interviews that there is inconsistent implementation of national laws and regulations. Additionally, no organization or entity is responsible for routinely monitoring and evaluating policy implementation.

USG investments in HIV have influenced the overall policy process in Ukraine. USAID projects have facilitated multisectoral stakeholder involvement in policy development and have contributed to the development of the National AIDS Program 2009–2013, operational plans for implementing the NAP at the oblast level, regional coordination councils, and the new HIV law passed in 2010 and signed by the President in January 2011. Developed in consultation with a wide range of public sector, nongovernmental, and other donor stakeholders, a Partnership Framework between the USG and GOU was signed on February 15, 2011. The Partnership Framework defines goals and activities in the area of HIV programming for the next five years:

- *Goal 1:* Reduce the level of HIV transmission among IDUs and other MARPs.
- *Goal 2:* Improve quality and cost-effectiveness of HIV prevention, care, and treatment services for MARPs, particularly IDUs and their sexual partners.
- *Goal 3:* Strengthen national and local leadership, capacity, institutions, systems, policies, and resources to support the achievement of NAP objectives.

USAID/Ukraine asked HPP to conduct this assessment to provide baseline data for measuring progress toward policy reform over the five-year implementation period of the Partnership Framework. Through a legal and regulatory review and key informant interviews at the national and regional levels, the HPP team has identified key findings related to each of the framework's goals.

Goal 1: Reduce the level of HIV transmission among IDUs and other MARPs

The USG and CMU recognized the importance of HIV prevention among IDUs and MARPs with specific intentions expressed by the CMU to create a policy environment conducive to HIV prevention. The following findings are specifically related to the monitoring and achievement of Goal 1:

- MAT services have been highly controversial in Ukraine at the political as well as service delivery levels. The GOU has clearly stated its support of MAT and intention to strengthen and broaden access to MAT services throughout the country. In addition to the lack of sufficient political will within the MOIA and other entities to implement and monitor MAT, there is a lack of guidance on the storage and dosing of liquid methadone in clinics and significant bureaucratic limitations on MAT providers that make the service inefficient and unappealing to providers.
- While harm reduction has been cited in Ukrainian laws and regulations and has been implemented in some form for the past 15 years, the government has not adopted standards for providing harm reduction services. The standards have been developed, reviewed, set aside, and revisited multiple times, according to key informants. Key informants noted plans to convene a working group to review these draft standards and finalize them for inter-ministerial approval this year.
- Several ministries are responsible for elements of the national response to HIV in Ukraine. While these ministries attend and participate in national and regional council meetings and have their own policies, standards, and approaches to addressing HIV in Ukraine, these policies are not harmonized and are not enforced and monitored across ministries.

- Definitions of MARPs across policy documents are unclear, and there are gaps in policy and programming for addressing population groups recognized as MARPs internationally. Additionally, there are insufficient estimates of the number of MARPs and data about MARPs and high-risk behavior. MSM and transgender populations are not defined as MARPs. The new HIV law specifies that “the list of MARPs will be developed and reviewed by a special authorized healthcare central executive body, based on WHO criteria and guidelines.”
- Ukrainian law protects patient confidentiality and specifies penalties for disclosure of HIV status and discrimination against PLHIV. The challenge faced in Ukraine is to implement and enforce these laws in order to reduce stigma and discrimination and encourage IDUs and other MARPs to be tested routinely and register for care and treatment. This will ultimately contribute to reduced HIV transmission.
- While great efforts have been made by the MOFYS in policy development to address the needs of vulnerable children and adolescents, it is still unclear how government and NGOs can meet the needs of street children, adolescent sex workers, and young IDUs. In part, this is due to a lack of specific definitions and mechanisms for implementing regulations related to these population groups. A more complex challenge is the political and ethical issues and a lack of inter-ministerial agreement on how to meet the need of these particularly vulnerable young populations.
- Of all the ministries involved in the national response, the MOH and MOFYS appear to have the strongest collaboration and coordination at the service delivery level. Key informants note that this is left to the individual personalities of the staff involved rather than to sufficient mechanisms to ensure coordination at all levels.

Goal 2: Improve quality and cost-effectiveness of HIV prevention, care, and treatment services for MARPs, particularly IDUs and their sexual partners

The USG and CMU will focus on improving the quality and cost-effectiveness of HIV services for MARPs, with particular focus on addressing the needs of IDUs and their sexual partners. The following findings are specifically related to the monitoring and achievement of Goal 2:

- The inclusion of sexual partners of IDUs in the Partnership Framework may also serve as a significant step in reducing sexual transmission of HIV. Key informants reported that exceedingly few programs specifically address the needs of sexual partners of IDUs.
- Centralized procurement policies and supply management systems were highlighted through the legal and regulatory review as well as in almost each key informant interview as a significant barrier to high-quality, cost-effective HIV services. These procurement policies and systems are too rigorous and the results inconsistent to meet scale-up needs. Many key informants expressed grave concern that drugs remain too expensive, and it will not be possible to meet the burgeoning need for ART without a reduction in the cost of ART.
- While Ukraine does not suffer from a lack of a highly-trained workforce, routine capacity building and updating in the area of HIV and AIDS is at the expense of the physician and is not practiced widely. Additionally, many key informants pointed out the need for task shifting. For instance, the need to provide quality care and services to PLHIV at the primary level rather than only at the AIDS Center. Or the need to be able to diagnose TB through one physician at the AIDS Center rather than through diagnosis in a consortium at the TB dispensary, which may put the client at risk of TB infection.
- Clinical guidelines for providing ART were recently updated, but other clinical guidelines, such as those related to providing treatment and care to pediatric clients, are outdated and require significant effort to update and harmonize with international best practices. One key informant

noted that those physicians with access to international information are already treating clients according to international standards, but that these physicians are few.

- Based on key informant interviews, it is unclear how medical providers see themselves in the policy process. Some medical providers feel empowered to advocate for their patients and for improvements in regulations that would positively impact the quality and cost-effectiveness of services provided. Many others do not see a role for themselves in this process.
- Despite the GOU efforts to establish and mainstream VCT clinics (*Dovira* cabinets) and integrate routine HIV testing in the antenatal care and maternity homes, CT for most of the population is dependent on the client going to the *Dovira* Cabinet or specifically requesting HIV testing. A CT working group has submitted regulations to the MOH for initial review that would allow providers to initiate CT in hospitals and clinics and more closely meet international best practices.
- PLHIV in Ukraine are often at risk of or already have TB co-infection, are drug dependent, or face other medical and social obstacles. Case management for these clients is important to ensure consistent, high-quality medical and social services. There are insufficient policies and mechanisms for ensuring a continuum of care and implementing case management practices.

Goal 3: Strengthen national and local leadership, capacity, institutions, systems, policies, and resources to support the achievement of NAP objectives

- Over the past several months, Ukraine has witnessed a lack of coordination and collaboration among ministries to respond to the administration's request for data related to IDUs and HIV. This has resulted in documented violations of the rights of IDUs and PLHIV attending MAT clinics, as well as decreased effectiveness of NGOs providing outreach services to MARPs. While the MOH issued a press release stating that MAT continues to be a national priority and an integral part of HIV prevention and treatment services, there is a lack of consistent coordination at the cabinet or inter-ministerial level on drug policy and drug control, the provision of MAT as a health service, and human rights of PLHIV, IDUs, and other MARPs.
- Though the GOU has taken on the responsibility to provide funding for most ART provided in Ukraine (80%), current funding levels and ART provision does not meet the current need nor will it meet the steadily growing need for ART and OI prevention and treatment. It is unclear whether there is a national strategy for scale-up of ART provision to meet the need according to international treatment guidelines.
- The NAP includes a detailed action plan that specifies roles and responsibilities for different stakeholders; however, often there are several stakeholders responsible for each component of the action plan. There appears to be a lack of capacity for management and accountability of the roles and responsibilities detailed in the NAP, which puts the achievement of these components at risk.
- The MOH and MOFYS have strong relationships with NGOs providing HIV prevention, care, and support services. NGOs have the capacity to reach individuals in need and provide focused, case-specific services. This approach does not appear to be used by other ministries in the national response to HIV.
- Policy reform and harmonization, specified as a specific strategic intervention in the Partnership Framework, will require selecting measurable, actionable indicators to monitor the implementation and enforcement of these policies. For example, implementation and enforcement of rights-based policies was a concern raised by key informants at the national and regional levels.
- USAID has provided consistent support over the past decade to strengthen the policy process and build capacity of different stakeholders in advocacy, policy development, policy dialogue, and

monitoring and evaluation. There is a need to build on this existing capacity, as well as the strong local capacity in data analysis to build sustainable, local capacity to analyze HIV policy and its relationship to broader health reform.

ANNEX A. LIST OF INFORMANTS

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