



**HEALTH
POLICY
PROJECT**

HIV Policy Assessment:

Ukraine

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- Marina Shevchenko, consultant on access to high-quality, low-cost drugs and procurement and supply management of HIV/AIDS drugs and commodities
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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 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 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

This assessment was designed 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 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 laws and regulations were developed with the support of donor-funded projects and with advocacy by international organizations.

While there is a strong HIV policy foundation, policies are not effectively or consistently implemented. 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.” Gaps and barriers in HIV policy implementation in Ukraine include the following:

- A lack of detailed mechanisms, such as operational guidelines or standards, to support the implementation of HIV laws and regulations.
- Inadequate strategic planning or a lack of detail in implementation plans.
- Insufficient resources mobilized to implement the laws and regulations.
- A lack of awareness and acceptance of legal protections for vulnerable groups among key stakeholder groups, including law enforcement, local government, and healthcare providers.

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 but rather 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	√	√	Limited	None
Injecting drug users	30	√	Weak data	√	Limited	√	None
Medication-assisted treatment	13	√	Collection ongoing	√	√	Programs operating, but barriers exist	Limited
Hepatitis	4	√	Weak data	New policies being developed	New policies being developed	None	None
Children and adolescents—medical services	75	√	Collection ongoing	√	√	Strong, but with gaps	Limited
Children and adolescents—social services	134	√	Weak data	√	√	Strong, but with gaps	Limited
Counseling and testing	15	√	Collection ongoing	New policies being reviewed	√	√	None
Access to high-quality, low-cost medications	91	Limited	Collection ongoing	√	Limited	Improved, but significant barriers remain	Limited
Procurement and supply management	91	Limited	Collection ongoing	√	Exists but significant barriers	Significant barriers	Limited
TB/HIV co-infection	47	√	Weak data	New policies being reviewed	√	Inconsistent and barriers exist	Limited

Note: √ = progress made in area.

This report presents key findings on topics ranging from stigma and discrimination to IDUs and medication-assisted treatment. Specific barriers identified through this assessment include the following:

- *Stigma and discrimination*: While Ukrainian law prohibits discrimination based on HIV status, protects patient confidentiality, and guarantees equal rights for people living with and affected by HIV, these protections do not extend to some vulnerable groups and no enforcement mechanisms or systems exist to support these populations in exercising their legal rights.
- *Multisectoral response*: While there are several examples of successful multisectoral collaboration, the lack of a strong national coordinating body significantly hampers Ukraine’s ability to muster an effective integrated national HIV response. Much could also be done to strengthen inter-ministerial cooperation, increase effectiveness of regional coordination councils, and improve communication and management of clients across different health structures.
- *Gender and gender-based violence (GBV)*: There is a lack of attention to GBV within national HIV/AIDS policies and programs and of capacity to prevent and respond to GBV among government and civil society stakeholders. 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. These shortcomings are exacerbated by a general lack of awareness of gender issues and limited understanding of how to design gender supportive programs among both nongovernmental organizations (NGOs) and government.
- *IDUs*: While IDUs are clearly noted as a primary risk group in legal and regulatory documents and service provision, no central authority is responsible for organizing and implementing IDU programs, including care and support for HIV-positive IDUs. Data on IDUs are not officially recognized and thus cannot be officially used in planning and resource allocation. Further, recent changes to drug possession regulations threaten to reduce the impact of needle and syringe exchange programs.
- *Medication-assisted treatment (MAT)*: The legal framework for MAT lacks sufficient detail—including protocols on liquid methadone—and regulations are inconsistent across ministries and at various levels. MAT services remain highly controversial in Ukraine, both politically and at the service delivery level, and the availability of MAT services remains inadequate. Unlawful barriers and hindrances to MAT exist, often perpetuated by local authorities and law enforcement agencies. The Global Fund and USAID remain the only sources of funding for MAT, and significant bureaucratic burdens on MAT providers limit its appeal to providers.
- *Children and adolescents—medical issues*: To ensure children’s access to HIV services and safeguard their right to confidentiality, pediatric and adolescent antiretroviral therapy (ART) guidelines and regulations in temporary placement settings for children should be revised. While pediatric specialists with access to English language materials and the Internet can apply the latest international guidance to their practice, many physicians are unable to provide services according to international standards until clinical guidelines are updated.
- *Children and adolescents—social protection*: Important gaps remain in the legal and regulatory framework regarding the social protection of children and adolescents, particularly in relation to the care of children in institutional settings. Children living and working on the street and “neglected children” are not clearly defined in the legal and regulatory framework, making it difficult to provide services to them. Additionally, in temporary placement settings, caregivers are not legally authorized to provide medical care to children who are not officially designated as “orphaned” or “deprived of parental care.” Dissolution of the Ministry of Family, Youth and Sports—the executive body administering social protection programs—has resulted in uncertainty regarding future responsibility for social protection programs.

- *HIV counseling and testing (HCT):* The licensing and accreditation system for HCT facilities has not been established, leaving NGOs vulnerable to threats of closure. The current legal status of mobile clinics is uncertain; although, new regulations for provision of HCT in mobile clinics remain in draft, as do two other key policies: a new HCT protocol, which includes provider-initiated counseling and testing; and the Ministry of Health regulation on quality assurance of laboratory testing.
- *Access to medications:* Current need for ART cannot be met due to the high price of medications, and the government has not exercised available options to increase access to low-cost, generic medications. Estimated need for ART and corresponding ART targets outlined in the National AIDS Program have not been adjusted to reflect updated standards and clinical protocols that include early initiation of patients on ART.
- *Drug and commodity procurement and supply management:* 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.
- *Tuberculosis (TB)-HIV co-infection:* TB and HIV programs function as separate vertical programs, and in most cases, lack true coordination, collaboration, and integration of services. This often leads to a loss of patients and insufficient quality of services. There is also no uniform process for handling registration of TB/HIV deaths, which causes an apparent increase in AIDS-related deaths, while TB deaths remain hidden. The National AIDS Center issued recommendations to all AIDS centers for handling this in January 2011.
- *Hepatitis:* Access to diagnostic testing for hepatitis is limited, and there is no funding for hepatitis treatment. Current regulations do not require Hepatitis B vaccination (even for medical providers), and only acute cases of hepatitis are registered. There is no established system, nation program, or government funding for the prevention and treatment of viral hepatitis—although a national viral hepatitis program is currently being drafted.

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 important 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
UNODC	United Nations Office on Drugs and Crime
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, Donetsk, Odesa, Mykolaiv, Sevastopol, the Autonomous Republic of Crimea, Kyiv, and Kherson. 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 still remain too 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 more than 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.

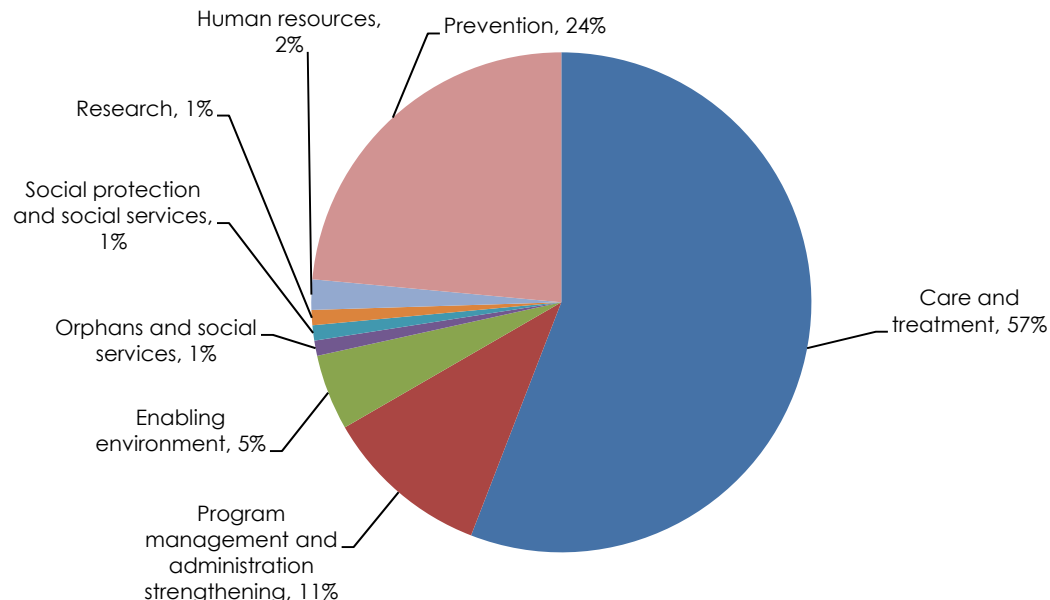
Evolution of Legal, Regulatory, and Policy Environment for HIV/AIDS in Ukraine

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 the 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 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. 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)."

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 regulations 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).

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. Provided with a list of international documents related to their topic area, the consultants developed a list of questions and criteria from international recommendations to guide the analysis of Ukrainian policy documents. The review and assessment of these policy documents were guided by the format and approach presented in the Health Policy Initiative's *Policy Advocacy Toolkit for Medication-Assisted Treatment (MAT) for Drug Dependence*. Tools 2.1.1 and 2.1.2 of the Toolkit (see Annex B of this report) were applied in the review of policies related to MAT and were adapted for each of the program areas investigated in this assessment. These tools provide a guiding framework for analyzing laws and regulations related to essential components and international standards and recommendations. HPP also compiled the source policy documents into a policy compendium.

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. Key informants responded to issues on varying topics. Some key informants responded to in-depth questions about one specific topic, while others were able to answer questions related to multiple topics. The HPP team used a semi-structured interview guide to collect data from key informants. The general interview tool included questions about the policy process, policy implementation, and barriers faced to implementation (see the sample general tool attached in Annex C). The team also used specific semi-structured interview guides for the program areas outlined in the scope of work. The crosscutting issues of legal and human rights and specific program areas outlined in the scope of work include the following:

- 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 73 interviews with key informants reflecting the national level based in Kyiv (46), 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 provided some insight into differences between areas where USAID has and has not been working. The different experiences in policy implementation identified during the visits to these two oblasts are not only related to USAID and other donor assistance but also related to differences in HIV prevalence, population density, and government resources spent on health and HIV in the region.

Several interviews were recorded with permission of the key informant, and these recordings were transcribed into the language of the recording (either Ukrainian or Russian). Detailed notes were handwritten for those interviews that were not recorded. Interview data were analyzed for key themes to relate findings to the legal and regulatory review. In cases of particular statements of interest in laws and regulations identified by the consultants conducting the review, interview data were reviewed to identify examples of how the laws or regulations are being implemented.

Limitations

This HIV Policy Assessment is a situational assessment and was not conducted as a program evaluation or implementation evaluation. The assessment was also focused at the national level and in two oblasts. Thus, the findings cannot be used to evaluate specific projects, nor can the findings provide adequate insight into the HIV policy and policy implementation situation in other regions in Ukraine. The methodology consisted of a review of policy documents and key informant interviews. Results of interviews may be subject to biases of personal opinion and recollection.

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 of findings

Strengths

- Strong legal protections against discrimination for PLHIV.
 - 1991 and 2010 HIV/AIDS laws prohibit discrimination based on HIV status.
 - Infringement of individuals' rights based on discrimination is considered a crime.
 - Constitution and HIV/AIDS law guarantee a citizen's right to bring a case or complaint to court.
 - Criminal Code protects confidentiality of PLHIV from disclosure of HIV status by a medical worker.
- HIV/AIDS law mandates inclusion of S&D-related subjects in curricula of secondary, vocational and technical, and higher education facilities.
- Key informants report reduced discrimination against children living with HIV and increased access to education and other programs and services.

Specific policy gaps

- Some vulnerable groups (MSM, other sexual minorities, transgenders) are not specified within key laws and policies (e.g., HIV/AIDS law, NAP).
- No systematic mechanism exists for tracking cases of S&D against PLHIV and other vulnerable groups (rather informal NGO registers mainly used for advocacy).
- No indicators to measure implementation or effectiveness of S&D-related laws and policies are included in the NAP.
- Changes in the drug possession law perpetuate criminalization of IDUs and perception of IDUs as criminals.
- Healthcare workers serving PLHIV, clients with TB, and clients at narcology clinics receive "hazard pay," which may encourage stigmatization.
- Development/implementation of S&D-related curricula is dependent on financing through the NAP.
- The labor code barring discrimination based on HIV status remains in draft form.
- No legal requirement mandates that employers institute HIV prevention programs or HIV policies.
- NAP ministerial action plans do not include development or implementation of curricula to address S&D of MARPs, nor address the private sector and law enforcement/security forces.

Other barriers

- PLHIV and vulnerable populations exhibit a lack of awareness of rights protections and reluctance to seek legal recourse.
- PLHIV, other vulnerable groups, and service providers exhibit a lack of understanding of S&D.
- Stigmatizing and discriminatory service provider attitudes toward PLHIV and other vulnerable groups are fueled by burn out, lack of information on and fear of HIV, and poor communication skills.
- Medical workers are sometimes unwilling to report potential exposure or request post-exposure prophylaxis (PEP) due to fear of stigmatization or loss of employment.

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)⁴ follows international guidance by clearly prohibiting general discrimination on the grounds of HIV status, as did the previous 1991 HIV/AIDS law.⁵ 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 to be made and reviewed by a special authorized healthcare central executive body, based on WHO criteria and guidelines.”

The Criminal Code (Article 161)⁶ 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.⁷

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 NAP⁸ 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.

⁴ Law #2861-VI, December 23, 2010, “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population.”

⁵ Law #1972-XII, December 12, 1991, “On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Legal and Social Protection of the Population.”

⁶ Criminal Code of Ukraine: Law #2341-III, May 4, 2001.

⁷ Constitution of Ukraine: Law #254k/96-BP, June 28, 1996.

⁸ 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.”

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.⁹

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.

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. In many oblasts, AIDS Centers are only available in the oblast capital city, so 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 Ministry of

⁹ Law of Ukraine “On Measures to prevent the illicit circulation of drugs, psychotropic substances and precursors and use and abuse thereof.”

Education and Science (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.¹⁰ A Joint Order issued by different ministries (2007) stipulates that HIV-positive children attend education facilities “on common terms” with all children.¹¹ 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.

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.¹² 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 lead to increase of discrimination is the provision of increased pay to healthcare workers providing services to PLHIV, clients with TB, and clients at narcology clinics.¹³ 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.¹⁴ 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.

¹⁰ Presidential Decree #411/2008, May 5, 2008, “On Additional Measures to Ensure Protection of Rights and Legal Interests of Children” (*Paragraph 4*).

¹¹ 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.”

¹² MOH Order #634, July 29, 2010, “On Amending the Order of the Ministry of Healthcare of Ukraine as of 08. 01. 2000 # 188.”

¹³ MOLSP and MOH Joint Order #308/519, May 10, 2005, “Terms of payment of employees of health and social care institutions.”

¹⁴ 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.”

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 the HPP 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 internationally recognized 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)¹⁵ 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 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,¹⁶ the national council has not adequately coordinated the national response, having been 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 operation 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. The HIV/AIDS Service Capacity Project encourages inclusion/involvement of vulnerable communities in the policy process to represent interests of their community in the oblast coordination councils.

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

¹⁵ CMU Act #926, July 11, 2007, “Selected Matters of Response to TB and HIV Infection and AIDS.”

¹⁶ See this report’s section titled “Multisectoral Response and Linkages with Other Health and Development Programs.”

sector link to other sectors, such as social services and education.¹⁷ 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 of findings

The ongoing administrative reform process has the potential to profoundly affect the HIV policy environment, but its precise impact remains difficult to gauge, with reforms still underway. Two important changes so far include the elevation of the MOH Committee on HIV and Socially Dangerous Diseases to the status of a State Service (functions to be determined) and the dissolution of the MOFYS (responsibilities being re-assigned).

Strengths

- Collaboration between social and medical services is facilitated by strong collaboration between the MOH and MOFYS (although the MOFYS has recently been dissolved).
- The government is increasingly willing to collaborate with/involve civil society and the private sector (HIV/AIDS law emphasizes NGO and private sector involvement in service provision).

Specific policy gaps

- A strong national coordinating body for HIV is missing—stripped of its “coordination” role by the CMU, the National Council is focused mainly on Global Fund business.
- Inter-ministerial coordination is limited, and other ministries are reluctant to implement MOH decrees, despite the Ministry of Justice’s approval.
 - The Ministry of Internal Affairs (MOIA) focuses largely on drug control rather than acting as a partner in public health.
 - Ministry of Finance (MOF) funding decisions, affecting MOH policy and program implementation, appear insufficiently informed by technical expertise.
 - The Penitentiary Services are not ensuring that homeless shelters routinely send clients to health facilities to receive TB treatment.
- Capacity and effectiveness of regional HIV councils vary widely.
- Coordination of care and support to PLHIV has improved but is highly dependent on the individuals involved; referral and information-sharing processes need improvement (for diagnosis, case management, and control of HIV/TB co-infection).
- Public contracting of social services has a limited legal and regulatory base; key informants report that the barrier is more often a lack of political will to procure NGO and private sector services.

Other barriers

- Political instability continues to cause frequent high-level staffing changes, inhibiting policy momentum on HIV issues.

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.

¹⁷ The review of linkages between TB and HIV programs is presented in the “TB/HIV Co-Infection” section of this report. A review of linkages between narcology and HIV programs is presented in the “Injecting Drug Users” section. A review of linkages between CT sites and AIDS Centers is presented in the “HIV Counseling and Testing” section.

The 1991 HIV/AIDS Law of Ukraine¹⁸ 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.¹⁹ The 2009 NAP envisages the continued strengthening of multisectoral approaches to address HIV/AIDS.

The current 2010 HIV/AIDS Law²⁰ 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, in keeping with UNAIDS' recommendations to countries to establish the Three Ones.²¹ 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 MOIA 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 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."

¹⁸ Law #1972–XII, December 1991.

¹⁹ MOH Order #225, April 14, 2006.

²⁰ Law #2861-VI, December 2010.

²¹ UNAIDS. (2004). "Three Ones Key Principles: Guiding principles for national authorities and their partners." Accessed on June 23, 2011, at: http://data.unaids.org/UNA-docs/three-ones_keyprinciples_en.pdf.

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

“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 long-standing, 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. Another Joint Order established multidisciplinary teams to provide health and social services to HIV-positive and -affected families.²² The successful strategy described in the Order approving the National Program on PMTCT and Support to Affected Children 2006-2008 has continued to be implemented by order of current legislation through the 2009 NAP.²³

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, obstetric and 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 levels, 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.²⁴ 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.

²² Joint Order of the MOH, MOES, MOFYS, State Committee on Enforcement of Sentences, MOLSP # 740 / 1030 / 4154 / 321 / 614, November 23, 2007, “On Measures to Prevent Mother-to-Child Transmission of HIV, Medical Care and Social Services for HIV-Infected Children and Their Families.”

²³ Law #1026–VI, February 2009.

²⁴ 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.”

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 of findings

Strengths

- MSM are defined as a vulnerable group in the Partnership Framework and a key target group in Ukraine’s HCT protocol.
- Ukrainian laws and regulations define GBV and grant survivors the right to PEP (although this is the sole mention of sexual violence in the HIV legal and regulatory framework).

Specific policy gaps

- Gaps in defining and targeting vulnerable groups.
 - MSM, transgenders, and other sexual minorities are neither defined as vulnerable groups nor as groups vulnerable to GBV in the NAP or the 2010 HIV/AIDS law.
 - The legal framework does not specify equal rights for transgenders or sexual minorities (but could fall under the “other” clause of the relevant Constitutional provision).
 - Female sex partners of IDUs are not noted as a risk group.
 - Sex workers are assumed to be female—no mention of sex workers who are also MSM.
- National HIV/AIDS policies and programs lack attention to GBV.
 - Comprehensive healthcare services for GBV survivors are not detailed in HIV-related legislation, and no clinical management guidelines exist for such services.
 - Sexual violence is only mentioned once, with no reference to GBV among sexual minorities, transgenders, or men.
 - Linkages between social and medical services around GBV are poor.
- Cumbersome reporting requirements discourage GBV survivors from filing reports and receiving PEP.
- Penalties imposed for domestic violence are mainly monetary, thus affecting the whole family instead of just the offender.
- Implementation and monitoring of the Prevention of Domestic Violence Act is limited, and public officials need more training on GBV and sexual violence.
- NAP lacks a distinct section on HIV prevention among women and on RH services for HIV-positive women (including quality and accessibility of RH services).
- Data gaps exist, especially sex-disaggregated data, and there is no official agreement on the size of the MSM population or the HIV prevalence rate among MSM.

Service gaps

- Many HIV and IDU support services, including rehabilitation for drug dependency, are targeted to men, restricting women's access.
- HIV testing, care, and support programs are more effective at reaching men than women.
- Rural and other marginalized families have limited access to GBV services.

Other barriers

- Social norms can put women and girls at increased risk for HIV and create barriers to services.
 - Female IDUs are often last in the group of drug users to use shared syringes.
 - Concern about HIV-related stigma may discourage women from using infant formula.
 - Women may face resistance from male partners when seeking to access HIV-related services.
 - Women may lack the necessary resources to access such services.
- NGOs and government lack awareness of gender issues and understanding of how to design gender supportive programs.
- Ministries, institutions, service providers, and civil society lack awareness of the need for GBV programs and the capacity to prevent and respond to GBV.
- Survivors are reluctant to report GBV due to stigma and/or fear of the police (who may have been the instigators).
- Local authorities exhibit stigma, discrimination, and harassment of individuals and organizations.

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.”²⁵ 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

²⁵ Constitution of Ukraine: Law #254k/96-BP, June 28, 1996, (Article 24).

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,”²⁶ MSM are not clearly defined as a vulnerable group in the HIV/AIDS law, nor are they mentioned in the text of the NAP.²⁷ MSM are 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 groups²⁸, 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.²⁹ To make informed decisions and plan effectively for service provision to different MARPs, international guidance recommends collecting accurate estimates of population size and prevalence. As stated earlier, there is currently insufficient agreement on the estimates of population size and HIV prevalence among MSM in Ukraine.

As described above,³⁰ one key informant expressed concern that the absence of constitutionally and legally-assured equal rights for the LGBT community provides insufficient protection from

²⁶ Law #2861-VI, December 2010.

²⁷ 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>

²⁸ MOH Order #415, August 19, 2005, “On improvement of voluntary HIV counseling and testing.”

²⁹ MOFYS, MOLSP, and MoH Joint Order #3123/275/770, September 13 2010, “On approval of standards of social services provision to risk group representatives.”

³⁰ See page 9.

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.”³¹

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).

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)³² 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,

³¹ Letter from Mykolaiv City Mayor to Mykolaiv Association for Gays, Lesbians and Bisexuals “LIGA.” 17.01.2011 Ref. No 14397/510-14-15.

³² 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.

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.”³³ 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 2010³⁴ referenced a continued concern that there is insufficient evidence of effective implementation of Ukraine’s Prevention of Domestic Violence Act.³⁵ 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.”³⁶ 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 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 following international best practices that encourage GBV programs to address both men and women. 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

³³ Law #2861-VI, December 2010.

³⁴ 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.

³⁵ Law of Ukraine of 15.11.2001 № 2789-III “On Prevention of Family Violence.”

³⁶ 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.

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 of findings

Injecting drug users

Strengths

- IDUs clearly noted as a primary risk group in legal and regulatory documents and service provision.
- The 2010 HIV/AIDS law and 2009 NAP encourage the exchange and distribution of needles and syringes.
- The ART protocol for IDUs and regulations state that clients cannot be denied access to ART based on injecting drug use, and that MAT may strengthen ART adherence.

Specific policy gaps

- No central authority is responsible for organizing and implementing IDU programs.
- Data on IDUs are not officially recognized and thus cannot inform planning and resource allocation.
- The new MOH drug circulation law lowers the threshold for possession of opiates, discouraging IDUs from turning in used syringes and endangering harm reduction workers transporting the syringes.
- No clear strategy exists for disposing used syringes and needles collected through exchange and distribution programs outside government medical facilities.
- Pharmacy-based needle distribution and exchange programs remain experimental and are barred from collecting used syringes by sanitary-epidemiological service regulations.
- The MOH has not yet adopted STI syndromic management, despite many draft protocols.
- NAP does not include specific programs focused on sexual partners of IDUs.
- Mandated treatment for an IDU may result in his/her dismissal from employment or an educational institution/program.

Service gaps

- IDUs are often assumed to be male, thus female IDUs lack access to services.

Other barriers

- Inter-ministerial collaboration is limited (see MAT section for details).

Medication-assisted treatment (opioid substitution therapy)

Strengths

- The legal and regulatory framework provides a strong foundation for MAT (harm reduction has been defined for 15 years).
- The MOH has formed a new working group on MAT.

Specific policy gaps

- The legal and regulatory framework lacks sufficient detail on MAT, and no comprehensive strategy exists for providing harm reduction services.
- No MAT funding comes from the state budget—only through the Global Fund grant and USAID supported SUNRISE project.
- Regulations (e.g., on age restrictions) are inconsistent across ministries and at various levels.
- Guidance on storage, dosing, and security is neither sufficiently widespread, nor is it part of routine training for medical workers.
- No regulations exist on the dispensation and accounting of “liquid methadone,” which is legal but not procured by the government.
- Provisions are not included for MAT clients to continue treatment during incarceration or for prisoners to start MAT.
- Lengthy delays occur in receiving approvals for distributing medications.
- Clients who require home-based treatment do not have access to MAT.
- Clients hospitalized in facilities without MAT services have restricted access to MAT.
- MAT regulations require clients to register in a MAT clinic (previously, clients could remain anonymous).
- Complicated MAT licensing requirements and burdensome paperwork limit the number of MAT service sites and affect service quality.
- “At will” inspection of facilities makes provision of MAT more difficult, as the presence of authorities and the interrogation of clients discourages patients from accessing MAT and hinders treatment.

Service gaps

- The availability of MAT is insufficient, contributing to low ART rates for IDUs.

Other barriers

- MAT services remain highly controversial; conflicts among the medical services, the Prosecutor’s office, and MOIA continue.
- Some narcology professionals are reluctant to assume additional work and/or are concerned that MAT will reduce demand for traditional narcology services.
- Local authorities and law enforcement agencies have created unlawful barriers and hindrances to MAT (e.g., forcing doctors to disclose confidential patient records).

Hepatitis

Strengths

- Clinical protocols for Hepatitis B and C exist.

Specific policy gaps

- A national program for vaccination and treatment of viral hepatitis has just been initiated.
- No established system, national program, or government funding exist for prevention, diagnosis, and treatment of viral hepatitis.
- Regulations do not require Hepatitis B vaccination (even for medical providers).
- There is limited diagnostic testing for hepatitis and no funding for hepatitis treatment.
- Only acute cases are registered, and chronic cases are not monitored.
- Regional-level data to inform development of the national program is lacking.

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 guidance by the WHO, the United Nations Office on Drugs and Crime (UNODC), UNAIDS, and other global agencies, comprehensive programs targeting the needs of IDUs should provide the following components (WHO et al., 2009):

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 international recommendations for 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 re-assigned as a part of the administrative reform process.^{37,38} 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 a strategy for providing harm reduction services. Standards for providing harm reduction services have been developed and adopted, but a strategy outlining interventions, population estimates, and coverage targets is lacking. Key informants noted plans to convene a working group to develop a strategy and finalize them for inter-ministerial approval this 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 have not been formally recognized by the GOU.³⁹ These data are not considered in the process of identifying the NAP targets and determining funding allocations from public budget sources. These data are used unofficially in the design and monitoring of the Global Fund grants, which are endorsed by the National AIDS-TB Council and some of the Regional Coordination Councils.

The process of providing medical services to IDUs is outlined by clinical protocols and standards of care that are adopted through an MOH order.⁴⁰ 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 inter-ministerial standards of treatment and social services.⁴¹

By law, government, private sector, and CSOs are allowed to implement programs for exchange and distribution of needles and syringes for IDUs.⁴² Programs for pharmacy-based distribution and exchange of syringes used by IDUs, however, are still in the experimental stage.⁴³ The Alliance has recently begun

³⁷ Presidential Decree #1085/2010, December 9, 2010, “On optimizing the central executive government authority system.”

³⁸ Delegation of the MOFYS capacity and functions to other newly established government authorities is not yet effective or clear.

³⁹ 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.

⁴⁰ 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.”

⁴¹ 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*).

⁴² Law #1972–XII of December 1991, amended by Law #2861–VI of December 2010.

⁴³ MOH Order #56, February 3, 2009, “About the pilot project to exchange used syringes.”

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 collected outside the public medical and public health system. 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 agreement with medical facilities, they must purchase appropriate supplies to destroy or clean the syringes, or they must contract with commercial disposal services.⁴⁴

There is growing concern among NGOs about the new MOH Order on drug circulation, in which the 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.⁴⁵ 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 Order⁴⁶ and two MOH Orders⁴⁷ 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 and from USAID. With the initiation of a new working group by the MOH as well as a MOH statement that MAT

⁴⁴ MOH Order #223 of October 22, 1993, “On the collection, disinfection and delivery of medical devices used for single use made of plastic.”

⁴⁵ MOH Order #634, July 29, 2010, “On Amending the Order of the Ministry of Healthcare of Ukraine as of 08. 01. 2000 # 188.”

⁴⁶ Presidential Order #1208, December 12, 2007, “On Additional Urgent Measures Aimed at HIV/AIDS Prevention in Ukraine” (*Article 3, Paragraph 2*).

⁴⁷ 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.”

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 MAT clientele;⁴⁸ 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 18.⁴⁹

Methadone and buprenorphine are explicitly registered in Ukraine for use in opioid dependence treatment programs.⁵⁰ 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,⁵¹ 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.⁵²

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.⁵³ 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 requisite directives and guidelines for using and prescribing liquid methadone, a lack of directives and 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. The

⁴⁸ Order #645, November 10, 2008, "On Approving the Methodological Guidelines 'Medication Assisted Therapy for Persons with Opioid Dependence Syndrome.'"

⁴⁹ 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."

⁵⁰ 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.'"

⁵¹ Civil Code of Ukraine, Chapter 21, Article 286, "The Right to Secrets about the State of Health."

⁵² Order #645, November 2008.

⁵³ 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).

Association of Narcologists of Ukraine recommends that in order for a client to receive MAT, they should have participated in a rehabilitation program or other sort of treatment no less than three times. MAT program enrollment requirements had not yet been issued by regulatory act at the time this assessment was conducted. One key informant reported 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 opportunity to obtain MAT. Key informants reported that 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. This is not permitted or supported by law or regulation. 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. The MOH recently issued an Order whereby methadone may now be issued by pharmacies with a prescription. Thus, the liquid form of methadone may now also be received in pharmacies if a physician’s prescription is available.⁵⁴

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, 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, 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

Treatment rates for active IDUs account for only 7.5 percent of the total number of patients receiving ART in 2009. The UNGASS country progress report attributes low treatment rates to adherence problems related to insufficient availability of substitution maintenance therapy (Ministry of Health, Ukraine, 2010). Key informants also reported that access to ART by PLHIV is limited by the insufficient quantity of ART courses available.

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.⁵⁵

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.

⁵⁴ MOH Order # 150 as of 22 March 2011 “On amending the MOH Order # 360 as of 19 July 2005.”

⁵⁵ MOH Order #476 of August 2008 and MOH Order #551 of July 2010.

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, the international guidelines⁵⁶ for using 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

According to international recommendations, clinical and social services for IDUs should include prevention, diagnosis, and treatment of viral hepatitis. Despite that all hepatitis epidemic response activities in Ukraine are regulated by an Order issued by the MOH of the USSR in 1989,⁵⁷ there was no active process for registering cases of hepatitis prior to 2008.⁵⁸ Even now, only acute cases are registered, while chronic cases are not monitored.

In Ukraine, government response to specific diseases or health problems is typically guided by a national program describing the disease, the burden of the disease in the country, and specific priority areas requiring attention. While the standards for treatment of HIV-positive IDUs specify “medical assistance in the event of hepatitis,”⁵⁹ there was no national program for viral hepatitis at the time of this study, nor is there government funding for treatment. Current protocols for the diagnosis and treatment of Hepatitis B and C among IDUs exist; however, there is no established system for the prevention, diagnosis, and treatment of viral hepatitis. 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.

Soon after the drafting of this report, the HPP team learned that the Cabinet of Ministers of Ukraine recently approved a concept paper for a new program on diagnosis and treatment of viral hepatitis.⁶⁰ The concept paper describes the poor rate of timely detection of viral hepatitis, poor rates of vaccination for Hepatitis B, and a lack of treatment and physicians adequately trained to provide treatment. The concept specifies that these are important areas for intervention and that a national program on viral hepatitis is currently being developed.

⁵⁶ WHO. 2003. “Guidelines for the Management of Sexually Transmitted Infections.” Accessed on June 23, 2011, at: <http://whqlibdoc.who.int/publications/2003/9241546263.pdf>.

⁵⁷ Order of the MOH of the USSR #408, December 7, 1989, “On efforts to reduce the viral hepatitis incidence in the country.”

⁵⁸ MOH Order #476 of August 2008.

⁵⁹ MOH Order #476 of August 2008.

⁶⁰ Cabinet of Ministers of Ukraine Order #206-r of March 9, 2011 “On the concept of a targeted social program for prevention, diagnostics and treatment of viral hepatitis through the year 2016.”

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 of findings

Strengths

- NAP guarantees the availability of ART for all children, provides full funding for PMTCT services, and lists youth as a priority group for HIV-prevention activities.
- HIV/AIDS Law allows HCT for youth ages 14–18 without presence of a legal representative and guarantees HIV-positive women free access to PMTCT.
- The PMTCT program is relatively effective (e.g. free access to HCT by pregnant women, obstetrical care guidelines with WHO-recommended techniques, guidelines for FP provision to PLHIV, and protocols for FP/HIV service integration).

Specific policy gaps

- Providers remain confused about whether a parent/guardian needs to be present for post-test counseling of youth ages 14–18.
- Pediatric and adolescent ART guidelines are outdated.
- No special certification exists for service provision to HIV-positive children in the health sector (only an MOFYS guideline for the social services sector).
- While law prohibits mandatory HIV testing of minors, procedures for providing care to children in homes for minors and centers for social and psychological rehabilitation allow for mandatory HIV testing.
- Lack of HIV testing regulations in temporary placement settings and lack of staff training lead to disregard for children’s right to confidentiality.
- There is a shortage of trained teachers and comprehensive HIV awareness-raising activities in educational institutions.
- Monitoring limitations exist.
 - System distorts epidemiological data by listing all children born to HIV-positive mothers as HIV positive and not promptly removing HIV-negative children from the register.
 - Current monitoring forms for PMTCT do not correspond with clinical protocols.
 - PMTCT monitoring data from the National AIDS Center differ significantly than those from the MOH’s Department for Motherhood and Childhood.

Service gaps

- Key informants report inadequate FP services for the whole population and restricted access to FP counseling, services, and methods by vulnerable groups.

Other barriers

- The dissemination of policy documents, training on new standards and protocols, and communication between providers and government is insufficient.
- Absence of a pediatrician at the Ukrainian National AIDS Center cited by respondents as a barrier.

The 2009 NAP includes youth as a priority target group for prevention activities. The program also includes children living on the street 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 HCT⁶¹ and “youth-friendly clinics,” with HIV prevention as a major objective.⁶² Prior to 2004, pediatricians, obstetricians, gynecologists, and others providing care to HIV-positive women and children had no guidelines or protocols for providing PMTCT and other related services.

HIV testing and diagnosis

International human rights agreements and guidelines for HCT outline the rights of youth to consent, confidentiality, and privacy in accessing sexual and reproductive health services, including HCT.⁶³ The 1991 AIDS law⁶⁴ outlined procedures for HIV testing for youth. Before amendments to the Civil Code, 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. The new edition of the Civil Code of Ukraine⁶⁵ 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.⁶⁶ 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. This is due, in part, to significant attention accorded to PMTCT in the regulatory framework since 2000. Since the development of the first National PMTCT Program in 2001,⁶⁷ PMTCT coverage has increased to 95 percent of pregnant women (Ministry of Health, Ukraine, 2010). Additionally, unlike other HIV/AIDS services, PMTCT services were integrated into other health programs, such as obstetrics and gynecology, early in the national response.⁶⁸ 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 over the past six years. In 2004, 8.2 percent of children born to HIV-positive mothers were diagnosed with HIV,⁶⁹ compared with only 3.9 percent in 2010.

⁶¹ MOH Order #382, June 2, 2009, “On Approving the Interim Standards of Medical Care for Adolescents and Youth.”

⁶² 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.”

⁶³ United Nations, Committee on the Rights of the Child, Convention on the Right of the Child, General Comment No 3: HIV/AIDS and the Right of the Child, January 2003; The Declaration of Commitment on HIV and AIDS released at the United Nations General Assembly Special Session (UNGASS) on HIV and AIDS in June 2001.

⁶⁴ Law #1972-XII, December 1991.

⁶⁵ Civil Code of Ukraine (*Section 3, Article 284*).

⁶⁶ Law #2861-VI, December 2010.

⁶⁷ MOH Order #488, December 7, 2001, “Prevention of mother to child transmission of HIV in 2001-2003.”

⁶⁸ MOH Order #503, December 28, 2002, “On improving outpatient obstetric and gynecological care in Ukraine.”

⁶⁹ Key informant interviews in Mykolaiv, February 2011.

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,⁷⁰ the procedures have significant flaws and are rarely followed by regional AIDS centers.⁷¹ 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,⁷² and improving PMTCT is a major objective of the 2009 NAP, which aims to achieve a 5 percent 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.⁷³

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.⁷⁴ Since 2009, PMTCT is financed via the national budget. 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.⁷⁵ The 2004–2008 NAP guaranteed free access to VCT for pregnant women.⁷⁶

In November 2007, the MOH adopted a clinical protocol on obstetrics care related to PMTCT, which includes all WHO-recommended techniques.⁷⁷ The joint order⁷⁸ 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

⁷⁰ MOH Order #936, December 16, 2009, "On Approving the Method for Needs Assessment for Supply of Antiretroviral Drugs"

⁷¹ This issue is discussed further in the section on HIV/AIDS drug and commodity procurement and supply.

⁷² 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."

⁷³ MOH Order #313, May 8, 2009, "On Optimizing Training for Specialists on HIV and Prevention of Mother-to-Child Transmission of HIV."

⁷⁴ MOH Order #421, June 27, 2006, "On Approving the Model Regulations on *Dovira* Units (Trust Centers)."

⁷⁵ CMU Resolution #2026, December 18, 1998, "Matters of HIV/AIDS Prevention and Population Protection Efforts."

⁷⁶ 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.'"

⁷⁷ MOH Order #716, November 14, 2007, "On approving the Clinical Protocol on Obstetrics Care 'Prevention of Mother-to-Child Transmission of HIV.'"

⁷⁸ 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."

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.”⁷⁹ 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.

Early diagnosis of HIV in children

A 2007 joint order⁸⁰ outlines procedures for early diagnosis of HIV in infants under the age of 18 months using PCR⁸¹ 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 6.2 percent (in 2008–2009) 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 2007.⁸² A 2007 joint order includes regulations on the integration of pediatric ART with the primary care system.⁸³ 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.”

⁷⁹ *Ibid.*

⁸⁰ 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.”

⁸¹ Polymerase chain reaction.

⁸² MOH Order #182, April 13, 2007, “On Approving Clinical Protocols.”

⁸³ 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.

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 1998.⁸⁴

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 of findings

Strengths

- Children living with HIV are guaranteed social protection and free medical and social services (those under 16 receive monthly state assistance), and parents receive an allowance and/or are entitled to leave from employment.
- Several regulations encourage NGO participation in social service provision to HIV-positive and vulnerable children.
- By law, HIV-positive children must be allowed into schools, camps, and any other public setting; key informants report reduced discrimination against HIV-positive children.
- The MOFYS formed a multidisciplinary team to provide social and prevention services to MARAs.

Specific policy gaps

- Dissolution of the MOFYS, responsible for the regulation and administration of children and adolescent programs, has caused concern over the future of these programs.
- No provision exists for temporary placement of children without official designation as orphans and children deprived of parental care (OC or CDPC)—thus caregivers are not legally authorized to provide medical care to them.
- Data on populations of children and adolescents in need of social services and the number of children and youth living and working on the street are inadequate or unofficial.
- Children living and working on the street and “neglected children” are not clearly defined in the legal and regulatory framework, hindering service provision to them.
- Centers for HIV-positive children are often located in the city outskirts and are perceived by several key informants to be an ineffective use of resources and a source of stigmatization.
- No assessment tool exists for gauging the needs of HIV-positive children.
- No standards exist for provision of social support and social services to homeless children; no procedures and tools exist to assess their needs or create action plans.

⁸⁴ MOFYS Order #1695, April 22, 1998, “On Approving the Procedures for Certification of Workers of Centers for HIV-infected Children and Young People.”

- Regulations on family-based children's homes do not contain provisions for children living with HIV.
- HIV-specific services are not included in the list of social services for OC and CDPC or the list of services in social and rehabilitation centers ("Children's Town").
- No document establishes standards for provision of social services for children placed in adoptive families or family-based children's homes or for children in guardianship and trusteeship.
- Legislation governing temporary stay institutions does not require employees to respect HIV-positive children's rights or specify mechanisms to protect their confidentiality.
- Rights of homeless and neglected children are not regulated, and they do not have a mechanism to exercise their rights or receive benefits.
- No clear minimum age exists for sexual consent. Civil code allows marriage of children ages 14–18 if in the child's best interests; marriageable age for females (17) is lower than males (18).
- No standardized protocols and authorities exist for training school teachers, headmasters, and employees of orphanages and other social welfare institutions involved in HIV prevention for children and adolescents.
- New drug possession regulations may result in more children entering the juvenile justice system (see IDU section for details).
- The family code of Ukraine condones abandonment of "children born with physical or mental disabilities and under other circumstances of importance."
- HIV is not mentioned in the National Program to Overcome Children's Homelessness and Neglect (2006–2010).
- Ukraine's Poverty Reduction Strategy Paper does not include families and children as a prominent component.

Service gaps

- There is a limited amount and low-quality of state services to protect and assist families with children.
- Workers in temporary institutions are often unaware of children's right to healthcare and routinely violate children's confidentiality.
- Specialized, youth-friendly services targeting at-risk children for treatment and rehabilitation are lacking.
- HIV-prevention programs for MARAs have low coverage, scope, and quality.

Other barriers

- There are high rates of separation of children from the family environment.
- Training of professional groups (e.g., law enforcement, social workers) dealing with children is inadequate, particularly on children's rights.
- Discrimination against children with disabilities, children in street situations, children living with HIV/AIDS, and refugee children continues.
- Healthcare providers often demand payment for health services from homeless children and youth.
- "Rounding up" children off the street and forcing them into temporary stay institutions continues, and these institutions may not offer the full spectrum of children's services.

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.⁸⁵ The government also adopted several additional measures related to rights and social protection for children:

- Law on amending different legal acts of Ukraine relevant to distribution of 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).
- 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,⁸⁶ and those under the age of 16 years are provided with monthly state assistance.⁸⁷ When an

⁸⁵ 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.

⁸⁶ 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.”

⁸⁷ 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

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.⁸⁸ Children living with HIV are guaranteed the right to receive social services from the SSCFCY.⁸⁹ 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.⁹⁰

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.⁹¹ 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.” 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.⁹²

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 14.⁹³ 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.⁹⁴

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.”

⁸⁸ Law #2109–III of 11/16/2000, “On State Social Allowance to Persons Disabled from Childhood and to Disabled Children” (*Article 3*).

⁸⁹ 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*).

⁹⁰ 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.”

⁹¹ CMU Resolution #148, February 15, 2006, “On Approval of Standard Provision on the Center for HIV-Infected Children and Young People.”

⁹² 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.”

⁹³ 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.”

⁹⁴ Law #2081 of 11/19/1992 (as amended on 10/13/2010), “On Basic Principles of Ukrainian Legislation on Health Care.”

State guardianship and different forms of custody

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.⁹⁵ 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.⁹⁶

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.⁹⁷ The regulations about adoptive families clearly indicate that OC and CDPC living with HIV can be reared in adoptive families. However, the regulations on family-based children's homes do not contain a provision for children living with HIV.⁹⁸ Provisions are made to train potential adoptive parents and foster parents to raise HIV-positive children.⁹⁹

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.¹⁰⁰

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.¹⁰¹ To this end, family forms of guardianship for OC and CDPC have been

⁹⁵ 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.”

⁹⁶ CMU Resolution #878 of 9/8/2005, “On Approval of Standard Provisions on Social Hostel for OC and CDPC.”

⁹⁷ 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*).

⁹⁸ 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*).

⁹⁹ 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.”

¹⁰⁰ 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*).

¹⁰¹ 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.”

identified as a priority.¹⁰² It is also possible to return OC and CDPC to parental care. However, no formal mechanism for returning children to the care of biological parents has been adopted.¹⁰³

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 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.¹⁰⁴

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.¹⁰⁵ 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.¹⁰⁶ Responsibility for monitoring the rights of OC and CDPC is assigned to the

¹⁰² 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.'"

¹⁰³ 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."

¹⁰⁴ 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.

¹⁰⁵ 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*).

¹⁰⁶ 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'"

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.¹⁰⁷

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.¹⁰⁸ 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.¹⁰⁹ However, information about a child's health (including HIV status) may not be concealed from prospective adoptive parents.¹¹⁰ 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.¹¹¹

(*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*).

¹⁰⁷ 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 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*).

¹⁰⁸ 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*).

¹⁰⁹ 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*).

¹¹⁰ CMU Resolution #905 of 10/8/2008, "On Approval of the Procedures to Implement Adoption and Supervise the Observance of Rights of Adopted Children."

¹¹¹ Law #2341–III of 5/4/2001 "The Criminal Code of Ukraine" (*Article 132*).

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. In line with the Presidential Decree issued in 2008, the MOES is required to introduce measures to overcome and prevent stigmatization of HIV-positive children to ensure their ability to exercise their right to education.¹¹²

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).¹¹³
- 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.”¹¹⁴ This may increase the likelihood of a child

¹¹² Presidential Decree #411/2008 of 5/5/2008, “On Additional Measures to Ensure Protection of Rights and Legal Interests of Children” (Paragraph 4).

¹¹³ Civil Code, Ukraine.

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, children living on the streets 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. Children living on the streets 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.

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.¹¹⁵

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.¹¹⁶ 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.¹¹⁷ 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

¹¹⁴ Family Code (article 143, paragraph 3).

¹¹⁵ 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.

¹¹⁶ 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*).

¹¹⁷ *Ibid.*

for children to be provided in social and rehabilitation centers (“Children’s Town”).¹¹⁸ 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.¹¹⁹ However, these procedures have not been effectively implemented. In December 2009, the MOFYS issued an order¹²⁰ 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.¹²¹

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 of findings

Strengths

- The HIV/AIDS Law permits testing of youth ages 14–18 without parental consent.

Specific policy gaps

- Clinical guidelines for HCT are outdated compared with international guidelines.
- Several regulations are still in draft form: HCT protocol including provider-initiated counseling and testing (PICT), guidelines for provision of HCT in mobile clinics, and MOH regulations on quality assurance of laboratory testing.
- Funding for HIV testing is limited.
 - The national budget only funds tests for pregnant women and blood donors.
 - Oblasts are to pay for tests for 5 percent of the local population; however, these tests are reserved for

¹¹⁸ 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.”

¹¹⁹ 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.”

¹²⁰ 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.”

¹²¹ 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.

MARPs and depend on funding availability.

- The current legal status of mobile clinics is uncertain; regulations remain in draft form.
- Access to rapid HIV testing is limited.
 - In the government sector, funds for rapid testing are reserved for maternity hospitals. Donors and grants support some rapid testing for additional populations.
 - The MOH recently approved protocols for wider use of rapid testing, but it will still depend on the availability of local funding.
 - Current legislation does not permit use of rapid tests across health facilities and in mobile clinics for regular HCT services.
- The licensing and accreditation system for HCT facilities has not been established, leaving NGOs vulnerable to threats of closure.
- No strategy exists for targeting HCT services to MARPs.
- HIV/AIDS Law language has caused confusion about whether providers have to provide post-test counseling for youth in the presence of a parent/guardian.
- Current regulations require HCT post-test counseling to be provided by a physician, thereby limiting expansion of HCT services.
- Patients are required to register with an AIDS center to receive care, thus many choose not to and are lost to follow-up and treatment.
- Partner notification procedures are unclear.

Other barriers

- Oversight of HCT services is inconsistent.
- Awareness of HCT services is low, and the involvement of *Dovira* cabinets, TB, narcology, and STI centers in HCT is insufficient.
- Training for HCT specialists is limited (*A USAID project is working with the post-graduate medical academy in Kyiv to initiate in-service training in HCT*).
- Informants noted that epidemiologists sometimes do not register HIV cases because they believe rapid testing is inaccurate and do not agree with using two rapid tests to confirm HIV.

Access to HIV counseling and testing services

In 2009, 49 percent of new cases had already progressed to AIDS by the time they were diagnosed (Ministry of Health, Ukraine, 2010), which points to a need to improve access to HCT services. Legislation provides for free of charge access to HCT at any healthcare facility regardless of its ownership (private, non-profit, or government), as long as it holds an appropriate license and is formally accredited.¹²² Some NGO leaders that served as key informants for this assessment expressed concern that 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

¹²² 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.

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.¹²³ 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.¹²⁴ 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.¹²⁵ 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,¹²⁶ 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 ground-breaking 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.”

Mobile clinics providing HCT

Mobile clinics operating out of healthcare facilities as well as NGO mobile clinics are permitted to provide HCT services.¹²⁷ 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

¹²³ The guidelines for providing CT are defined in the MOH Order #415, August 2005, which standardizes the procedure.

¹²⁴ MOH Order #236, April 2006 and MOH Order #446, July 2006.

¹²⁵ MOH Order #102, February 2008.

¹²⁶ See page 5.

¹²⁷ MOH Order #415, August 2005.

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,¹²⁸ 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.¹²⁹ 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.¹³⁰

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.

Internationally recommended 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.

¹²⁸ *Ibid.*

¹²⁹ Law# 2861-VI, December 2010.

¹³⁰ Law of Ukraine # 2861-VI as of 12.23.2010.

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,¹³¹ 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.¹³² 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.¹³³ In 2010, the supply of HIV rapid tests was mainly provided by the Global Fund Round 6 HIV Grant (via the Alliance as the relevant co-Principal Recipient) and Clinton Foundation.

According to current legislation, the use of rapid tests across health facilities and in mobile clinics for regular HCT services is not permitted. International guidelines recommend the use of rapid HIV testing to minimize loss of clients before they are aware of their HIV status. A new MOH Order “On adoption of the procedure for HIV infection testing and testing quality assurance, forms of the primary accounting documentation and instructions on completing them” has been registered in the Ministry of Justice and will formally regulate the use of rapid tests more widely.¹³⁴ This protocol will allow for the use of rapid tests in any facility, including those focused on providing services to vulnerable populations, 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.

¹³¹ Law 1026, Feb. 2009 (National AIDS Program) an MOH order 415 provide for trainings of physicians on CT.

¹³² Law 2861, Dec. 2010, MOH Order 255, June 2003.

¹³³ MOH Order 639, August 2009.

¹³⁴ MOH Order #1141 as of December 21, 2010 “On adopting Provisions for HIV-infection testing and assuring quality of testing; forms of primary reporting documentation on HIV-infection testing and instruction for completing them.”

Summary of findings

Strengths

- NAP guarantees that the government will provide 80 percent of needed ART drugs.
- There is a joint working group on intellectual property and access to medicines.
- ART standards and protocols revised in 2010 reflect changes in international standards recommending early initiation of PLHIV on ART.
- NAP guarantees funding for PMTCT program supplies and availability of pediatric ARV formulations.
- The registration process for medications is well-defined (but cumbersome).

Specific policy gaps

- NAP includes an estimate of the overall need for ART; however, this estimate and corresponding targets do not reflect updated standards and protocols on early initiation of patients on ART.
- Funding for ART is insufficient due to the high price of medications, and most available funding is used for first-line ARVs. Limited ARV supplies delay initiation of patients on ART.
- The strategy for scaling up access to ART is unclear.
- The registration process for new medications is cumbersome, and for five years after a medication is registered, the guidelines prohibit using this registration information for registering another medication.
- Use of generic medications is hindered by inflexible patent laws and banned generic versions of drugs that are under patent; patent owners can prevent pre-clinical and clinical trial data being used in the registration of a generic drug.
- OI drugs are only partially covered by regional budgets, contributing to discontinuation of treatment and increased drug resistance.
- Inconsistent central procurement of ARVs and other medications has led to stockouts (see section on HIV/AIDS drug and commodity procurement and supply).
- Research and testing on drug resistance is not funded by the government.

Other barriers

- In rural areas, PLHIV and their partners face significant barriers to receiving high-quality, comprehensive medical services, and key informants report, in some regions, poor communication between the AIDS center and physicians at the district level.

Since 2004, when large-scale introduction of ART began in six regions with support from the Global Fund, ART coverage has expanded to all 27 regions of Ukraine. In 2004, only 250 PLHIV in Ukraine were receiving lifesaving ARVs (Ministry of Health, Ukraine, 2010). As of January 1, 2011, 22,697 of Ukraine's estimated 350,000 PLHIV were receiving ART. 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 (Ministry of Health, Ukraine, 2010).

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 prevent 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 CD4¹³⁵ counts of 350 and below, regardless of symptoms, whereas the previous guidelines recommended initiating ART in patients with advanced clinical disease

¹³⁵ Cluster of differentiation 4 (cell count).

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. Some service providers were not aware of this change in guidelines and 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 or zero. 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 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).¹³⁶

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

¹³⁶ 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.”

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 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.¹³⁷

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.”¹³⁸ 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 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 2010.¹³⁹ This working group is tasked with improving Ukrainian legislation regulating registration of medications and protection of intellectual property rights.

¹³⁷ 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.”

¹³⁸ 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*).

¹³⁹ Order # 787/130 of the MOH of Ukraine of 09/16/2010.

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.¹⁴⁰

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.¹⁴¹ 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 medical devices. Then, in 2010, the CMU issued a mechanism to prevent the circulation of counterfeit, substandard, and unregistered drugs.¹⁴²

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)¹⁴³
- Regulation of storage and quality control of medicines in healthcare settings (2003)¹⁴⁴
- Procedure for clinical trials of medicines and expertise of clinical trials (2009)¹⁴⁵
- Concept of the pharmaceutical sector in the health of Ukraine for 2011–2020 (2010)¹⁴⁶

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.”

¹⁴⁰ Cabinet of Ministers Decree # 902 of 09/14/2005, “On the approval of the Procedure for state quality control of medications imported to Ukraine.”

¹⁴¹ *Ibid.*

¹⁴² 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.”

¹⁴³ 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).

¹⁴⁴ 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).

¹⁴⁵ 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).

¹⁴⁶ 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.”

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 of findings

Barriers to access to treatment can be compounded by problems with the HIV drug and commodity procurement and supply management system. While progress has been made in the PSM system, significant shortfalls and challenges remain. AIDS treatment remains expensive, and stockouts and shortages of ARVs negatively impact treatment adherence. Disruptions in the supply of ARVs, documented in January 2011, have further restricted access to ART for PLHIV.

Strengths

- In February 2010, the MOH aimed to strengthen the procurement and supply management system for HIV-related commodities by
 - Establishing internal working groups on key topics;
 - Adopting new tendering regulations that prohibit contract prices from exceeding established ceiling prices;
 - Outlining measures to combat corruption in medical procurements; and
 - Establishing an MOH Permanent Working Group for specialized management of public procurement.
- ARV, STI, and OI drugs are included in the essential drugs list.
- In 2009–2010, the MOH issued emergency orders to correct delays and shortcomings in the distribution system for HIV drugs and commodities.

Specific policy gaps

- The transparency of and CSO participation in the MOH permanent tender committee is limited.
- Foreign-based organizations and manufacturers face barriers in the tendering process, as tenders are only available in Ukrainian and goods can only be procured from companies formally registered and licensed to operate in Ukraine.
- Regions are dependent on the central procurement process for ARVs and other essential HIV-related drugs and commodities.
- The supply and distribution system for HIV-related drugs and consumables is inefficient, especially related to forecasting needs, distributing commodities from the central level, and creating a buffer to prevent shortages and stockouts.
- Gaps and shortfalls exist in laboratory quality assurance (e.g., reagents used as control samples may only be procured if passed through the full government registration system).
- No transparent methodology exists for estimating the overall need for ARVs, and needs were not re-assessed in reflection of recent changes to the ART treatment protocols.

Other barriers

- Coordination among the MOH, MOF, and Ministry of Economy is insufficient, causing procurement delays and difficulty in securing necessary funding.
- The notification of adverse medication effects is compromised by a fear of receiving reduced supplies of scarce medications and lack of training.

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.¹⁴⁷ All ARVs, as well as many other drugs and commodities used to provide HIV services, are centrally procured. The essential drug list¹⁴⁸ 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.¹⁴⁹ 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 law¹⁵⁰ 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.¹⁵¹ In December 2008, the MOH established an inter-ministerial working group to improve the procurement system for HIV/AIDS-related goods, works, and services.¹⁵² The 2009 NAP included the establishment of a commission at the MOH on developing nomenclature for HIV-related drugs and commodities.¹⁵³

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

- Established internal working groups¹⁵⁴ 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.¹⁵⁵

¹⁴⁷ Laws 493/95-VR (December 1995) and 2289-IV (June 2010).

¹⁴⁸ CMU Resolution 1071 (September 1996).

¹⁴⁹ CMU Resolution 1247-p (September 2008)—*On Approving the Plan of Activities for Improvement of Circulation of Medicines and Medical Products*.

¹⁵⁰ Law 2289-V (January 6, 2010)—*On Execution of Public Procurement*.

¹⁵¹ MOH Order 102-Adm (March 2008).

¹⁵² MOH Order 827 (December 2008).

¹⁵³ MOH Order 1057 (December 2010).

¹⁵⁴ MOH Order 104 (February 2010).

¹⁵⁵ MOH Order 73 (February 2010).

- Outlined measures to prevent and combat acts of corruption in the procurement of medical drugs, commodities, and services.¹⁵⁶
- Set up the MOH Permanent Working Group for specialized management of public procurement.¹⁵⁷

Availability of ARVs and HIV-related drugs

The new 2010 AIDS law¹⁵⁸ 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.¹⁵⁹ 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.¹⁶⁰ 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 2010.¹⁶¹ 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 2009.¹⁶² 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 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

¹⁵⁶ MOH Order 94 (February 2010).

¹⁵⁷ MOH Order 61 (February 2009).

¹⁵⁸ Law 2861-VI (December 2010).

¹⁵⁹ CMU Resolution 333 (March 2009).

¹⁶⁰ National AIDS Program, Law 1026-VI (February 2009).

¹⁶¹ MOH Order of № 551 of July 2010, "On approval of clinical protocol antiretroviral therapy of HIV infection in adults and adolescents."

¹⁶² MOH Order 936 (December 2009).

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,¹⁶³ which is the central body of executive power. The actions of this body are directed and coordinated by the CMU through the MOH.

Current regulations¹⁶⁴ 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,¹⁶⁵ in accordance with a European Parliament and European Council Directive,¹⁶⁶ 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.¹⁶⁷ 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.

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.

¹⁶³ CMU Resolution of 20 December 2008 № 1121.

¹⁶⁴ CMU Regulation 1497 (November 2004).

¹⁶⁵ CMU Resolution 641 (July 2008).

¹⁶⁶ European Parliament and European Council Directive 98/79/EC, dated October 27, 1998.

¹⁶⁷ CMU Resolution 1497 (September 2004) and Order 51 (May 2010) of the State Inspectorate for Quality Control.

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.¹⁶⁸ The Reference Laboratory is responsible for distributing test kits and equipment procured via the state budget to HIV/AIDS reference laboratories.¹⁶⁹ “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 kits¹⁷⁰
- Test kits and consumables to determine the level of viral loads¹⁷¹
- Distribution of the ARV drug Kaletra for treatment of children with HIV/AIDS (provided as a charity)¹⁷²
- ARVs for treatment and prevention¹⁷³
- Reagents and consumables to determine CD4 count¹⁷⁴

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, 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 of findings

Strengths

- Inter-ministerial coordination of care for individuals with TB/HIV co-infection has improved with the issuance of several joint orders (e.g., on standards of social care for TB/HIV patients).

¹⁶⁸ MOH order 704 (August 2010).

¹⁶⁹ MOH Order N 230, of April 17, 2006, “On Setting Up a HIV/AIDS Reference Laboratory Under the National AIDS Center of the MOH.”

¹⁷⁰ MOH Order 893 (October 2010), Order 103 (February 2010).

¹⁷¹ MOH Order 615 (August 2009).

¹⁷² MOH Orders 666 and 726 (August 2010).

¹⁷³ MOH Orders 795 (September 2010) and 1008 (November 2010).

¹⁷⁴ MOH Order 1050 (November 2010).

- New infection control standards were issued in 2010.

Specific policy gaps

- No uniform process exists for handling registration of TB/HIV deaths, causing an apparent increase in AIDS-related deaths, while TB deaths remain hidden.
- Official diagnosis and treatment of TB cases can only be performed in TB dispensaries, increasing loss to follow-up and treatment and exposing HIV-positive individuals to increased risk of TB infection.
- The TB surveillance system is insufficient (although a TB register is envisaged in the new TB law—passed its first reading in Parliament).

Other barriers

- TB doctors are unaware of drug interactions between TB drugs and ARVs or that TB in an HIV-positive individual is a precondition to start ART. Many delay initiation of ARVs until after completion of a TB course.
- Frequent violations of new infection control standards occur.

Coordination on TB/HIV

The importance of coordination on TB/HIV is acknowledged in both HIV and TB laws, and the current law on TB¹⁷⁵ and law on HIV/AIDS¹⁷⁶ 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).¹⁷⁷ Since 2007, the National Council on HIV/AIDS has also included TB.¹⁷⁸ 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.¹⁷⁹ 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 Ministry of Labor (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.¹⁸⁰

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 resolution approved an implementation plan for providing assistance in the social re-adaptation of prisoners.¹⁸¹ 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.¹⁸²

¹⁷⁵ Law of 05.07.2001 № 2586-III, "On Fighting Tuberculosis."

¹⁷⁶ 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.

¹⁷⁷ Law of 08.02.2007 № 648-V approving the National Program against TB in 2007–2011.

¹⁷⁸ Resolution of the CMU of 11.07.2007 № 926, "Some aspects of the TB and HIV/AIDS control."

¹⁷⁹ CMU Resolution of 31.05.2006 № 759, "On establishment of the Committee for HIV/AIDS and other socially dangerous diseases."

¹⁸⁰ Joint Order MOFYS, MOL, MOH from 13.09.2010 № 3123/275/770.

¹⁸¹ 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."

¹⁸² Joint

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 system¹⁸³ and HIV/AIDS reporting forms,¹⁸⁴ 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.¹⁸⁵

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.¹⁸⁶ According to an MOH order related to health facility staffing, AIDS Centers should have a TB doctor present on staff.¹⁸⁷ 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.

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.¹⁸⁸ Since 2009, a temporary regulatory document defines the procedure for using rapid tests for HCT services in

youth on case management of tuberculosis in the event of TB patients release from penal institutions, detention prisons, and

¹⁸³ MOH forms N 502-1/o, N 502-2/o.

¹⁸⁴ MOH forms N 1 – HIV/AIDS and N2 – HIV/AIDS.

¹⁸⁵ Letter of the Ukrainian Center for Prevention of AIDS of 13.01.2011 #41.

¹⁸⁶ MOH Order of № 551 of July 2010, “On approval of clinical protocol antiretroviral therapy of HIV infection in adults and adolescents.”

¹⁸⁷ MOH Order N 122 of 12.03.2008 about modification in MOH order of 23.02.2000 N 33.

¹⁸⁸ 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.

TB, STI, and narcology clinics.¹⁸⁹ 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.¹⁹⁰ 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 200.¹⁹¹ A course for TB/HIV is scheduled to be introduced in 2011 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.¹⁹² 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 facilities with local decontamination facilities.¹⁹³ 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.

¹⁸⁹ Temporary Instruction of application of rapid tests in TB, STI, and narcology clinics (approved by the MOH Order of August 2009 N 639).

¹⁹⁰ MOH Order of May 2008 № 276 approves the Protocol of treatment of patients with HIV/TB co-infection.

¹⁹¹ *Ibid.*

¹⁹² MOH Order of August 2010 N 684.

¹⁹³ Law of 08.02.2007 № 648-V approving the National Program against TB in 2007–2011.

CONCLUSION

The sheer number, depth, and breadth of policy documents included in the legal and regulatory review demonstrates the government's level of effort and involvement in creating a strong enabling environment for the national response to HIV/AIDS in Ukraine. Both policy documents and key informant interviews also reveal an increasing willingness on the part of the GOU to encourage civil society participation in the policy process and in the provision of HIV-related programs and services. Nevertheless, key gaps and challenges remain.

Ukraine's relatively strong HIV legal and regulatory framework is undermined by inadequate implementation of laws and policies. The lack of a strong national coordinating body significantly hampers Ukraine's ability to muster an effective integrated national HIV response. The MOH has been unable to foster sufficient inter-ministerial cooperation to bring about a truly integrated national HIV response. Ministries continue to differ in their interpretation of laws and policies related to key issues, and regulations and implementation vary considerably both between national and regional levels and across regions. The administrative reform process has intensified challenges relating to multisectoral coordination, as roles and responsibilities have shifted and some key functions have yet to be reassigned.

Implementation is also hindered by insufficient dissemination of policy documents, a lack of training on new standards and protocols, and limited communication between providers and government. Overall, training on HIV issues across key sectors—including health, education, law enforcement, and the judiciary—is insufficient. Putting policies into practice is further impeded by highly variable regional and district funding for HIV programs and materials, resulting in disparities in service coverage and quality.

No enforcement mechanisms exist to prevent violations of the rights of vulnerable populations, including PLHIV. Although there are CSOs that serve as watchdogs and advocates in the area of human rights and stigma and discrimination, evaluation of policy implementation is infrequent and is not a role or responsibility of any specific organization or agency. Strengthening the capacity of individuals and organizations within and outside government to evaluate policy implementation would improve translation of policies into action. Key informants' reports of unlawful barriers to implementation of HIV laws and policies—often perpetuated by local officials and law enforcement agencies—indicate the need to increase key stakeholders' awareness and understanding of legally guaranteed rights and protections, particularly as these apply to vulnerable populations.

The HIV policy environment could be strengthened by addressing shortcomings in planning and policy formulation processes. Data gaps, particularly related to vulnerable populations, reduce the effectiveness of planning and forecasting. Key informants also noted that the government endorsement of policy documents is lengthy, inflexible, and dependent on individuals not knowledgeable about the issues. While multiple sectors and disciplines are engaged in legal and policy development, the level of consistent, active involvement by appropriate individuals from these sectors varies. While PLHIV participation has increased, their involvement at the national and regional levels in policy formulation needs improvement, and other vulnerable populations should be encouraged to participate (such as sexual minorities and IDUs, who are currently excluded from the policy process).

Ukraine has made considerable progress in fostering an enabling policy environment for HIV over the past decade. Signing of the Partnership Framework represents an important opportunity for further strengthening. Addressing the gaps and challenges outlined in this report could have significant positive impacts on Ukraine's HIV policy environment. Ultimately, Ukrainian stakeholders must decide which issues are the most pressing. The findings of this assessment should prove useful in facilitating dialogue among key stakeholders regarding the way forward.

ANNEX A. LIST OF INFORMANTS

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Spinul, Igor, Director, Former Prisoners Action “Podolannya”

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Vysotska, Galyna, Center of MiO at the Oblast Center for AIDS Prevention and Response, Mykolaiv

ANNEX B. MAT TOOLKIT (TOOLS 2.1.1 AND 2.1.2)

Tool 2.1.1 Inventory of Documents

Country: _____ Date completed: _____

Name of data collector _____

Position: _____

Contact information for data collector:

Email address: _____

Telephone/fax: _____

Instructions to data collector:

Please fill out this page and indicate the best way to contact you (email, telephone, fax, etc.) should we need further information from you.

Refer to the instructions page for directions on how to fill out the inventory. The inventory includes 10 content areas. Please provide information only on those areas that you are familiar with and leave the others blank. Within the areas that you are familiar with, please be sure to answer “yes” or “no” to each item. All data collectors should address the open-ended question number 11 at the end of the inventory.

When you have completed the inventory, please send all the pages and all the documents you have referenced to [team leader should fill this in before distributing to team members].

1. Authorization			
1.1a Is there any <i>mention</i> [see definition of terms] of <i>treatment</i> [see definition of terms] in government facilities for <i>drug dependence</i> [see definition of terms], in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.1b <i>If yes to any in 1.1a</i> , is there any mention of treatment for drug dependence in government facilities with <i>methadone and/or buprenorphine</i> , in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.2a Is there any mention of treatment in non-government facilities for drug dependence, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.2b <i>If yes to any in 1.2a</i> , is there any mention of treatment for drug dependence in non-government facilities with <i>methadone and/or buprenorphine</i> , in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

1.3 <i>If any document in 1.2b allows non-government facilities to treat drug dependence with methadone and/or buprenorphine, is there explicit mention of licensing, provider qualifications or other requirements for non-government services providing methadone and/or buprenorphine, in [check each]</i>			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.4 <i>If any document in 1.2b allows non-government facilities to treat drug dependence with methadone and/or buprenorphine, is there express mention of prices that non-government services are permitted to charge for methadone and/or buprenorphine, in [check each]</i>			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

2. Budget			
2.1 Are there budgets and/or any explicit directives to allocate budget/financing for government provision of methadone and/or buprenorphine, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
2.2 Are there national estimates of the number of people who are drug dependent?			
<input type="checkbox"/> Yes → Attach document(s) <input type="checkbox"/> No		Notes:	

2.3 Are there national targets or estimates of the number or percentage of drug users who will or should receive methadone and/or buprenorphine treatment, in [check each]?			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
Title or number:			
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			
2.4 Are there national targets or estimates of the number or the amount of methadone and/or buprenorphine that will be needed for drug treatment settings, in [check each]?			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
Title or number:			
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			

3. Registration, scheduling and procurement			
3.1 Is <i>methadone</i> included in the country's approved drug list, as found in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
Title or number:			
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			

3.2 Is <i>methadone</i> expressly registered or banned for use in substance dependence programs, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.3 Is <i>buprenorphine</i> included in the country's approved drug list, as found in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.4 Is <i>buprenorphine</i> expressly registered or banned for use in substance dependence programs, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.5 Are methadone and/or buprenorphine (either one or both) included in the country's own essential drug list, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

3.6 Is local country manufacture (subject to licensing, oversight, etc.) of either methadone and/or buprenorphine expressly permitted or banned, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.7 Is importation (subject to licensing, oversight, etc.) of either methadone and/or buprenorphine expressly permitted or banned, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

4. Participation			
4.1 Are there written, express provisions that either encourage or exclude active participation of injecting drug users in the development of policies and/or regulations in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

4.2 Are there written, express provisions that either encourage or exclude active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, in the development of policies and/or regulations in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
4.3 Are there written, express provisions that either encourage or exclude active participation of injecting drug users in program design, implementation and/or monitoring in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
4.4 Are there written, express provisions that either encourage or exclude active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, in program design, implementation and/or monitoring in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

5. Storage, distribution and dispensing of controlled substances			
5.1 Are there written, express provisions for storage of methadone and/or buprenorphine, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
Title or number:			
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			
5.2 Are there written, express provisions that either allow or prohibit methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs (such as in general hospitals or in prisons), in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
	Title or number:		
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			
5.3 Are there written, express provisions that either allow or prohibit authorized treatment facilities to dispense methadone and/or buprenorphine for later use outside the treatment facility, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
	Title or number:		
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			

5.4 Are there written, express provisions that specify the numbers and/or locations of authorized treatment facilities to dispense methadone and/or buprenorphine, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
Title or number:			
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			

6. Clinical Treatment and Continuum of Care			
6.1 Are there express provisions that designate some authority as the formal coordinator to develop individual medical drug abuse treatment plans, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
	Title or number:		
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			
6.2 Is there explicit mention of the range and/or quality of care in services providing methadone and/or buprenorphine, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document:		
Title or number:			
Page number where reference for this item is found:			
Chapter or provision number of relevant reference:			

6.3 Are there express provisions for referral and counter-referral between treatment facilities and other agencies and services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:			
6.4 Are there express provisions for referral and/or case management between closed facilities (e.g., in-patient treatment facilities, prisons, etc.) and the community, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.5 Are there express provisions for integration of services and standardized procedures for patients with both need for treatment of opioid dependence and another health or medical condition such as HIV, pregnancy, etc., in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

6.6 Are there express provisions that either allow or prohibit patients receiving methadone or buprenorphine treatment prior to imprisonment to continue treatment while in prison or other closed facility, or to start treatment while in prison, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.7 Are there express provisions that mandate or promote cooperation between drug treatment programs and law enforcement agencies, for example to permit referral to treatment instead of prosecution for minor drug offences, to ensure confidentiality of patient's information, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.8 Are there express provisions to ensure that drug treatment programs establish an individualized treatment plan for each patient, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

6.9 Are there express provisions that describe the range and/or dosing levels of methadone and/or buprenorphine that are permitted to be prescribed for drug treatment, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.10 Are there express provisions to ensure that injecting drug users have access to HIV and AIDS prevention, care and treatment medical services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.11 Are there express provisions to ensure that injecting drug users have access to Tuberculosis prevention, care and treatment medical services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.12 Are there express provisions to ensure that injecting drug users have access to Hepatitis prevention, care and treatment services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No

	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.13 Are there express provisions to ensure that injecting drug users have access to psychological services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.14 Are there express provisions to ensure that injecting drug users have access to social services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

7. Standards of care			
7.1 Are there express provisions that establish and provide for professional competence of medical personnel and other health personnel who provide methadone and/or buprenorphine, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
7.2 Are there express provisions to provide medical doctors and other health personnel with basic and/or continuing training in the use of methadone and/or buprenorphine for the treatment of opioid dependence, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Operational plans	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:			
7.3 Are there express provisions that require the same standards of ethical treatment in to the treatment of drug dependence as other health care conditions (e.g. patient's right to autonomy and self determination, obligation for beneficence and non-maleficence from treating staff), in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

7.4 Are there express provisions that protect or exclude confidentiality of client medical records and/or medical information in general, in [check all]			
Policy documents	Constitution	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:			
7.5 Are there express provisions that protect or exclude confidentiality of medical information in drug dependence treatment, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
7.6 Are there express provisions that permit or prohibit health care providers from passing treatment information to law enforcement bodies, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

8. Coverage and client access to treatment			
8.1 Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of their age, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.2 Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of their gender, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.3 Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of length of illicit drug use, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.4 Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of their past history of attempts at abstinence or unsuccessful treatment attempts, in [check each]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No

	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.5	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of any kind of opioid dependence complications, in [check each]		
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.6	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of psychiatric conditions, in [check each]		
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.7	Are there express (explicit) directives to require review by a medical commission or prescription by a psychiatrist for dispensing or prescribing methadone and/or buprenorphine for an individual client, in [check each]		
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

9. Women who inject drugs			
9.1 Is there explicit mention of women's specific needs for dosing levels of medications and/or other drug treatment services, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
9.2 Is there explicit mention of access to family planning and/or other reproductive health services by women who inject drugs, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
9.3 Is there explicit mention of the rights of women in treatment for drug dependence to retain or regain custody of their children except in cases of child abuse, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
9.4 Is there explicit mention of methadone and/or buprenorphine treatment for pregnant or lactating women who inject drugs, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

9.5	Is there explicit mention of access to prenatal care by women who inject drugs, in [check all]		
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10. Civil, economic, social and cultural rights of people who use drugs			
10.1	Are there express provisions that permit or prohibit mandatory testing for illicit drug use, in [check all]		
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.2	Are there express provisions that permit or prohibit <u>mandatory treatment</u> for people who use illicit drugs, in [check all]		
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10.3 Are there express provisions that permit or prohibit other mandatory medical services or procedures (for example, HIV testing, contraceptive sterilization) for people who use opioids and because of their drug use, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.4 Are there express provisions that either guarantee or restrict the free movement of people who use opioids (such as mandatory quarantine, detention) because of their drug use, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.5 Are there express provisions that either guarantee or restrict employment opportunities for people who use opioids because of their drug use, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10.6 Are there express provisions that either permit or prohibit discrimination based on medical or physical disability, in [check all]			
Policy documents	Constitution	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.7 Are there express provisions that either permit or prohibit discrimination based on mental health condition, in [check all]			
Policy documents	Constitution	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.8 Is drug dependence classified as a disability and/or a mental health condition, in [check all]			
Policy documents	Constitution	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10.9 Are there express provisions that either guarantee or restrict any other civil, social or cultural benefits (such as voting, freedom of association, access to housing, education, custody of children) for people who use opioids because of their drug use, in [check all]			
Policy documents	Legislation	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	High-level policies	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Regulations	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Guidelines and/or protocols	<input type="checkbox"/> Yes → Attach document(s)	<input type="checkbox"/> No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

11. Please use the space below for any other remarks or observations about the areas covered in this inventory or to describe important topics concerning MAT, especially methadone and/or buprenorphine, that were not included in the inventory. Attach any related materials – e.g. press release, brochures, news articles, declarations.

Background on inventory scoring form for documents pertaining to medication-assisted therapy for opioid dependence

The first step of the Inventory is to compile a reference library of documents addressing specific aspects of internationally accepted “best practices” for MAT using methadone or buprenorphine. The second step is to analyze or score the compiled documents.

Before beginning to score the individual items, the analyst should take time to become familiar with all of the documents in the reference library, especially if they were compiled by other people. For each item in the Inventory, the analyst should re-read the documents specifically referenced for that item and score them in the aggregate. Also include any other document(s) in the reference library that pertain to the item, even if they were not noted in the original inventory form.

Different documents may conflict with one another. For example, Methadone may be listed as an illicit drug in one document and permitted as a controlled substance in another. In this case, in Section 3 (Registration, scheduling and procurement) under item 3.1, two response options should be checked: “Methadone is expressly registered or scheduled” and “Methadone is expressly banned or prohibited.” The relevant document(s) and sections should be cited in the box for each checked option.

If no written documents pertaining to the aspect in question were discovered (i.e., all document types were checked as “no”) and none of the other documents in the reference library is applicable, check the last box for the item (“No mention of methadone in the policy documents”).

At least one response option should be checked for each inventory item. The last box, “No mention...” should be checked only if none of the previous boxes were checked.

The analyst may find that a particular document that was classified in the first stage of the inventory as a “regulation” is in fact a “guideline,” or vice-versa. The analyst should correct and make note of any documents that were misclassified by type.

In a few cases, the analyst will be asked to include a specific piece of information from the document(s). For example, item 2.4 asks about published estimates of the number of people potentially in need of MAT. If such an estimate exists, it should be included on the score sheet. Similarly, items 3.6 and 3.7 ask about authorization of local country manufacture and importation of methadone and buprenorphine. If authorization exists and if the authorized manufacturers and/or importers are listed, they should be included on the score sheet in the spaces provided.

The analyst should confine the ratings to what is contained in the written documents. He/she should not attempt to assess the adequacy of their content—for example, whether the estimated number of drug-dependent people potentially in need of MAT (item 2.4) is reasonable or whether the specification of range and/or quality of care of MAT services (item 6.1) meets the latest international standards. In addition, the analyst’s ratings should not be influenced by how well the policy provisions have been circulated, support for or opposition to them, or the extent to which they have been put into practice. These more subjective ratings can be collected through key informant interviews and direct observation during Policy Assessment Index (PAI) application (See Tool 2.2.2).

Tool 2.1.2 Inventory Scoring Form

Country: _____ Date completed: _____

Name of analyst _____

Position: _____

Contact information for analyst:

Email address: _____

Telephone/fax: _____

Instructions to analyst:

Please fill out this page and indicate the best way to contact you (email, telephone, fax, etc.) should we need further information from you.

Refer to the instructions page for directions on how to score the inventory. The inventory includes 10 content areas. Please be sure to score all items for all content areas and read all cited documents, even if you are already familiar with their provisions.

When you have completed scoring the inventory, please send all the pages to [team leader should fill this in before distributing to team members].

1. Authorization
1.1a Government facilities are authorized to provide treatment for drug dependence
<input type="checkbox"/> Government facilities are authorized to provide drug treatment <i>Citations:</i>
<input type="checkbox"/> Government facilities are expressly banned or prohibited from providing drug treatment <i>Citations:</i>
<input type="checkbox"/> No mention of drug treatment in government facilities in policy documents
1.1b Government facilities are authorized to provide methadone for drug dependence
<input type="checkbox"/> Government facilities are authorized to provide methadone treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> Government facilities are expressly banned or prohibited from providing methadone treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> No mention of methadone treatment for opioid dependence for drug treatment in government facilities in policy documents
1.1c Government facilities are authorized to provide buprenorphine for drug dependence
<input type="checkbox"/> Government facilities are authorized to provide buprenorphine treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> Government facilities are expressly banned or prohibited from providing buprenorphine treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> No mention of buprenorphine treatment for opioid dependence for drug treatment in government facilities in policy documents
1.2a Non-government facilities are authorized to provide treatment for drug dependence
<input type="checkbox"/> Non-Government facilities are authorized to provide drug treatment <i>Citations:</i>
<input type="checkbox"/> Non-Government facilities are expressly banned or prohibited from providing drug treatment <i>Citations:</i>
<input type="checkbox"/> No mention of drug treatment in non-government facilities in policy documents
1.2b Non-government facilities are authorized to provide methadone for drug dependence
<input type="checkbox"/> Non-Government facilities are authorized to provide methadone treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> Non-Government facilities are expressly banned or prohibited from providing methadone treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> No mention of methadone treatment for opioid dependence for drug treatment in non-government facilities in documents
1.2c Non-government facilities are authorized to provide buprenorphine for drug dependence
<input type="checkbox"/> Non-Government facilities are authorized to provide buprenorphine treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> Non-Government facilities are expressly banned or prohibited from providing buprenorphine treatment for opioid dependence <i>Citations:</i>
<input type="checkbox"/> No mention of buprenorphine treatment for opioid dependence for drug treatment in non-government

facilities in documents	
1.3	Licensing, provider qualifications or other requirements for non-government services providing methadone and/or buprenorphine are provided
<input type="checkbox"/> Licensing, provider qualifications are specified <i>Citations:</i>	
<input type="checkbox"/> Non-government services are not permitted to provide MAT using methadone or buprenorphine	
<input type="checkbox"/> No mention of licensing, provider qualifications in policy documents	
1.4	Prices that non-government services providing methadone and/or buprenorphine are allowed to charge are specified
<input type="checkbox"/> Prices are specified → prices: <i>Citations:</i>	
<input type="checkbox"/> Non-government services are not permitted to provide MAT using methadone or buprenorphine	
<input type="checkbox"/> No mention of prices in policy documents	

2. Budget	
2.1	There are budgets and/or explicit directives to allocate budget/financing for government provision of methadone and/or buprenorphine.
<input type="checkbox"/> There are directives to allocate budgeting/ financing for government provision of methadone and/or buprenorphine treatment for opioid dependence <i>Citations:</i>	
<input type="checkbox"/> No mention of budget allocation in policy documents	
2.2	There are national estimates of the number of people who are opioid drug dependent.
<input type="checkbox"/> Yes → Number of drug dependent people: _____ Source, year: <input type="checkbox"/> No	
2.3	There are national targets or estimates of the number or percentage of opioid dependent drug users who will or should receive methadone and/or buprenorphine treatment.
<input type="checkbox"/> Yes → Estimated use of MAT using methadone or buprenorphine: _____ Source, year: <input type="checkbox"/> No	
2.4	There are national targets or estimates of the number or the amount of methadone and/or buprenorphine that will be needed for drug treatment settings.
<input type="checkbox"/> Yes → Estimated medications needed: _____ Source, year: <input type="checkbox"/> No	

3. Registration, scheduling and procurement	
3.1	<i>Methadone</i> is included in the country's approved drug list.
<input type="checkbox"/> Methadone is expressly registered or scheduled <i>Citations:</i>	
<input type="checkbox"/> Methadone is expressly banned or prohibited <i>Citations:</i>	
<input type="checkbox"/> No mention of methadone in the country's approved drug list	

3.2 <i>Methadone</i> is expressly registered and/or scheduled for use in opioid dependence treatment programs.	
<input type="checkbox"/> <i>Methadone</i> is expressly registered or scheduled <u>for opioid dependence treatment</u> <i>Citations:</i>	
<input type="checkbox"/> <i>Methadone</i> is expressly banned or prohibited <u>for opioid dependence treatment</u> <i>Citations:</i>	
<input type="checkbox"/> No mention of <i>methadone</i> <u>for opioid dependence treatment</u> in policy documents	
3.3 <i>Buprenorphine</i> is included in the country's approved drug list.	
<input type="checkbox"/> <i>Buprenorphine</i> is expressly registered or scheduled for opioid dependence treatment <i>Citations:</i>	
<input type="checkbox"/> <i>Buprenorphine</i> is expressly banned or prohibited <u>for opioid dependence treatment</u> <i>Citations:</i>	
<input type="checkbox"/> No mention of <i>buprenorphine</i> in the country's approved drug list	
3.4 <i>Buprenorphine</i> is expressly registered and/or scheduled for use in opioid dependence treatment programs.	
<input type="checkbox"/> <i>Buprenorphine</i> is expressly registered or scheduled <u>for opioid dependence treatment</u> <i>Citations:</i>	
<input type="checkbox"/> <i>Buprenorphine</i> is expressly banned or prohibited <u>for opioid dependence treatment</u> <i>Citations:</i>	
<input type="checkbox"/> No mention of <i>buprenorphine</i> <u>for opioid dependence treatment</u> in policy documents	
3.5 <i>Methadone</i> and/or <i>buprenorphine</i> are included in the country's own essential drug list.	
<i>Methadone:</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	Source, year:
<i>Buprenorphine:</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	
3.6 Local country manufacture of <i>methadone</i> and/or <i>buprenorphine</i> is authorized or permitted.	
<input type="checkbox"/> Local manufacture of <i>methadone</i> is allowed <input type="checkbox"/> Local manufacture of <i>methadone</i> is banned <input type="checkbox"/> No mention of local manufacture	Authorized manufacturers:
<input type="checkbox"/> Local manufacture of <i>buprenorphine</i> is allowed <input type="checkbox"/> Local manufacture of <i>buprenorphine</i> is banned <input type="checkbox"/> No mention of local manufacture	Authorized manufacturers:
<i>Citations:</i>	
3.7 Importation of <i>methadone</i> and/or <i>buprenorphine</i> is authorized or permitted.	
<input type="checkbox"/> Import of <i>methadone</i> is allowed <input type="checkbox"/> Import of <i>methadone</i> is banned <input type="checkbox"/> No mention of import	Authorized importers:
<input type="checkbox"/> Import of <i>buprenorphine</i> is allowed <input type="checkbox"/> Import of <i>buprenorphine</i> is banned <input type="checkbox"/> No mention of import	Authorized importers:
<i>Citations:</i>	

4. Participation	
4.1	There are written, express provisions that encourage active participation as consultants of injecting drug users in the development of policies and/or regulations.
[] Yes → Mechanism:	
[] No	
Citations:	
4.2	There are written, express provisions that encourage active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, as consultants in the development of policies and/or regulations.
[] Yes → Mechanism:	
[] No	
Citations:	
4.3	There are written, express provisions that encourage active participation of injecting drug users as consultants in program design, implementation and/or monitoring.
[] Yes → Mechanism:	
[] No	
Citations:	
4.4	There are written, express provisions that encourage active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, as consultants in program design, implementation and/or monitoring.
[] Yes → Mechanism:	
[] No	
Citations:	
5. Storage, distribution and dispensing of controlled medications	
5.1	There are written, express provisions for storage of controlled medications in general and/or methadone and/or buprenorphine in particular.
[] Yes → Mechanism:	
[] No	
Citations:	

5.2 There are written, express provisions that allow methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs.	
<input type="checkbox"/> Methadone and/or buprenorphine are <u>allowed</u> in (specify): <input type="checkbox"/> Methadone and/or buprenorphine are <u>prohibited</u> in (specify): <input type="checkbox"/> No provisions exist regarding methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs	
Citations:	
5.3 There are written, express provisions that allow authorized treatment facilities to dispense or prescribe methadone and/or buprenorphine for later use outside the treatment facility.	
<input type="checkbox"/> Treatment facilities are <u>allowed</u> to dispense MAT for use outside the facility <input type="checkbox"/> Methadone and/or buprenorphine are <u>prohibited</u> from dispensing MAT for use outside the facility <input type="checkbox"/> No provisions exist regarding dispensing MAT for use outside the facility	
Citations:	
5.4 There are written, express provisions that specify the numbers and/or locations of authorized treatment facilities to dispense or prescribe methadone and/or buprenorphine.	
<input type="checkbox"/> Yes <input type="checkbox"/> No mention of identification of suppliers	Authorized number or locations:
Citations:	

6. Clinical treatment and Continuum of care	
6.1 There are express provisions that designate some authority as the formal coordinator to develop individual medical drug abuse treatment plans.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.2 There is express mention of the range and/or quality of care in services providing methadone and/or buprenorphine in the treatment for opioid dependence.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.3 There are express provisions for referral and counter-referral between treatment facilities and other agencies and services.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.4 There are express provisions for referral and/or case management between closed facilities (e.g. in-patient treatment facilities, prisons, etc.) and the community.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:

6.5 There are express provisions for integration of services and standardized procedures for patients with both need for treatment of opioid dependence and another health or medical condition such as HIV, pregnancy, etc.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.6 There are written, express provisions that allow patients receiving methadone treatment prior to imprisonment to continue treatment while in prison or other closed facility, or to start treatment while in prison.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.7 There are express provisions that mandate or promote cooperation between drug treatment programs and criminal justice system, for example to permit referral to treatment instead of prosecution for non-violent drug offences.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.8 There are written, express provisions to ensure that drug treatment programs establish an individualized treatment plan for each patient.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.9 There are express provisions that describe the range and/or dosing levels of methadone and/or buprenorphine, that are permitted to be prescribed for opioid dependence.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.10 There are written, express provisions to ensure that injecting drug users have access to HIV and AIDS prevention, care and treatment medical services.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.11 There are written, express provisions to ensure that injecting drug users have access to Tuberculosis prevention, care and treatment medical services.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.12 There are written, express provisions to ensure that injecting drug users have access to Hepatitis prevention, care and treatment services.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.13 There are written, express provisions to ensure that injecting drug users have access to psychological services.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
6.14 There are written, express provisions to ensure that injecting drug users have access to social services including case management.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:

7. Standards of care	
7.1 There are express provisions that establish and provide for professional competence of medical personnel and other health personnel who provide methadone and/or buprenorphine in the treatment for opioid dependence.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
7.2 There are express provisions to provide medical doctors and other health personnel with basic and/or continuing training in the use of methadone and/or buprenorphine for the treatment of opioid dependence.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
7.3 There are express provisions that require the same standards of ethical treatment in to the treatment of drug dependence as other health care conditions.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Citation:
7.4 There are express provisions that protect confidentiality of client medical records and/or medical information in general.	
<input type="checkbox"/> Medical records are explicitly protected <input type="checkbox"/> No provisions exist regarding confidentiality of medical records	
Citations:	
7.5 There are express provisions that protect confidentiality of medical information in drug dependence treatment.	
<input type="checkbox"/> Medical information in drug dependence treatment is explicitly protected <input type="checkbox"/> Medical information in drug dependence treatment is explicitly excluded from protection <input type="checkbox"/> No provisions exist regarding dispensing confidentiality of medical information in drug dependence treatment	
Citations:	
7.6 There are express provisions that prohibit health care providers from providing treatment information to law enforcement bodies without specific court authorization.	
<input type="checkbox"/> Health care providers are explicitly prohibited from passing treatment information to law enforcement without court authorization <input type="checkbox"/> Health care providers are explicitly allowed to pass treatment information to law enforcement without court authorization <input type="checkbox"/> No provisions exist regarding passing treatment information to law enforcement	
Citations:	

8. Coverage and client access to treatment	
8.1 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment, to clients because of their age.	
<input type="checkbox"/> MAT is explicitly available to all who need it regardless of age	
<input type="checkbox"/> Age restrictions on MAT are specified	Excluded ages:
<input type="checkbox"/> No mention of age restrictions	
Citations:	
8.2 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients	

because of their gender.	
<input type="checkbox"/> MAT is explicitly available to all who need it regardless of gender	
<input type="checkbox"/> Gender restrictions on MAT are specified	Gender restrictions:
<input type="checkbox"/> No mention of gender restrictions	
Citations:	
8.3 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment clients because of length of illicit drug use.	
<input type="checkbox"/> MAT is explicitly available to all who need it regardless of length of drug use	
<input type="checkbox"/> Restrictions because of length of use are specified	Restrictions:
<input type="checkbox"/> No mention of restrictions for length of use	
Citations:	
8.4 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of their history of attempts at abstinence or unsuccessful treatment attempts.	
<input type="checkbox"/> MAT is explicitly available to all who need it regardless of past history	
<input type="checkbox"/> Restrictions because of past history are specified	Restrictions:
<input type="checkbox"/> No mention of restrictions because of past history	
Citations:	
8.5 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of any kind of opioid dependence complications.	
<input type="checkbox"/> MAT is explicitly available to all who need it regardless of dependence complications	
<input type="checkbox"/> Restrictions because of dependence complications are specified	Restrictions:
<input type="checkbox"/> No mention of restrictions because of dependence complications	
8.6 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of psychiatric conditions.	
<input type="checkbox"/> MAT is explicitly available to all who need it regardless of psychiatric conditions	
<input type="checkbox"/> Restrictions because of psychiatric conditions are specified	Restrictions:
<input type="checkbox"/> No mention of restrictions because of psychiatric conditions	
Citations:	
8.7 There is no requirement of review by a medical commission or prescription by a psychiatrist for dispensing or prescribing methadone and/or buprenorphine in the treatment for opioid dependence, for an individual client.	
<input type="checkbox"/> MAT is explicitly available to all who need it without medical or psychiatric review	
<input type="checkbox"/> Review by medical commission or psychiatrist is explicitly required	Specifications:
<input type="checkbox"/> No mention of review	
Citations:	

9. Women who inject drugs	
9.1 There is explicit mention of women's specific needs for dosing levels of medications and/or other drug treatment services.	
<input type="checkbox"/> There are special dosing guidelines for women	Citation:
<input type="checkbox"/> No mention of special dosing guidelines for women	
9.2 There are express provisions to ensure that women injection drug users can obtain family planning and other reproductive health services.	
<input type="checkbox"/> Access to FP/RH is guaranteed but use is not required	Citations:
<input type="checkbox"/> FP use is required of women in treatment	Citations:
<input type="checkbox"/> No mention of access to FP/RH	
9.3 There are express provisions to protect or promote the rights of women in treatment for drug dependence to retain or regain custody of their children for cases without child abuse.	
<input type="checkbox"/> Custody rights of women in treatment are explicitly protected	Citations:
<input type="checkbox"/> Custody rights are explicitly denied to women in treatment	Citations:
<input type="checkbox"/> No mention of custody rights	
9.4 There are written, express provisions to ensure that pregnant or lactating women have access to methadone and/or buprenorphine treatment.	
<input type="checkbox"/> Pregnant/lactating women are guaranteed access to methadone and/or buprenorphine	Citations:
<input type="checkbox"/> Pregnant/lactating women are restricted in access to methadone and/or buprenorphine	Citations:
<input type="checkbox"/> No mention of pregnancy/lactation	
9.5 There are express provisions to ensure that pregnant women who use drugs have the same access to prenatal care as any other pregnant women.	
<input type="checkbox"/> Access to prenatal care is protected	Citation:
<input type="checkbox"/> No mention of access to prenatal care	

10. Civil, economic, social and cultural rights of people who use drugs	
10.1 Mandatory testing for illicit drug use.	
<input type="checkbox"/> Mandatory testing for illicit drug use is permitted	Citations:
<input type="checkbox"/> Mandatory testing for illicit drug use is prohibited	Citations:
<input type="checkbox"/> No mention of mandatory testing for illicit drug use	

10.2 Mandatory treatment for illicit drug use.	
<input type="checkbox"/> Mandatory treatment for illicit drug use is permitted	Citations:
<input type="checkbox"/> Mandatory treatment for illicit drug use is prohibited	Citations:
<input type="checkbox"/> No mention of mandatory treatment for illicit drug use	
10.3 Imposition of medical services or procedures (such as mandatory HIV testing, contraceptive sterilization) on people who use opioids because of their drug use.	
<input type="checkbox"/> Mandatory medical procedures for drug users are explicitly specified	Citations:
<input type="checkbox"/> Mandatory medical procedures for drug users are explicitly prohibited	Citations:
<input type="checkbox"/> No mention of mandatory medical procedures because of drug use	
10.4 Restrictions on the free movement of people who use opioids (such as mandatory quarantine, detention) because of their drug use.	
<input type="checkbox"/> Movement of drug users is explicitly restricted	Citations:
<input type="checkbox"/> Free movement of drug users is explicitly protected	Citations:
<input type="checkbox"/> No mention of free movement of drug users	
10.5 Restrictions on employment opportunities for people who use opioids because of their drug use.	
<input type="checkbox"/> Restrictions on employment for drug users are explicitly permitted	Citations:
<input type="checkbox"/> Restrictions on employment for drug users are explicitly prohibited	Citations:
<input type="checkbox"/> No mention of employment restrictions because of drug use	
10.6 Discrimination based on medical or physical disability is prohibited.	
<input type="checkbox"/> Discrimination based on medical or physical disability is explicitly prohibited	Citations:
<input type="checkbox"/> Discrimination based on medical or physical disability is explicitly allowed	Citations:
<input type="checkbox"/> No mention of protection from discrimination based on medical or physical disability	
10.7 Discrimination based on mental health condition is prohibited.	
<input type="checkbox"/> Discrimination based on mental health condition is explicitly prohibited	Citations:
<input type="checkbox"/> Discrimination based on mental health condition is explicitly allowed	Citations:
<input type="checkbox"/> No mention of protection from discrimination based on mental health	

10.8 Is drug dependence classified as a disability and/or a mental health condition?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
Citations:	
10.9 Restrictions on other civil, social or cultural benefits (such as voting, freedom of association, access to housing, education, custody of children) for people who use opioids because of their drug use.	
<input type="checkbox"/> Restrictions on other rights and/or benefits are explicitly permitted	Citations:
<input type="checkbox"/> Restrictions on other rights and/or benefits are explicitly prohibited	Citations:
<input type="checkbox"/> No mention of restrictions on other rights and/or benefits because of drug use	

Hints from Malika

1. Before starting to score, skim every document from the beginning to end. You may find a lot of useful information for multiple items.
2. Re-read each item twice before you start to answer it, to make sure you understand what is being asked.
3. Begin each item by reviewing the national consultant's attachments. Check the attachments carefully – you may find that some attachments listed by the consultant do not relate to the item in question and/or that attachments to other items may have important information for the item in question.
4. Do not forget to put the page number and section title of each source along with its citation.
5. Print out all documents that are related to the substitution therapy. You will have a lot of detailed questions on this issue!
6. The actual scoring will take two or three times longer than you think it will.

This work is not boring! Enjoy it ☺

ANNEX C. GENERAL KEY INFORMANT INTERVIEW GUIDE

Name of Respondent: _____

Respondent's Title: _____

Respondent's Organization: _____

Date and Time of Interview: _____

Location of Interview: _____

General Questions (all respondents)

1. **How would you rate the level of HIV/AIDS policy development in Ukraine?**
 - a. Very good
 - b. Good
 - c. Moderate
 - d. Insufficient
 - e. Don't know/won't say

2. **How would you rate the level of HIV/AIDS policy implementation in Ukraine?**
 - a. Very good
 - b. Good
 - c. Moderate
 - d. Insufficient
 - e. Don't know/won't say

3. **Which type of organization or entity, in your opinion, has the most influence over HIV policy processes?**
 - a. Political sector (Parliament, governors)
 - b. Government sector (ministries and services)
 - c. Commercial sector (for-profit, corporations)
 - d. Professional associations
 - e. National NGOs
 - f. International organizations
 - g. Other _____
 - h. Don't know/won't say

4. **Is there a coordination authority for the national response to HIV at the national level? How efficiently is it functioning?**

5. Are there coordination authorities for the response to HIV at the regional level? How efficiently are they functioning?

6. In your opinion, is there adequate and substantive involvement of different sectors in HIV policy development?

- a. Yes
- b. No
- c. Don't know/won't say

Please explain your response to this question, and provide an example.

7. In your opinion, how do political factors at different levels facilitate or hinder the process of implementing the new HIV law?

8. What are the key priorities in HIV/AIDS policy development and policy implementation, in your opinion?

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