

*HIV/AIDS treatment and care
in Ukraine*

Evaluation report
April 2013



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HIV/AIDS treatment and care in Ukraine

Evaluation report

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in September 2012**

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Thematic Area: HIV/AIDS treatment and care

1. Scope of programs and activities

Antiretroviral therapy (ART) is the core of HIV/AIDS treatment and care. Timely provision of ART to people living with HIV (PLHIV) saves lives, and prevents the development of opportunistic infections, including active tuberculosis. ART is also an effective intervention in prevention of sexual transmission of HIV in discordant couples.

An evaluation of HIV/AIDS treatment and care was performed from the perspective of the WHO/UNAIDS Treatment 2.0 Framework (1) which indicates 5 priority work areas: Optimize Drug Regimens; Provide Access to Point-of-Care Diagnostics; Reduce Costs; Adapt Delivery Systems; Mobilize Communities.

In addition, HIV testing practices were evaluated as an entry point for HIV treatment and care.

Finally, the implementation of HIV/AIDS treatment and care services was reviewed with regard to sustainability, and compliance with human rights.

2. Strengths and Achievements

Table #1: Major expected results, targets and main achievements

Major expected results 2009 - 2013	Targets and Main Achievements
NAP 2009 - 2013	
To cover 60% of most-at-risk groups with HIV prevention services	Access to provider-initiated rapid HIV testing for key populations has increased through support of TGF grant. In 2011 58,5% of FSWs were tested for HIV and know the results; MSM – 37,8%, PWIDs – 35,7%
To provide ART to not less than 80% of patients who need it	Decentralization of ART services is on-going and new ART sites have been opened (in total 145 sites offer ART)
To decrease the mortality rate among people with HIV and AIDS by 10%	The proportion of patients in need who are receiving ART is 69,9% of in-need patients under medical supervision at AIDS centers, and 22% of the estimated number of PLHIV in need of ART
To ensure access to OST for 20 000 people who inject drugs	With support from TGF, the number of OST sites and number of OST clients is increasing, reaching 145 sites and more than 7000 clients
To ensure the development of a network of specialized services providing medical and social care for PLHIV	The first steps towards integration of services for PLHIV have taken place: A state service (Derzhsluzhba) on TB and HIV has been established; an informational document on opportunities for integration of services in Ukraine has been developed; 30 centers for integrated TB/HIV/PWID service delivery, situated on the premises of one of the vertical service facilities, have started operating in 27 regions

To prevent the development of HIV drug resistance	<p>A shift in financing of ART towards increasing governmental contribution and decreasing Global Fund financing was observed</p> <p>Regulatory documents on the optimization of services and collaboration between services are under development: a) on collaboration of the MOH with other Ministries on TB, HIV; b) an order of the MOH on continuum of care; c) an MOH order on use of OST; d) an order of the MOH on TB/HIV collaboration</p>
Other programs (outside NAP 2009 - 2013)	

3. Weaknesses and Challenges

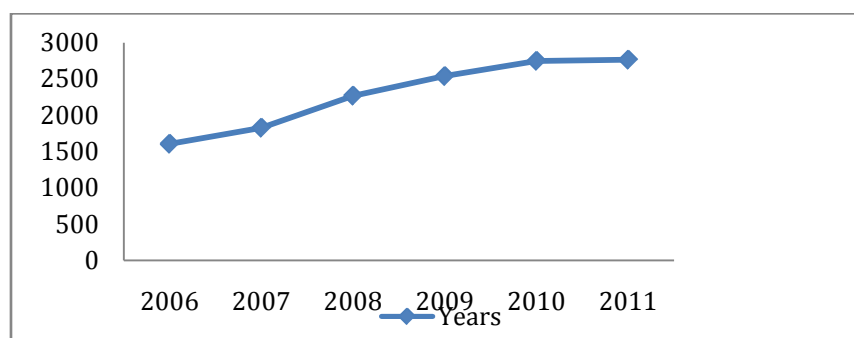
Priority area: HIV testing (*in addition to the findings addressed in the report of consultants evaluating HTC*)

Each region reports to the National AIDS Centre on aggregated data for confirmed HIV test results received from laboratories that performed HIV testing. The reasons for testing for HIV, and population groups tested, are reported according to codes.

Among populations reported as having tested for HIV (pregnant women, donors, PWID, sexual contacts of a person infected with HIV, etc), population groups diagnosed with viral hepatitis B and C are not included in the reporting form and are not offered provider-initiated HIV testing and counseling. Given that hepatitis C and B viral infections have the same modes of transmission as HIV, the risk of co-infection is high. This is confirmed by data from AIDS centers: Kiev City AIDS Center reported that among 420 PLHIV tested for viral hepatitis markers in 2011, 52% had HIV/HCV co-infection, 4% had HIV/HBV co-infection, 2% had 3 infections simultaneously (HIV/HCV/HBV), and 40% of PLHIV co-infected with viral hepatitis had markers of chronic hepatitis C and B which requires treatment. At Zhitomir AIDS Center, HCV a/b were identified in 56% PLHIV (802 of 1425 tested as of 01.09.2012). *Not offering HIV testing to patients at the sites where they were diagnosed with hepatitis B or hepatitis C viral infections (most likely in infectious disease facilities) is a missed opportunity for early HIV diagnosis and engagement in HIV treatment and care of co-infected patients.*

TB is the most frequent AIDS-related disease in PLHIV (60% of 18 751 PLHIV registered for HIV care at the AIDS centers had pulmonary or extra pulmonary TB as of 01.01.2012). The number of TB/HIV related deaths is increasing over time (please see graph 1). However, coverage of TB patients with HIV testing is not monitored by HIV or TB services at the national level. Despite the perception that all TB patients are tested for HIV, there is concern about low levels of HIV testing among TB patients. For example, in 2011, Zhitomir TB hospital provided HIV testing to only 52% (1074 out of 2063) of patients hospitalized for TB. No information was available on the number of TB patients with known HIV positive status prior to admission to the hospital, making accurate evaluation of coverage with HIV testing difficult. *This is another missed opportunity to identify TB patients with HIV who require immediate ART.*

Graph 1. Number of TB/HIV related deaths



The Ukrainian AIDS Center has suggested revising the existing reporting form # № 502 - 5/o, “Notification about HIV seromonitoring results,” to include disaggregated data on individuals tested for HIV because of clinical indications, and has added a line for “tested at TB services”. This raises concerns that the key indicator on diagnosed HIV-infection among TB patients will be difficult to monitor, as the number of tests in patients with active TB would be conflated with the number of HIV tests performed for other patients visiting a TB facility. This might result on a drawdown of already limited financial resources. It is important to allocate a separate code for TB patients tested for HIV in order to monitor HIV prevalence in patients with active TB. Other patients with AIDS-associated diseases tested for HIV can remain under code 113 (clinical indications). Prisoners have rather high HIV prevalence: in 2011, 10% (2463 out of 23 779 tested were found HIV-infected). Since HIV testing in the prison system is client-initiated, it is not possible to evaluate coverage of prison populations under a provider-initiated HIV testing system.

Priority area: Optimize Drug Regimens

Desk review of national guidelines and policy recommendations

The National Clinical Protocol on ART for adults and adolescents, revised in 2010, offers a flexible approach to ART 1st and 2nd line regimens. Practically all available ARVs are listed for 1st and 2nd line ART. For the 1st line: doctors can chose NRTI combinations TDF+FTC (or 3TC), ZDV+3TC, ABC+3TC, ddI+3TC, d4T+3TC, or 3 NRTIs; for the NNRTI component: EFV or NVP; several PIs are offered as well: LPV/r, ARV/r, FPV/r.

For 2nd line ART, besides all above-mentioned ARVs, other PIs included are SQV/r, DRV/r.

ETR and RAL are suggested for 3rd line ART.

As a result, unreasonably high numbers of different ART regimens are prescribed to PLHIV:

- 38 regimens for 1st line ART (32 124 PLHIV)
- 48 regimens for 2nd line ART (2097 PLHIV)

Such policies and practices are not aligned with a public health approach, and are costly given the limited budget of the country.

In the suggested criteria for ART initiation in adults, presented in the latest National Treatment Guidelines (pp. 27-28), there are inconsistencies between the text (first paragraph in section 5.2 “Indications for ART initiation”) and table 2 (“Indications for ART initiation in patients with chronic HIV-infection”); the suggested criteria conflate updated WHO recommendations (CD4 <350, pregnancy regardless of CD4, VL or clinical signs, HBV/HIV co-infection requiring HBV treatment, active TB) with outdated recommendations (AIDS-related illness or CD4<200 regardless of clinical signs, CD4 200-350 regardless of clinical signs, etc.), as well as recommendations taken from other sources (HIV-associated nephropathy, PLHIV above age of 50, introduction of HIV DR testing for treatment-naïve patients, etc.). The criteria for initiation of ART in HCV/HIV co-infected patients are not mentioned at all. This mixture of conflicting recommendations complicates guideline usage.

This protocol does not take into account the limited financial capacity of the country to provide ART for all who need it, and requires immediate revision.

Clinical protocols on ART for PWIDs, on paediatric HIV treatment and other clinical protocols, have not been revised since 2007, and have outdated recommendations on ART and management of patients with HIV.

Priority area 2: Point of HIV care, diagnostic and monitoring technologies

With support from the Global Fund grant, the International HIV/AIDS Alliance in Ukraine offers HIV rapid tests to key populations, including people who inject drugs (PWID), sex workers (SW) and street teenagers. HIV positive clients are referred to an AIDS Center. However no accompaniment is offered and no follow up is conducted to determine who accessed or did not access health care facilities; this indicates a broken link in the chain of services. The grant ends in 2013, which raises concerns about the sustainability of this service.

Enrolment in care entails client-initiated registration at an AIDS Center for life-long care and treatment. Coverage of enrolment in HIV care is not sufficient in Ukraine. Overall, fewer than 2/3 of all people diagnosed with HIV are enrolled in HIV care. In 2011, only 67% of newly diagnosed PLHIV in Ukraine were enrolled in HIV care (22793 out of 33781 diagnosed with HIV), in 2010 -63%, in 2009 – 55,8%. In addition, some PLHIV who registered for treatment and care are lost to follow up. At Zhitomir AIDS Center, out of 2179 PLHIV registered for care, 1500 were seen for care in 2011, and 600 (27,5%) who did not attend care services, were not followed up by health care workers from the AIDS Center. This indicates another break in services, which can contribute to further HIV transmission, as these PLHIV do not get ART and support for safe behaviour.

In the absence of a proactive approach from AIDS Centers to support enrolment in care, it is mainly those PLHIV who feel ill who will seek care. In 2011, at the Kiev AIDS Center, 56% (585 out of 1050) of people who were diagnosed with HIV and enrolled in care had WHO clinical stages 3 and 4, indicating late presentation and immediate need for ART. The situation worsened in 2012. In the first 6 months of 2012, 80% (!) of patients diagnosed with HIV and enrolled in care (343 of 513) had WHO clinical stages 3 and 4.

Although clinical protocols recommend laboratory monitoring of CD4 counts every 3-6 months prior to initiation of ART, access to CD4 count services before initiation of treatment is limited due to insufficient numbers of CD4 tests procured. According to the Derzhsluzhba information, the government covers the cost of CD4 tests before initiation of ART for about 18% of PLHIV registered in care. Those PLHIV who have access to CD4 services before ART initiation have a CD4 count below the threshold. In Zhitomir, among patients who accessed CD4 count services, 40% PLHIV (131 of 328) had counts <350. This is another indication of late presentation and late initiation of ART.

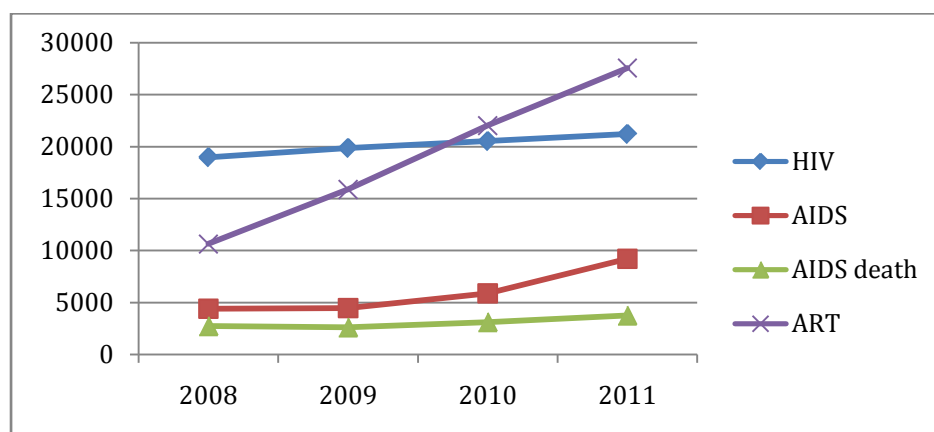
Viral Load tests are also procured in limited amounts (about 35% of need) and are available only for PLHIV on ART, in spite of the recommendation of the National Clinical Protocol to perform VL testing every 6 months prior to initiation of treatment.

Lack of laboratory monitoring of PLHIV to support timely initiation of treatment leads to late initiation of ART in the course of HIV infection. ART initiation is based on clinical criteria rather than the WHO-recommended threshold of $CD4 \leq 350$ cells/mm³.

ART access and coverage

National data indicates a significant increase in the number of PLHIV receiving ART over the last 4 years. However the scale is still not sufficient to make an impact on the epidemic. The number of AIDS cases as well as the number of AIDS-related deaths continues to grow. Please see Graph 2 below.

Graph 2. HIV-infection, AIDS, AIDS-related deaths and ART: 2008-2011



National ART need and ART coverage are calculated based on the limited financial resources allocated by the Ministry of Finance and the Global Fund for procurement of antiretroviral drugs (ARVs), rather than on actual or estimated need. According to the State Service (Derzhsluzhba), the number of those in need of ART on 01.08.2012 was 42,742 PLHIV, of whom 34,323 received treatment (80,3% coverage) as of September 2012. In this manner, ART coverage appears quite high. However, the estimated national ART need for 2012 was 120,000 PLHIV (Information bulletin N 38), and thus estimated ART coverage is only 28%.

Two site visits revealed very limited access to and low coverage with ART. At the Kiev City AIDS Center, out of 430 PLHIV registered for care during the first 6 months of 2012, 343 (89%!) already had clinical symptoms of progressive HIV infection, classified as WHO stages 3 and 4, indicating immediate need for life-saving ART. However only 98 (28,5%) of these people initiated ART. Due to the lack of access to CD4 count services, which are recommended as a criterion for initiation of ART, the actual need for ART has not been not recognised. In 2011, out of 1050 PLHIV registered for care, 585 (55,7%) had advanced HIV disease (stages 3 and 4), but ART was initiated by only 189 (32%) of them. Although in 2011 ART was initiated by 443 PLHIV, 254 of them were on waiting lists from previous years. Sixty-six PLHIV registered for care died in 2011 before initiating ART, due to the long waiting list.

At the Zhitomir AIDS Center, out of 458 PLHIV registered for care in 2011, CD4 tests were performed for 328 (71%), and the number of PLHIV with a CD4 count of ≤ 350 cells/mm³ was 131 (40%), indicating the immediate need for ART. However ART was prescribed to only 23 of them (17%).

Under conditions in which ARV medications are in short supply, physicians must make difficult decisions in selecting PLHIV for treatment. Injecting drug use, expected poor adherence, etc. are criteria used by physicians for not prescribing ART. Often delaying prescription of ART for eligible PLHIV is due to an extensive health evaluation performed by referral to “narrow” specialists, and delays caused by waiting for laboratory test results. Usually a decision on ART initiation and selection of PLHIV for treatment is undertaken by a special commission composed of physicians and administrative staff, which considers each case individually.

Contrary to the National Clinical Protocol on ART in adults and adolescents, which recommends starting ART for all patients with active TB, too few PLHIV with active TB receive ART. According to data from Derzhsluzhba, as of 01.08.2012, out of 4883 PLHIV with TB, 3453 (71%) received ARV therapy. This calculation is again based on a “planned” number of TB patients for ART, according to available resources. A site visit to the TB hospital in Zhitomir revealed that the level of ART prescription may be significantly lower. Out of 21 PLHIV with active TB hospitalized at the time of the assessment, only 4 were receiving ART. ARV medications are given by AIDS Center physicians directly to patients and not to the medical personnel of TB hospitals, indicating a lack of collaboration between TB and HIV services. The usual practice is to initiate ART after discharge from a TB hospital. Delay of ART initiation in PLHIV with active tuberculosis until they are discharged increases mortality rate among TB/HIV patients. In 2011, at the TB hospital of Zhitomir, 31 PLHIV with active TB died; in the first 8 months of 2012, 24 PLHIV with TB died. There was no information on whether these people were receiving ART. In the Kiev City AIDS Center, in the first 6 months 2012, out of 430 PLHIV tested

for TB, 285 (66%) were identified with active TB, including 44 relapsed and 43 MDR forms. Co-trimoxazole was prescribed to all TB patients, but life-saving ART was prescribed to only 38 (13%) of PLHIV with active TB out of 285 eligible! There is an obvious discrepancy between national and local data, which can primarily be explained by insufficient planning of ART for PLHIV with active TB at the national level.

Priority area 3: Reduce cost

Effective and sustainable procurement and supply systems for HIV medicines and commodities provides a high leverage opportunity to improve treatment and care services, and reduce cost. Procurement and supply of HIV treatment and care commodities has been reviewed in Ukraine several times over the past decade by different stakeholders and international partners. A number of issues that cut across all functional areas of procurement and supply management (PSM) hinder transparent, effective and efficient practices, and may negatively affect implementation and scale up of Ukraine's programme for HIV/AIDS control. These include the following:

- There has been little sustained commitment to reforming current processes and insufficient action to follow previous recommendations to strengthen systems.
- In several instances, there is no clear separation of responsibilities across different PSM functions, to ensure equitable, broad-based decision-making and avoid disproportionate influence or conflict of interest by any individual or organization regarding PSM decisions. Lack of a clear policy and enforcement measures to avoid any such conflict of interest in all aspects of PSM perpetuates the appearance of impropriety, and increases the potential for corruption.
- There are also overlapping mandates and functions among key structures and departments involved in PSM, resulting in fragmentation and inefficiency in regulatory and other processes.
- The legal and regulatory systems are strictly defined, but they currently do not help to increase transparency, ensure standardized, internationally accepted approaches to PSM, or maintain consistent availability and appropriate use of medicines of assured quality at a reasonable cost.

The system for selection of ARVs and other HIV-related commodities for state procurement and distribution has incorporated some desirable elements of transparency, including the use of standard treatment regimens, recommended by WHO. However, non-standard ART regimens are common, resulting in inefficient use of resources. One recently procured medicine (abacavir) consumed 1/3 of TGF procurement budget for the current year.

The annual process of product quantification (forecasting), which is based primarily on consumption and available budget, may take place 12 to 18 months before delivery to sites. This does not accommodate changes in patient load and ART regimens, and does not address the need for calculation of buffer stock, or lead times. Capacity in quantification is insufficient to meet needs, particularly at the oblast level, and especially taking the wide diversity of treatment regimens into consideration (38 for first-line and 48 for second-line treatment currently used).

One of the biggest impediments to effective, transparent procurement of quality medicines and other commodities for HIV/AIDS, is the lack of a well-written procurement law, which would provide sufficient product specification and quality assurance, and supplier selection criteria that include evaluation of past performance. Current processes are guided by a myriad of decrees, orders, and other regulations, and the resulting processes lack transparency. Drug product specifications in tender documentation are not sufficient to guarantee the quality of procured supplies. Inclusion of WHO prequalified products (with known price and assured quality) into tender requirements has been recommended to the government several times. However, this recommendation has not been implemented. In the absence of a comprehensive procurement law with provisions for medicines as a special commodity, some suppliers have exercised undue influence in tender decisions through litigation or other means.

The cost of medicines and commodities is covered by 2 financial sources: the State budget and the Global Fund grant. A price comparison provides insight on possible avenues for cost reduction:

- Cost of CD4 tests: 18 USD per test from the State budget and 7 USD from TGF
- Cost of VL test: 45 Euro per test from the State budget and 35 Euro from TGF
- State spent 240 000 USD for procurement of HIVDR tests for 480 assays (500 USD per test!) while HIV drug resistance in naïve patients is <5% and WHO recommended ART regimens do not require HIVDR testing.

Supply chain management processes at the national level indicate that there is clear capacity in Ukraine to meet the needs of the HIV/AIDS programme. However, there is a difference in the level of service provided by the supplier serving the Global Fund program, and the one serving the government. Current regulations obscure the true cost of medicines and their distribution, by not allowing GOU budget line items to include services such as distribution. Because of this, local distribution costs must be part of the product price offered to the GOU, making it impossible to separate out and compare these costs.

To ensure that national-level information on stocks and consumption is of high-quality, each treatment site must have an appropriate stock control system that feeds into the wider system. The information should be used for planning activities, estimating demand, allocating resources, improving accountability, and monitoring program implementation. Currently, the pharmaceutical management information system (PMIS) is not at the required level and staff are generally overwhelmed by filling in and submitting multiple forms to different recipients on a regular basis, without actually using the data at site-level.

A comprehensive monitoring and evaluation (M&E) plan for HIV/AIDS PSM is not in place. Monitoring of current indicators is focused on financial and other aspects, and does not include PSM early warning indicators. The regularly collected PSM-related data are not used in a way that will achieve structural improvements of the system. This is a lost opportunity that should be rectified.

There is no system in place for regular price monitoring and evaluation; education in rational pharmacotherapy and pharmacovigilance reporting is weak.

Priority area 4: Adapt delivery system

HIV treatment and care are delivered across the country at 145 sites: 27 oblast level AIDS Centers, 15 city centers, infectious disease offices or “Trust Points” in provincial hospitals and out-patient polyclinics. There is concern regarding the ineffective use of human resources for service delivery at AIDS Centers. For example, the AIDS Center in Zhitomir has an unreasonably large number of staff. For 1500 PLHIV registered for care, the AIDS Center has:

- 18,5 positions for physicians
- 27 medical nurses
- 4 laboratory experts
- 13 laboratory technicians and psychologists

The eighteen and a half physicians' positions are occupied by 12 specialists, of whom only 2 are infectious disease experts who treat HIV patients. The large number of medical personnel in the AIDS Centers was also observed in 2007 (Vinnitsa) and appears to be more the rule than the exception. Human resources in HIV services are regulated by MOH Order # 33 from 23.02.2000, with an amendment on HIV services which was introduced on 12.03.2007. According to this amendment #52, human resources are calculated based on the following criteria: 1 physician per 1000 PLHIV or 1 per 300 HIV+ children, and all the other non-HIV specialists are calculated as 0.5 FTE per 100 000 population. This could have been understood to refer to any type of physician involved in provision of care to PLHIV, and may have allowed for poorly controlled human resource management. This approach has led to an excessive number of narrow experts who do not have enough patients at the AIDS Centers. For example, a dentist serves only 4 PLHIV during a day and provides fillings only at the Zhitomir AIDS Center. WHO recommendations, provided in 2007, regarding the need to revise policies on structure, resources and functions of the AIDS Centers have not been taken into consideration.

Cohort analysis at the national level indicates a good level of retention in ART: cohort 2010 (7282 PLHIV) – 82% on ART after 12 months; cohort 2009 (5791 PLHIV) – 78% on ART after 24 months of treatment, cohort 2008 (2801 PLHIV) – 76% on ART after 36 months. However, the high numbers of patients adhering to treatment represent only those PLHIV who were selected for ART. Limited access to antiretroviral drugs and lack of integration with OST services force physicians to choose patients for treatment. Anticipated adherence is among the major criteria for selection. *Data on ART in PLHIV who use drugs was not available so enrolment and retention in ART of drug users remains unknown.*

The usual practice of TB diagnosis in PLHIV assumes referral of PLHIV to territorial out-patient clinics for TB diagnosis, without follow up, rather than integration of TB diagnosis into AIDS Centers. However Ukraine has taken the first steps towards integration of TB/HIV services. When provided the opportunity to decide on the profile of employees, some AIDS Centers have employed TB experts. The Kiev City AIDS Center has a TB expert working 50% time, providing diagnosis and treatment of TB on-site and referring to the TB hospital, if required. However, this has not yet helped to increase access to ART for PLHIV with active TB, as in the first 6 months of 2012, only 38 (13%) PLHIV with active TB at the city AIDS center were prescribed ART out of 285 eligible, as mentioned above.

Lack of integrated services was indicated as a critical barrier in the WHO evaluation report in 2007. The new draft order, “Regulation of TB/HIV case management,” which is about to be endorsed, suggests limiting access to TB diagnostic services (to 25% of PLHIV registered for HIV care), thereby compromising access to TB diagnosis and treatment for PLHIV. The regulation does not encourage TB experts to collaborate with HIV experts on ART for TB/HIV patients, suggesting that ART should be prescribed and given to patients by an HIV expert (including for TB/HIV in-patients), and not in collaboration with TB expert. The document also does not suggest provision of opioid substitution therapy (OST) for TB/HIV coinfecting PWID patients. OST is essential treatment for IDUs, and without this component, the effectiveness of HIV and TB treatment for IDU is questionable. The document is not specific enough and does not suggest a mechanism for collaboration; it should be improved before release.

People who use drugs (PWUD) through injecting and non injecting, are a most at risk population group for HIV, viral hepatitis, and TB. Data indicates that in 2011, among 7290 PWUD who received treatment of drug dependency in Kiev, 81,5% had HIV infection including full-blown AIDS, 55% had viral hepatitis, and 14% had TB. However, there are no integrated services at the city narcological hospital. Hospitalised PWUD are offered HIV testing only if they have clinical symptoms of an AIDS-associated disease. If HIV positive, a patient is referred to the city AIDS Center after discharge. The hospital does not have a policy on management and monitoring of co-conditions or co-infections, and provides only fragmented services.

Opioid Substitution Therapy (OST) is a new project financed by the Global Fund. OST is becoming available in medical institutions at a growing number of sites across the country. At the time of evaluation, 7094 PWUD were on OST, mostly receiving methadone, 3050 (43%) were HIV infected, of whom 1107 were receiving ART. Unfortunately OST is not available in TB hospitals. A narcologist interviewed acknowledged that there is an increased risk of PWUD with TB or TB/HIV being refused hospitalisation, or of leaving the hospital in the absence of OST. Lack of integration of services, and the resulting incorrect treatment or non-treatment of TB and HIV, contribute to high mortality rates among TB/HIV and TB patients.

HIV treatment in prisons is entirely financed by the Global Fund grant and is therefore not sustainable. After 2015, donor support of the HIV programme is not planned. This is likely to impact retention in ART for inmates and those discharged, if the government does not increase financing for the ART programme and does not include inmates in the pool of those who need ART.

Priority area 5: Mobilize communities

This area has not been addressed, because it has been covered by other experts.

4. Key Bottlenecks and Solutions

4.1 National recommendations are not aligned with WHO recommendations, context of the HIV epidemic and available resources

HIV testing policy and practice should focus primarily on reaching population groups that are at risk of HIV, including people diagnosed with viral hepatitis B and C and patients with active tuberculosis. Monitoring of provider-initiated HIV testing coverage is an important indicator of programme effectiveness.

National clinical protocols on patient evaluation and ART for adults and adolescents should be revised in accordance with the WHO 2010 recommendations for resource-limited settings. The number of ART regimens for 1st and 2nd line should be limited to 2 per line; expensive testing for HIV DR should not be recommended for Ukraine, as it cannot be justified from either a technical point of view (HIV DR is below 5% of the population), or from a financial perspective.

There is a need to revise other clinical protocols in accordance with WHO updated recommendations, including paediatric HIV treatment, prevention of HIV mother-to-child transmission, and management of TB/HIV co-infected persons.

4.2 Lack of financial resources for antiretroviral drugs and diagnostics

Lack of financial resources to cover all PLHIV who need ART and laboratory monitoring (CD4 and Viral Load), is among the major bottlenecks for implementing treatment programmes. Allocation of financial resources within the HIV programme should focus mainly on expected outcomes. Decreased mortality and decreased number of AIDS cases are among the major outcomes in evaluation of national AIDS programme effectiveness. These outcomes can be achieved only with a significant increase of coverage with ART. Evidence for effectiveness of ART as a prevention intervention is a strong argument for scale up of ART, as it can have an impact on the number of new HIV cases. Thus, allocating financial resources for significant expansion of ART should be a priority, compared with other components of the national HIV programme.

To reduce the cost of HIV treatment programmes, the major focus should be on minimizing the number of ART regimens, as per WHO recommendations; to that end, a price reduction strategy should be applied. The country should revise its policy regarding procurement of HIV DR tests. Not procuring these tests is another money saving option.

Reallocation of available financial resources away from financing the excessive number of personnel in AIDS centers, and towards procurement of life-saving medications, is another option to consider.

A platform for collaboration between the MOH and Ministry of Finance should be established for discussion of the HIV programme budget. International financial support should be considered in cases where the government cannot commit financial resources to the ART programme.

4.3 Inadequate procurement and supply management of ARVs and commodities

Deficiencies in all areas of procurement and supply management indicate that the existing PSM system does not meet current internationally recognized standards. There is a concern among health professionals and patients regarding the quality of procured and distributed medicines and diagnostics, the unpredictability of the supply of medicines needed for long-term treatment of HIV/AIDS, and the risk of drug resistance in case of treatment interruption—a serious public health hazard.

The lack of integration between distribution, procurement and finance makes it difficult to set priorities in product release. Supply replenishment that takes place only once a year provides very limited flexibility for stock re-adjustments based on patient needs or changed regimens. This can result in continued prescription of regimens that are no longer suitable, due to stock limitations.

4.4 Insufficient coverage of enrollment and retention in HIV care and ART

PLHIV are lost to follow-up at every stage of HIV care: Not all PLHIV register for HIV care; not all who register for HIV care once, come for regular check ups or are seen at least once a year; not all who access care regularly and are eligible for ART have access to ART; not all who start ART continue it. As a result, only about half of PLHIV known to the health system are enrolled in care and treatment services. For infectious disease like HIV, such inadequate coverage can contribute to further dissemination of HIV.

There is a need to revise existing mechanisms of collaboration with civil society organizations and other state social services, in order to ensure regular contacts and support for PLHIV to receive care and life-saving therapy.

Planning of ARVs, CD4 and VL tests should no longer be based on the retrospective numbers of PLHIV in need of ART from previous years, but should be prospective and based on the estimated increasing need for ART. The number of PLHIV with CD4 count ≤ 350 at time of diagnosis, number of PLHIV diagnosed with TB, or the number diagnosed with hepatitis B and hepatitis C, are informative proxy indicators which should be taken into consideration in prospective planning for procurement of ARVs and laboratory tests.

4.5 Lack of integrated services

Poorly integrated services for PLHIV result in fragmented services that do not address the major health issues of patients. Newly developed normative regulations on TB/HIV services should include greater comprehensive integration of services. They should include access to OST for TB/HIV and TB drug-dependent in-patients. They should not limit access of PLHIV to TB diagnosis and treatment, and should be more specific in suggesting mechanisms for better collaboration. TB experts in hospitals should work in close collaboration with HIV experts, and should discuss, initiate and monitor ART in patients receiving TB treatment. ARVs from AIDS centers should be provided to the medical personnel of TB hospitals, rather than exclusively provided directly from AIDS Centers to patients. The regulations should support integration of services on the premises of narcological facilities, in order to ensure HIV and/or TB diagnosis, management and monitoring of drug dependent patients. Monitoring of data on services for TB/HIV/Drug dependent patients should be introduced into TB, HIV and narcological services. It is important to meaningfully involve PLHIV in the process of development of new regulations on integration of the services they need.

4.6 Lack of management and coordination between national and regional levels

Lack of coordination between central and regional mechanisms in the technical management and financing of AIDS Centers leads to ineffective use of financial and human resources. Services are delivered by a network of regional AIDS Centers that are technically and legally independent of the national AIDS Center called "Ukrainian AIDS Center". Regional AIDS Centers are funded and supported by local budgets and have resources for excessive recruitment of personnel. The MOH has very limited resources for procurement of the ARV drugs and laboratory tests which it distributes from the national to the regional level. The Ukrainian AIDS Center provides methodological supervision of the services, but has limited power to introduce new approaches to service delivery. In order to introduce new forms or approaches to service delivery, which, in many cases, requires additional resources or structural changes, the Ukrainian AIDS Center must seek support from local health administrations and coordinate its efforts with the State Services at the national level. The Ukrainian AIDS Center can suggest changes to the Order of the MOH on staffing, but cannot regulate human resource issues directly. Lack of clarity regarding the distribution of tasks between the national AIDS Center and the State Services contributes to the issue as well. There is a need to develop a new Human Resource Strategy for HIV services, taking into consideration health care reform, integration of services, and revised roles, responsibilities and subordination functions.

5. Cross cutting issues

5.1. Sustainability and access to services

Sustainability of services, particularly in the ART programme, is a major concern. The Global Fund grant is coming to an end, and 10020 PLHIV receiving ART financed by TGF will have to be taken on by the state for continued treatment and care. With the current lack of financial resources and low coverage of ART, the capacity of the state to significantly scale up ART is questionable, if resources are not raised.

Sustainability of other important projects funded through TGF is also uncertain. Sustained HIV rapid testing among key populations, as well as scale up and integration of OST, are evidence-based initiatives that are under threat of discontinuation.

With limited availability of ARV drugs, physicians must make difficult decisions regarding selection of PLHIV for ART. Active injecting drug users, whose potential adherence to ARV therapy is questioned by health care professionals, are often not prescribed ART, and are thus discriminated against.

5.2. Human rights

Ukraine has adopted a comprehensive framework of international human rights instruments and standards for the promotion and protection of the fundamental rights of humans, including the right to health. Ukraine has endorsed national laws, policies and programmes related to health, many of which reflect international human rights instruments, including the National AIDS Law (2010) and the National AIDS Programme 2009-2013—the strategy to achieve universal access.

Despite positive steps towards strengthening legislative provisions for equal access to HIV treatment and care, serious discrepancies prevail in implementation. These are most evident in the lack of access to ARV medicines and associated laboratory monitoring for those who need it, which contravenes the fundamental human right to health, the constitutional right of all Ukrainians to health care free of charge (Constitution of Ukraine 1996, Art 49) and the right to free access to ART and treatment of opportunistic infections (National AIDS Law Art 15).

Limited coverage of adequate testing, counseling and referral services, and periodic shortages of ARV medicines and commodities, result in lack of guaranteed access to and retention in ART for all those who are eligible. In addition, the lack of access to CD4 and VL tests presents barriers to timely enrolment for people who have been diagnosed with HIV. Consequently, many people initiate ART late in the course of the disease and are thus deprived of the optimal clinical benefits of ART.

Continuing poor integration of services for key populations at risk of HIV and opportunistic infections, particularly PWID—who not only constitute the population most at risk of HIV in Ukraine, but are also at increased risk of active TB and hepatitis B and C—contributes to unequal access to life-saving services for those who need them most.

6. Conclusions and Recommendations

6.1 Conclusions

In spite of efforts and progress in increasing financial allocations from the government, and the increased number of PLHIV who receive life-saving ART, the treatment programme cannot yet be deemed successful. The level of treatment coverage is very low, ART cannot yet be prescribed for prevention purposes (regardless of CD4 count in HIV-serodiscordant couples for prevention of sexual transmission). Hence, an increase in the number of PLHIV on ART does not have an impact on the epidemic curve yet in particular on the number of AIDS cases, AIDS-related deaths and new HIV cases (see graph 2 above).

Political commitment to prioritize financing for ART is an essential prerequisite for successful and strategic use of ART as a life-saving therapy and as an evidence-based prevention intervention—which will ultimately have an impact on the curve of the epidemic.

Early HIV diagnosis, early ART initiation and retention in ART of all those who need it, should become the goal of the HIV programme at all levels of planning and implementation. To support successful implementation, essential changes should be introduced at the health system level. These include integration of TB/HIV/PWID services, human resource strategy revision, revision of roles and responsibilities and development of clear mechanisms of coordination between national and regional AIDS Centers, and between local administrations and state services. This will allow for better use of available resources and reallocation of funds for provision of life-saving ART.

Involvement of non-governmental patient-based organizations in case management and supportive services for PLHIV (linking of HIV-positive individuals to AIDS Centers, follow-up for regular health check-ups, support for adherence) is a successful intervention for increasing enrolment and sustaining retention in HIV care and ART services.

Evaluation of health system performance with regards to HIV/AIDS should be based on coverage indicators, keeping the key goals in mind: early HIV diagnosis, early ART initiation and retention in ART for all who need it. NAP targets and indicators are not articulated concisely enough to make it possible to assess achievements.

To conclude, limited access to HIV treatment and care violates the internationally established fundamental human right to health and health care, to which Ukraine has committed. Hence, all recommendations put forward in this assessment should be considered guidelines to achieve equal rights to life-saving HIV treatment and care for all Ukrainians.

6.2 Recommendations

Table #2: Main bottlenecks, recommendations and expected results

Main bottleneck (prioritized)	Main recommendation	Expected result
1. National recommendations are not aligned with WHO recommendations, context of the HIV epidemic and available resources	<p>To revise the Clinical Protocol on Patient Evaluation and ART for Adults and Adolescents in accordance with WHO 2010 recommendations for resource-limited settings</p> <p>To update other clinical protocols, including on Management of HIV/TB co-infected patients, Management of hepatitis B/HIV co-infected patients, Prevention of HIV mother-to-child transmission, and Pediatric HIV treatment.</p>	<p>Revised protocol and a reduced number of regimens to a total of 2 each for 1st and 2nd line ART; this would save financial resources and allow increased coverage of ART</p> <p>Treatment of PLHIV will be performed in accordance with international standards, all TB/HIV patients will access ART, number of AIDS cases and AIDS related death cases will decrease</p>

	<p>To include recommendations on provider-initiated HIV testing for patients with diagnosed viral hepatitis B and hepatitis C in the HIV testing policy document and in table 1000</p> <p>To allocate a separate code for TB patients tested for HIV, as an important indicator for monitoring. Code 113 should include all other AIDS-associated diseases, except TB (policy document on HIV testing and table 1000)</p> <p>To include a number of population groups at risk of HIV in analysis of coverage with HIV testing, i.e. prisoners, patients with hepatitis B, hepatitis C, and with active TB.</p>	<p>Population groups at high risk of HIV will have better access to HIV testing and early HIV treatment and care</p> <p>Monitoring of HIV testing and HIV prevalence in the target population of patients with active TB will become possible (WHO STOP TB strategy indicator).</p>
2. Lack of financial resources for antiretroviral drugs and diagnostics	<p>To develop a strategy for price reduction of life-saving ART and essential laboratory tests that are needed for ART initiation and monitoring of treatment effectiveness (CD4 and viral load)</p> <p>Reduce the number of ART regimens for procurement to the minimum i.e. 2 regimens for 1st line and 2 regimens for 2nd line</p> <p>Stop procurement of expensive HIV DR tests, as these are unnecessary due to low HIV DR prevalence, and develop a clear strategy for ART regimen switching as recommended by WHO</p>	<p>Initiation of ART in accordance with recent WHO recommendations (based on CD4 count)</p> <p>Increased coverage of ART for those who need it</p> <p>Release of resources for procurement of ARVs, CD4 tests, increased coverage with ART</p>
	<p>Establish better mechanisms of collaboration between MOH and the Ministry of Finance for advocacy on resource allocation for ART</p> <p>Request continuation of financial support from TGF to cover the gap in ART</p>	<p>Increased state financial resources for ART</p> <p>No gap in financing the ART programme</p>
3. Inadequate procurement and supply management of ARVs and commodities	<p>To review the National Law on Procurement section on medicinal products and medical goods procurement</p> <p>To explore opportunities to delegate procurement of ARVs and diagnostics to the Ukrainian AIDS Center</p>	<p>Simplified mechanisms for procurement of medicinal products and allow more flexibility in planning based on need and demand</p> <p>Improved process of planning, procurement, and supply of ARV and diagnostics to the regional AIDS Centres</p>

4. Insufficient coverage of enrollment and retention in HIV care and ART	<p>To change planning for state procurement of ARVs and CD4 tests from retrospective to prospective, based on direct and proxy indicators of ART need</p> <p>To integrate social services (non-governmental or governmental) into the AIDS Centers</p>	<p>Increased coverage of PLHIV with HIV care Increased coverage of PLHIV on ART</p> <p>Decreased number of PLHIV lost to follow up</p>
5. Lack of integrated services	<p>Revise the draft document on TB/HIV collaborative services ensuring that:</p> <ul style="list-style-type: none"> a) narcological services are included, b) access to OST at TB hospitals for TB/HIV and TB drug dependent patients is ensured c) TB and HIV experts are in charge of treatment of TB/HIV patients and ARVs are transferred to medical personnel at TB hospitals d) roles and responsibilities for diagnosis and management of patients with co-conditions of TB, HIV and narcological services are clear 	<p>Timely initiation of ART for TB/HIV co-infected patients</p> <p>Higher retention in TB treatment in hospitals due to access to OST and thus decreased risk of run-away, interruption of treatment and development of MDR TB</p> <p>Improved access of drug-dependant people to services for HIV and TB</p>
6. Lack of management and coordination between national and regional levels	<p>To revise functions, tasks, distribution and coordination among MOH, Derzhsluzhba, the Ukrainian AIDS Center, regional health administrations and regional AIDS Centers</p> <p>To revise regulations on financing of AIDS Centers to allow the more efficient use of financial and human resources and increase available resources for procurement of life-saving ART</p>	<p>Release of resources which can be used for procurement of life-saving ART</p> <p>More efficient HIV programme planning, implementation and evaluation of programme planning based on outcomes indicators</p>

Action Plan

Table # : Action Plan for <thematic area>

Main recommendation	Recommended activities by responsible agency		
	Immediate term (3-6 months)	Short term (6-12 months)	Medium term (12-24 months)
1. Align national recommendations with the WHO recommendations, context of the HIV epidemic and available resources	a. For Ukrainian AIDS Center: to revise clinical protocol on Patient evaluation and ART for adults and adolescents in accordance with WHO 2010 recommendations for resource-limited settings	a. For Ukrainian AIDS Center: to update other clinical protocols, including on Management of HIV/TB co-infected patients, Management of hepatitis B/HIV co-infected patients, Prevention of HIV mother-to-child transmission, and Pediatric HIV treatment, in accordance with WHO 2010 recommendations	
	<p>b. For Ukrainian AIDS Center: to include recommendation on provider-initiated HIV testing for patients with diagnosed viral hepatitis B or hepatitis C in the HIV testing policy document and in table 1000</p> <p>c. For Ukrainian AIDS Center: To allocate a separate code for TB patients tested for HIV, as an important indicator for monitoring. Code 113 should include all other AIDS-associated diseases, except TB (policy document on HIV testing and table 1000)</p>		

<p>2. Ensure adequate financial resources for provision of ART and CD4 tests to all who need it, in accordance with WHO recommendations</p>	<p>a. For MOH: to stop procurement of HIV DR tests</p>	<p>a. For MOH: to plan and procure ARVs based on revised national clinical protocols, with the number of ART regimens reduced to the minimum</p>	<p>a. For MOH: establish better mechanisms of collaboration with the Ministry of Finance for advocacy on resource allocation for ART</p>
	<p>b. For MOH: to develop a strategy on price reduction for life-saving ART and essential laboratory tests needed for ART initiation and monitoring of effectiveness, according to WHO recommendations (CD4)</p>		<p>b. For MOH: in case of a financial gap between the need and available governmental resources, request continued financial support from TGF</p>
<p>3. Increase coverage of enrollment and retention in HIV care and ART</p>	<p>a. MOH, National and Regional AIDS Centers: to change planning for state procurement of ARV drugs and CD4 tests from retrospective to prospective, based on direct and proxy indicators of future ART need</p>	<p>a. For MOH, Ministry of Social Affairs and Derzhsluzhba: to discuss and develop regulations on integration of social services (governmental or non-governmental) into AIDS centers</p>	<p>a.</p>
<p>4. Integrate TB/HIV/Drug dependence treatment services</p>	<p>For Derzhsluzhba, Ukrainian AIDS Center and National narcological service: to revise the draft document on TB/HIV collaborative services ensuring that</p> <ul style="list-style-type: none"> a) narcological services are included, b) access to OST at TB hospitals for TB/HIV and TB drug dependent patients is ensured c) TB and HIV experts are in charge of treatment of TB/HIV patients and ARVs are transferred to medical personnel at TB hospitals d) roles and responsibilities for diagnosis and management of patients with co-conditions in TB, HIV and narcological services are clear 	<p>a. For Derzhsluzhba, Ukrainian AIDS Center and National narcological service: to introduce revised recommendations to the TB, HIV and drug dependence treatment services for implementation</p> <p>b. For MOH: Develop a new human resource strategy with a focus on integrated services, rather than strengthening the vertical AIDS structure with narrow experts</p>	<p>a. For Derzhsluzhba and Ukrainian AIDS Center and National narcological service: to monitor implementation of integrated service delivery</p>

<p>5. Improve management and coordination between national and regional levels</p>		<p>a. For MOH, Derzhsluzhba and local health administrations: revise functions, tasks distribution and coordination among MOH, Derzhsluzhba, the Ukrainian AIDS Center, regional health administrations and regional AIDS Centers,</p> <p>b. For MOH, Derzhsluzhba and local health administrations: revise regulations on financing of AIDS Centers to allow more efficient use of financial and human resources and increase available resources for procurement of life-saving ART</p>	
<p>6. Improve the procurement system of medicinal products and diagnostics for HIV programming</p>	<p>For Derzhsluzhba and the Ukrainian AIDS Center: to analyze the procurement procedures of ARVs and HIV related diagnostics at national and regional levels.</p>	<p>For MOH: update and/or develop procurement regulations and procedures to allow the Ukrainian AIDS Center to directly procure ARV and diagnostics for the National HIV Program.</p> <p>For Oblast Health Administrations: revise regulations and allocate financial recourse for procurement of HIV testing systems for key populations at the oblast level</p>	

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* **Note:** most information and data used as examples to describe the local situation were gathered from personal communications with staff working at the National and regional AIDS centers.

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