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ЗДОРОВ'Я

CONCEPT OF THE NATIONAL STRATEGY FOR HIV TESTING IN UKRAINE UNTIL 2030 (DRAFT)

KYIV – 2021

The concept of the National Strategy for HIV Testing in Ukraine until 2030 (draft) was prepared by the State Institution "Center for Public Health of the Ministry of Health of Ukraine" within the framework of the SILab project "Support for the systems of HIV surveillance and management/quality improvement for the laboratories of the Ministry of Health of Ukraine (MOH), enhancing the use of strategic information and building up public health potential" implemented by the Ministry of Health's Public Health Center, funded by the Centers for Disease Control and Prevention, USA (CDC), under the President's Emergency Plan for AIDS Relief (PEPFAR) by a team of authors:

Neduzhko Oleksandr, Martsynovska Violetta, Andrianova Iryna, Antonenko Zhanna, Bronova Vladyslava, Kvasnevska Yuliia, Kyslykh Olena

We express our sincere gratitude for the contribution to the creation of this document to specialists:

Kulchynska Roksolana, Azarskova Marianna, Sheiko Oleksandra, Hetman Larysa, Lehkostup Liudmyla, Semenenko Ihor, Haborets Tetiana, Hryshaieva Iryna, Maksymenok Olena Олена

LIST OF ABBREVIATIONS

ART	Antiretroviral therapy
IQA	Internal quality assessment
VL	Viral load (HIV)
EQA	External quality assessment
HCF	Health care facility
IBBS	Integrated biobehavioral study
IM	Instrumental methods
KP	Key populations at risk of HIV infection
PWID	People who inject drugs
PLHIV	People living with HIV
MC/MPOC	Mobile clinics/mobile points-of-care
NHSU	National Health Service of Ukraine
NGO	Nongovernmental organization
MGP	Medical guarantee program
HTS	HIV testing services
RES	Routine epidemiological surveillance
SEM	Seroepidemiological monitoring
SW	Sex workers
QMS	Quality Management System
TG	Transgender people
PHC	The State Institution “The Public Health Center of the Ministry of Health of Ukraine”
MSM	Men who have sex with men
RT	Rapid test
UNAIDS	Joint United Nations Program on HIV/AIDS
CDC	Centers for Disease Control and Prevention, USA
PEPFAR	President's Emergency Plan For AIDS Relief

INTRODUCTION

The Fast Track “90-90-90” goals set by the Joint United Nations Program on HIV/AIDS (UNAIDS) in 2014 were the starting point for monitoring and evaluating global efforts to combat the HIV epidemic ¹. In early 2021, most countries failed to meet these targets, but in recent years there has been a positive trend in all regions of the world to reduce the number of new HIV infections, except in Eastern Europe and Central Asia (EECA), where HIV incidence continues growing ².

Achieving the global Fast Track “95-95-95” targets by 2030 requires political commitment from countries to accelerate and innovate in the HIV / AIDS response, which will deliver a 95% reduction from the 2010 baseline in morbidity and mortality caused by HIV in the world. Ensuring the provision of effective HIV testing services is an essential component in achieving these goals by expanding access to HIV prevention, treatment, care and support.

Ukraine ranks one of the top places among the countries of the WHO European Region in terms of the number of HIV-positive people ³. The updated HIV/AIDS estimates ⁴ indicate that at the beginning of 2021, 257,548 [209,000 - 325,000] people living with HIV (PLHIV) lived in Ukraine, including 209,816 people in the territory controlled by Ukraine. According to the results obtained, in the forecast period, by 2025 inclusive, a slow increase in the estimated number of PLHIV is expected to reach 267 thousand people. Estimated HIV prevalence among adults aged 15 and over from 2021 to 2025 will remain unchanged at 0.7%.

¹ Fast-Track strategy to end the AIDS epidemic by 2030. <http://www.unaids.org/en/resources/campaigns/World-AIDS-Day-Report-2014>

² 2021 UNAIDS Global AIDS Update. <https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update>

³ ECDC and the WHO Regional Office for Europe. Annual HIV/AIDS Surveillance Reports – Access mode: <https://www.ecdc.europa.eu/en/all-topics-zhiv-infection-and-aidssurveillance-and-disease-data/annual-hiv-aids-surveillance-reports>

⁴ National Assessment of the HIV / AIDS Situation in Ukraine as of the Beginning of 2021 - Access mode: https://phc.org.ua/sites/default/files/users/user90/Natsionalna_otsinka_sytuatsyi_z_VIL_SNIDu_v_Ukraini_na_pochatok_2021.pdf

According to official statistics, as of January 1, 2021,⁵ there were 144,089 HIV-positive citizens of Ukraine (142,000 people aged 15 and older) under medical supervision in health care facilities (HCF) providing medical services to PLHIV. Taking into account the available data from the temporarily uncontrolled territories of Donetsk and Luhansk oblasts (oblasts are administrative regions of Ukraine) and the annexed Autonomous Republic of Crimea and the city of Sevastopol, the total number of PLHIV in Ukraine is about 177 thousand people (69% of the estimated number of PLHIV). As of the end of 2020, the ratio between estimated and actual data on the number of PLHIV was 1.47:1, almost a third of the estimated number of PLHIV in Ukraine were unaware of their HIV-positive status and / or were not under medical supervision in HCF.

Thus, it will be impossible to end the HIV epidemic in Ukraine without closing the gap in the number of PLHIV who know their status. This goal can only be achieved by ensuring an adequate level of HIV testing coverage and increasing the number of people who are aware of their HIV-positive status in order to involve them in antiretroviral therapy (ART) with an indeterminate level of HIV viral load in the blood (VL) <1000 RNA copies / ml.

This task remains difficult for Ukraine and is in fact a challenge in advancing the “95-95-95” targets for 2030, given that at the end of 2020 the gaps in meeting the targets for the estimated PLHIV 258,000 are:

- 26% (67.8 thousand) of PLHIV are unaware of their HIV-positive status;
- 33% (85.9 thousand) of PLHIV do not receive ART;
- 30% (83.6 thousand) of PLHIV did not reach a detectable level of VL <1000 RNA copies / ml.

⁵ Information bulletin "HIV infection in Ukraine", issue №52. State Institution "Public Health Center of the Ministry of Health of Ukraine" - Access mode: https://phc.org.ua/sites/default/files/users/user90/HIV_in_UA_52_2021.pdf

UNAIDS and WHO emphasize that the rapid spread of the COVID-19 pandemic caused by SARS-CoV-2 has created additional obstacles to achieving the goals of Fast-Track. This particularly affected the access of PLHIV to HIV services against the background of increasing inequality in the provision of these services by representatives of key populations and the financial deficit of the health budget during the COVID-19 pandemic⁶. At the 75th UN General Assembly in June 2021, all UN member states pledged to accelerate the integration of the HIV / AIDS response into strong and resilient health and social protection systems, and to ensure their recovery during and after the COVID-19 pandemic⁷.

Starting from March 2020, Ukraine has been affected by the crisis related to the COVID-19 pandemic. According to the main epidemic indicators, Ukraine remains one of the countries most affected by COVID-19 in the world. As of December 1, 2021, according to the Ministry of Health of Ukraine data, 3,450,341 cases of coronavirus disease were confirmed in the country, of which 86,532 were fatal⁸. Despite the introduced quarantine measures, it is still not possible to overcome the rapid spread of SARS-CoV-2 in the country. In order to quickly respond to changes in the epidemic situation within the framework of national security, in July 2021, the President of Ukraine approved measures to develop the public health system for the period until 2030⁹. Preventing the risks and consequences of cross-negative COVID-19 and socially significant diseases, including HIV, has been an important challenge for the health sector¹⁰.

⁶ <https://www.unaids.org/en/covid19>;

<https://www.who.int/news/item/15-07-2021-who-warns-that-hiv-infection-increases-risk-of-severe-and-critical-covid-19>

⁷ Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030. – Access mode : https://www.unaids.org/en/resources/documents/2021/2021_political-declaration-on-hiv-and-aids

⁸ <https://moz.gov.ua/article/news/operativna-informacija-pro-poshirennja-koronavirusnoi-infekcii-2019-cov19>

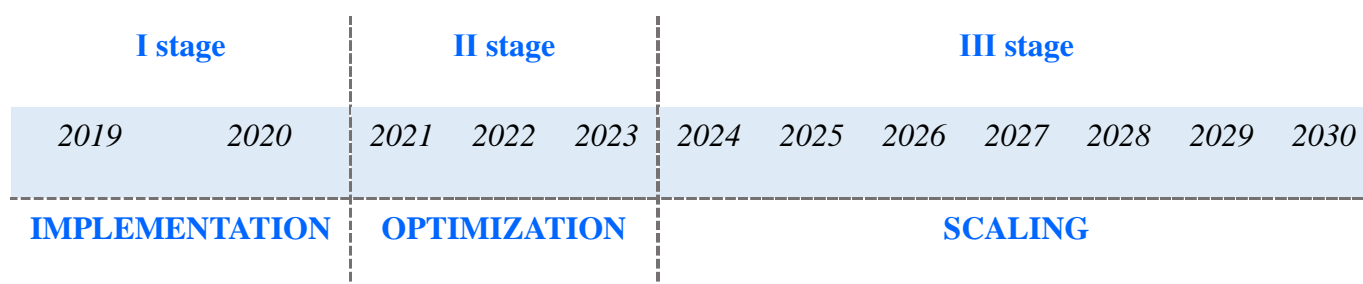
⁹ Decree of the President of Ukraine №369 / 2021 "On the decision of the National Security and Defense Council of Ukraine of July 30, 2021" - Access mode: <https://www.president.gov.ua/documents/3692021-39713>

¹⁰ Strategic Review of Crisis Response and Post-Crisis Recovery in Ukraine in the Context of the COVID-19 Pandemic. UN Development Crisis Coordination and Governance Programs in Ukraine - Access Mode:

To bring Ukraine closer to the global target indicators of progress in ending the HIV epidemic, first of all, the achievement of the most important first "95", on which the implementation of the remaining indicators actually depends, a new policy on the provision of HIV testing services is needed, focused on the epidemiological context in the conditions the COVID-19 pandemic and the use of modern approaches to the diagnosis of HIV infection, differentiated testing models to ensure fair and reliable access of key populations to HIV prevention, treatment, care and support services.

In 2018, at the initiative of the State Institution "The Public Health Center of the Ministry of Health of Ukraine" (PHC of the Ministry of Health) and the US Centers for Disease Control and Prevention (CDC), the National HIV Testing Strategy in Ukraine: 2019-2030 was developed ¹¹, aimed at achieving the goals of the "Political Declaration on HIV / AIDS issues: accelerating the pace towards intensifying the fight against HIV and ending the AIDS epidemic by 2030", approved by the UN General Assembly in June 2016, and the goals and objectives of the " Strategy for ensuring a sustainable response to the epidemic / AIDS for the period up to 2020 and an action plan for its implementation ", approved by the order of the Cabinet of Ministers of Ukraine dated March 22, 2017 No. 248-r.

The strategy identified three stages in the implementation of HIV testing services by 2030:



https://www.ua.undp.org/content/ukraine/uk/home/library/democratic_governance/strategic-review-of-response-to-the-crisis-and-post-crisis-recov.html

¹¹ National HIV Testing Strategy in Ukraine for 2019-2030. - Access mode: https://www.phc.org.ua/sites/default/files/uploads/files/Natsionalna_strategia_testuvannia_na_VIL_v_Ukraini_2019-2030.pdf

The National Strategy for HIV Testing in Ukraine: 2019-2030 requires harmonization with the new goals and objectives of the State Strategy in the field of counteracting HIV / AIDS, tuberculosis and viral hepatitis for the period up to 2030, approved by the order of the Cabinet of Ministers in 2019¹², updated WHO recommendations in HIV testing services¹³ and should consider measures that will ensure the availability of HIV testing services in the context of the COVID-19 pandemic.

Development and implementation of the “National Strategy for HIV Testing in Ukraine until 2030” is included in the Action Plan for 2021-2023 on the implementation of the National Strategy for Counteracting HIV / AIDS, Tuberculosis and Viral Hepatitis until 2030¹⁴.

It should be emphasized that the main to all regions and Ukraine as a whole is choosing a strategic mix of approaches for HIV testing services, based on evidence and available resources. Today in Ukraine such issues remain relevant: low efficiency and insufficient quality of HIV testing; lack of reliable data on the scope and outcome of HIV testing services, taking into account the characteristics of entry points and key populations most in need of such services; limiting epidemiological surveillance of new cases of HIV infection; the presence of a number of unresolved and unresolved cross-cutting issues, which will require a systemic reorganization of the provision of HIV testing services with a significant increase in the availability of this service and the introduction of strict control over the achievement of planned indicators.

Given the reform of the health care system, it is important for Ukraine to introduce new and effective models and approaches to HIV testing services using the

¹² National strategy in the field of counteracting HIV / AIDS, tuberculosis and viral hepatitis until 2030. - Access mode: <https://zakon.rada.gov.ua/laws/show/1415-2019-p#Text>

¹³ Consolidated guidelines on HIV testing services, 2019 – Access mode: <https://www.who.int/publications/i/item/978-92-4-155058-1>

¹⁴ <https://moz.gov.ua/uploads/ckeditor/Громадське%20обговорення/2020/10/21/План.pdf>

potential of both health care facilities, including primary care facilities and public organizations. At present, the current legislation of Ukraine does not regulate the issue of legalization of the provision of HIV testing services using rapid tests by persons without medical education (provided that they have appropriate training) and organizations that currently cannot have a license to practice medicine; introduction of new testing models (including self-testing).

In 2021, under the SILab project *"Support for the systems of HIV surveillance and management/quality improvement for the laboratories of the Ministry of Health of Ukraine (MOH), enhancing the use of strategic information and building up public health potential"* implemented by the Ministry of Health, funded by the Centers for Disease Control and Prevention (CDC), within the framework of the US President's Emergency Plan for AIDS Assistance (PEPFAR), the **Concept of the National Strategy for HIV Testing in Ukraine until 2030 (draft)** was prepared, which is the basis for updating the National Strategy for HIV Testing in Ukraine: 2019-2030 (2018) and is based on generally accepted global recommendations for improving HIV testing services, ensuring the results of quality assurance testing, improving epidemiological surveillance of HIV / AIDS, reducing stigma and discrimination in connection with HIV, and takes into account new policies to combat HIV / AIDS globally and nationally. Levels.

The main directions of the **Concept of the National Strategy for HIV Testing until 2030 (draft)** were identified and agreed at the meetings of the working group on improving epidemiological surveillance of infectious diseases in Ukraine, approved by the Public Health Center of the Ministry of Health dated April 15, 2019 №32-Agd, working meetings on monitoring the implementation of the National HIV Testing Strategy at the national and regional levels (September 03, 2021, September 13, 2021) and training on improving the effectiveness of the implementation of the HIV testing strategy for regional specialists (September 27-28, 2021).

CONCEPT OF THE NATIONAL HIV TESTING STRATEGY IN UKRAINE UNTIL 2030 (DRAFT)

Analysis of the situation with HIV testing for the period 2017¹⁵ – 2020

Given the data of routine epidemiological surveillance of HIV / AIDS (RES), integrated biobehavioral study (IBBS) and other research, Ukraine remains in the category of countries with a concentrated stage of the HIV epidemic. The most affected key populations for HIV infection (HIV) are people who inject drugs (PWID), sex workers for remuneration (SW), and men who have sex with men (MSM). Groups at high risk of HIV infection in the country also include people in prisons or other closed institutions, people whose gender identity does not match biological sex (TG), sexual partners of PLHIV and KP.

According to the IBBS, since 2013 the level of HIV prevalence among PWID has not changed and fluctuated between 21% - 23% with a slight decrease in 2020 to 20.3%¹⁶. According to the results of the IBBS in 2017 among SWs¹⁷ and MSM¹⁸ this index is 5.2% and 7.5%, respectively. According to the IBBS for 2019 the prevalence of HIV among convicts in Ukraine is 8.9%¹⁹. For the first time in 2020, IBBS was conducted among transgender people in Ukraine, as a result of which the prevalence of

¹⁵ 2017 is the base year for the analysis and calculation of indicators of the National Strategy for HIV Testing in Ukraine: 2019-2030 (2018).

¹⁶ Report on the results of the Integrated Biobehavioral Survey 2020 among people who inject drugs (2021) - Access mode: https://www.phc.org.ua/sites/default/files/users/user90/Results%20of%20IBBS_PWID%202020_ukr_online.pdf

¹⁷ Report on the results of biobehavioral research among sex workers in Ukraine - Access mode: https://aph.org.ua/wp-content/uploads/2015/06/RKS_Report__2019_web.pdf

¹⁸ Report on the results of biobehavioral research among men who have sex with men in Ukraine (2019) - Access mode: https://aph.org.ua/wp-content/uploads/2019/08/MSM_Report_22.10.2019_Sait.pdf

¹⁹ Analytical report on the results of the integrated biobehavioral study among convicts (2019) - Access mode: https://phc.org.ua/sites/default/files/users/user90/IBPD_prison_report.pdf

HIV among transgender women is 2%, among transgender men there are no positive results of HIV testing ²⁰.

According to the Sero-Epidemiological Monitoring (SEM), the annual number of HIV tests in Ukraine until 2020 was relatively stable - at the level of 2.3-2.5 million studies. In 2020, due to quarantine restrictions due to the COVID-19 epidemic, the activity of the population on HIV testing decreased compared to 2019 by almost 500 thousand and amounted to 1,960,769 people - 4.7% of the average annual permanent population (in 2017 - 5.7 %) ²¹.

In addition to the impact of measures related to the counteracting against COVID-19 on the scope of HIV testing services (HTS), quarantine measures, reorganization of hospitals and the involvement of infectious disease doctors who provided HIV services to help patients with COVID -19, etc.), it is impossible to exclude the impact of measures to implement health care financing reform, in particular the formation of packages of medical services, which include or not include HIV testing services, and tariffs for such services under the Medical Guarantee Program (MGP).

According to the SEM, the majority of HIV testing was carried out among donors and pregnant women: in 2020 - 52.8% (1,035,387 people), in 2017 - 54.7% (1,310,866 people). In six oblasts this indicator exceeded 70% (Volyn' (70.8%), Ivano-Frankivsk (93.1%), Kirovohrad (80.9%), Rivne (78.9%), Ternopil (75.1%) and Khmelnytskyi (74.4%), which indicates a relatively low coverage of VET in other groups. The share of surveyed persons belonging to KP from the total number of surveyed in 2020 in Ukraine was 13.5% against 20.4% in 2017. However, SEM data on KP testing are uninformative, as the survey uses test codes, which does not always allow tracking the affiliation of such people to a particular KP.

²⁰ Analytical Report. Biobehavioral Research among Transgender People (2021) - Access Mode: https://www.phc.org.ua/sites/default/files/users/user90/trans-IBBS-Ukraine_2020_all.pdf

²¹ Operational information on HIV / AIDS of the Public Health Center of the Ministry of Health of Ukraine - Access mode: <https://phc.org.ua/kontrol-zakhvoryuvan/vilnsnid/statistika-z-vilnsnidu/statistichni-dovidki-pro-vilnsnid>

The coverage of HIV testing of KP representatives according to the IBBS in 2017 was: PWID - 40.0%, SW - 59.8% and MSM - 45.0%. According to the goals of the State Strategy in the field of counteracting HIV / AIDS, tuberculosis and viral hepatitis until 2030, the coverage of KP representatives with comprehensive prevention services (including HIV testing) should be 70% in 2020, in 2025 - 80%, and in 2030 - 90% of the estimated number.

The results of the 2020 IBBS show that among the representatives of PWID in Ukraine, the “sticking point” in the HIV treatment cascade continues to be PWID awareness of their HIV-positive status - 64%, in 2017 this figure was 51.2%.

According to the 2020 IBBS, among transgender people who are the least studied KP, 56% of transgender women were tested for HIV. Among transgender men, this figure is even lower at only 38%. The obtained results of IBBS indicate the need to develop and implement sensitive to the needs of this KP interventions aimed at the availability of HTS and increase the motivation of TG to determine their own HIV status.

With the onset of the COVID-19 pandemic, the number of newly diagnosed HIV cases has dropped markedly. The growth rate of the registered incidence of HIV infection within the regions ranged from -10% to -50%. However, according to the SEM, the level of HIV infection in HIV testing (excluding donors and pregnant women) increased in 2020 to 2.19% against 1.96% in 2017, although the absolute number of detected cases of HIV infection is slightly lower (20 305 people against 21,315 people respectively). The situation with the late diagnosis of HIV persists.

In 2020, more than half of HIV infections were registered in the late stages of the disease: 54.5% of people with newly diagnosed HIV infection at the time of taking under medical supervision/control had a CD4 level of ≤ 350 cells / μL (in 2017 - 58.0%).

Among the key indicators of success in HTS are the increase in HIV testing using RTs (particularly in HSF), as well as the gradual spread of self-testing for HIV. In 2020, the percentage of people who were examined with the RT was 36.4% (713,566 people), which is significantly higher than in 2017 (20.1% - 481,541 people). Excluding donors and pregnant women, the percentage of those tested with RT from the total number of people tested for HIV increased from 43.3% to 58.2%, respectively. According to the results of 2020, the minimum use of RTs (10%) was observed in Volyn' (9.9%), Zakarpattia (6.0%), Ivano-Frankivsk (0.14%) and Khmelnytskyi (4.12%) oblasts.

The effectiveness of HTS with the use of RT (except for donors and pregnant women) in 2020 was 1.9%, which exceeded the effectiveness of the use of instrumental methods (IM) - 1.3%. It should be noted that in 2017 the opposite situation was observed: the percentage of HIV-positive results with the use of RT was 1.2% against 2.5% with the use of IM. Regarding the structure of all positive results, the vast majority (except donors and pregnant women) were found when using RTs (63.7%), while in 2017 the majority of HIV-positive people were found when testing using IM (72.8%).

According to the results of SEM in 2020 in some areas no positive results were obtained in the use of RT, or accounting and reporting on the use of RT was not carried out in full, which significantly limits the data of SEM. Thus, the report of Chernivtsi oblast did not show any positive results of RT testing, in Ivano-Frankivsk and Khmelnytskyi oblasts there were isolated cases of HIV infection using RT, which contradicts the general trends in the country and therefore requires additional analysis to identify gaps and use of appropriate measures.

Data on the number and characteristics of HTS sites for different testing modalities are limited. HTS is widely provided on the basis of HCF, as well as in mobile clinics (MC) and mobile points-of-care (MPOC), but at the national level the HCF is not recorded by "entry points" of the patient who received HTS, ie medical profiles of such HCF, their forms of ownership and subordination are not taken into account within

SEM. Non-governmental organizations (NGOs) implement various successful approaches to HTS provision and have wide access to KPs to provide such services. The effectiveness of HTS is assessed using a cohort approach - not only by the number of people who received a positive test result, but also by the number of people who applied to the HCF and were registered for further examination and treatment. However, HIV testing outside the HCF refers to triage, is not taken into account in the national HIV testing algorithm and official statistics. Provision of HTS by employees without special education on the basis of NGOs / communities in the country is not regulated.

The least widespread in the country practice of HTS in primary health care level is regulated by the order of the Ministry of Health of Ukraine from 19.03.2018 № 504 "On approval of the Procedure for providing primary care" . Therefore, the possibility of dynamic monitoring of PLHIV, including the appointment and delivery of ART, at the level of primary care is extremely limited. According to the National Health Service of Ukraine (NHSU), as of October 1, 2021, 621% of primary health care providers, including municipal providers - 62.2% (1,219), private individuals - 26.5% (520) and private (without PI) - 11.3% (222).

The situation with regard to PTS provision is better in secondary and tertiary level HCFs. RT and IM are actively used for HIV testing.

The registration of HIV-positive patients, the appointment and delivery of ART to them is carried out mainly by HCF infectious disease physicians who perform medical supervision of PLHIV. According to the NHSU, as of October 1, 2021, 375 service providers have concluded contracts in the field of “Diagnosis, treatment and support of persons with human immunodeficiency virus”, of which 99.5% (373) are municipal CHFs and 0.5% (2) are private (without PI). In addition, HTS included another 12 packages of medical services under the MGP.

In 2020, there are positive shifts in the spread of the practice of self-testing for HIV as an alternative way to increase the number and proportion of people who know

about their HIV status. Test systems for diagnosing HIV are available for sale (pharmacy network, Internet sites). With the support of international organizations, the distribution of free test systems for self-testing has begun. However, the latter remain expensive and not readily available for widespread use.

According to the results of 2020, the achievement of the first indicator of the HIV treatment cascade "90% of PLHIV know their status" in Ukraine as a whole was 69%. At the same time, only nine oblasts either reached the target (Zakarpattia, Zaporizhia, Kyiv, Luhansk and Ternopil), or significantly approached it (Vinnytsia, Dnipropetrovsk, Zhytomyr and Mykolaiv).

The problem that needs to be solved

Territorial differences in the intensity of the epidemic process, the involvement of KP, the growth of labor migration, internal displacement, other factors of influence and the peculiarities of the HIV epidemic determine the differences in the requirements for HTS. The issues of access to HTS at the primary level and in rural areas are particularly acute.

In combination with the lack of an approach to determining the case of HIV infection for the purposes of epidemiological surveillance in accordance with international standards, the incidence of HIV infection is deformed. The lack of normative and legal documents regulating the activities of monitoring and evaluation of HTS and epidemiological surveillance data does not allow to assess the trends of the epidemic process objectively and implement effective measures to control the HIV epidemic.

The limitation of funding for laboratories carrying out diagnostics and laboratory support of HIV infection has led to technical deterioration of equipment, personnel shortage and the impossibility of ensuring the required level of testing quality.

There is no information on the number and level of training of specialists providing HTS.

Taking into account the existing problems and the regional context, a priority for each region and Ukraine as a whole becomes the task of ensuring the synchronization of HTS tasks, activities and indicators with other areas of activity to counter the HIV epidemic.

In line with the global goals of the Joint United Nations Program on HIV / AIDS (UNAIDS) to end the global HIV epidemic Fast Track "95-95-95" by 2030, Ukraine must first achieve the goal of 95% people living with HIV are aware of their HIV-positive status. This figure is the starting point for the next two goals, where 95% of PLHIV receive ART and 95% of them have achieved a reduction to an indeterminate level of viral load less than 1000 RNA copies / ml.

In accordance with the State Strategy in the field of counteracting HIV / AIDS, tuberculosis and viral hepatitis for the period up to 2030, approved by the order of the Cabinet of Ministers of Ukraine dated November 27, 2019, No. 1415-r (the State Strategy) improving the system for the effective detection of HIV cases is defined as ***Operational Objective 2 of Strategic Objective 1 - to reduce HIV incidence and mortality from AIDS-related diseases, based on the Political Declaration on HIV / AIDS*** “Accelerating the pace to accelerate the fight against HIV and end epidemics 2030”.

This Concept has been developed to achieve this goal.

According to the indicators of the effectiveness of the National Strategy: the percentage of people who know about their HIV status should be 80% in 2020, 90% in 2025, and 95% of the estimated number of people living with HIV in 2030.

To improve the system of effective detection of HIV cases and achieve the required levels of coverage of the population with HIV testing, the following systemic problematic issues should be resolved:

- low informativeness of seroepidmonitoring data on the HTS coverage of KP and other groups of the population vulnerable to HIV;
- incomplete data on accounting and reporting on the use of RT for HIV testing in the regions;
- mainly a paper system of accounting and reporting on the provision of HTS and the lack of a single register for the HTS provision;
- limited data on the level of awareness of one's own HIV status among the population, primarily KPs and vulnerable groups regarding HIV infection, and retesting of people with HIV-positive confirmatory test when registered with the HCF;
- limited data on the number and characteristics of HSFs providing HTS;
- Insufficient use of rapid tests for HIV testing and low efficiency of their use in HCFs, especially those providing primary care;
- low availability of HIV testing services among KPs and the rural population;
- lack of practice in determining the case of HIV infection for the purposes of epidemiological surveillance in accordance with international standards,
- lack of routine testing for recent HIV infection, limited research on HIV genotyping;
- lack of regulation for testing providing by employees without medical education and organizations without a license to conduct business in medical practice;
- limited access and high cost of medical devices for HIV self-testing in the Ukrainian market, lack of data collection system on the effectiveness of self-testing programs;

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- unregulated procedures for assessment of characteristics, confirming the further suitability of medical devices for their use by the end user for the diagnosis of HIV, validation of new research methods;
- restrictions on funding for laboratories, depreciation of their material and technical base, staff shortage of qualified personnel;
- stigma, discrimination and violence against PLHIV and KP;
- breach of confidentiality regarding a person's HIV status;
- insufficient consideration in the HTS planning and implementation of the regional context of the epidemic process, the impact of the pandemic of COVID-19 and other biological threats, the processes of reforming the health care system, the processes of forming health guarantee programs.

The legal framework for HTS needs to be revised and modernized. At the legislative level, the basic principles for the provision of HTS are established by the Law of Ukraine "On Counteracting the Spread of Diseases Caused by the Human Immunodeficiency Virus (HIV) and Legal and Social Protection of People Living with HIV" and the Fundamentals of Ukrainian Legislation on Healthcare. At the same time, for a significant positive impact on the epidemic situation with HIV infection and achieving the indicator of 95% of PLHIV who know about their HIV status, the following issues remain unregulated at the legislative level:

- use of terminology in accordance with relevant international documents in the field of HIV / AIDS, in particular the identification of key and vulnerable populations for HIV infection to replace the definition of high risk groups for HIV infection;
- expanding the list of entities that can provide VET, carry out medical supervision for PLHIV, prescribe and deliver ART;
- development of effective mechanisms for involving PLHIV partners and their biological children in testing ensuring confidentiality;

- procedure for access to examination and treatment of persons who do not have identity documents and who have expressed their intention to undergo examination and treatment for the detection of socially dangerous infections, undergo such examination or receive treatment;
- determining the procedure for assessing the characteristics that confirm the further suitability of medical devices for their use by the end user for the diagnosis of HIV, verification of the testing algorithm to determine HIV status and evaluate its effectiveness;
- regulatory and legal consolidation of the terms "key" and "vulnerable populations as for HIV infection" and the criteria for their definition to replace the term "high risk groups as for HIV infection".

The existing legislative framework on HTS does not take into account the changes in the health care system that have taken place since 2017 in connection with the adoption of the Law of Ukraine "On State Financial Guarantees of Medical Services to the Population", does not allow for a flexible and prompt response to challenges in the field of counteracting the spread of HIV infection.

Purpose, goals and terms of implementation of the Concept of the National Strategy for HIV Testing in Ukraine until 2030

To have a decisive positive impact on the HIV epidemic in Ukraine, the main goal of the Concept of the National Strategy for HIV Testing in Ukraine until 2030 (Concept) is to achieve the indicator "95% of PLHIV know about their HIV status and have the opportunity to start treatment"

Achieving the goal of the Concept involves two stages: the first stage - 2022-2025, the second stage - 2026-2030.

The implementation of this Concept is planned to be carried out through the implementation of measures in accordance with the comprehensive strategic plans for the development of HIV testing in Ukraine, approved by the Ministry of Health of Ukraine in accordance with the stages - for 2022-2025 and for 2026-2030.

This Concept defines the operational goals, instruments and indicators of its implementation.

The implementation of the Concept is based on the following principles:

- differentiated service delivery - an approach that simplifies and adapts HIV services to implement a human-centered approach to HTS, better meet the needs of KP and PLHIV, optimize available resources in the health care system;
- integrated service delivery - management and delivery of health promotion and disease prevention, diagnosis, treatment, rehabilitation and palliative care services at various levels and places of care within the health care system and according to the needs of people throughout life;
- human-centered approach to health - health care services that focus on health, taking into account the needs and expectations of people and communities, not disease;
- HTS providing in compliance with the five principles declared by the WHO: informed consent; confidentiality; consultancy; correct test results; connection with care and treatment services and other services.

Ways and methods of the problem solution

The problem solution is provided by achieving the operational goals and objectives defined in the Concept.

Operational objectives define intermediate steps and areas of the activity focus, the totality and interconnectedness of which, together with tools in the field of data management, interagency and intersectoral cooperation, financial and regulatory instruments, are necessary to achieve the goal of this Concept.

Operational objective 1. Changes in the organization of the system of HIV testing services (HTS)

The tasks are:

- to ensure further expansion of access to HTS at the initiative of a health worker in all HCFs, regardless of ownership and subordination;
- to create an organizational and legal framework (legal regulation) to ensure the availability of HIV testing outside the HCF;
- to popularize HTS among the population, in particular, KP, with the involvement of the media (media), using social marketing, outdoor advertising, the Internet, social networks, etc. ; to stimulate demand for HIV testing services based on evidence-based health information;
- to promote self-testing for HIV and to increase the availability of self-testing test kits for the population;
- to increase the coverage of HIV testing of KP representatives, biological children and partners of HIV-positive people, in particular through index testing, HIV testing of discordant couples, testing based on social networks (Social network testing), etc.;
- to create an organizational and legal framework (legal regulation) for informing partners of HIV-positive people and partners of representatives of key

populations for their further involvement in HIV testing;

- to ensure the use of modern communication technologies in the system of HTS;

- to introduce HIV and syphilis testing using dual rapid tests among pregnant women and those seeking help to diagnose and treat STIs, as part of antenatal care and STI care;

- to ensure the integration of HTS with other services for the risk of HIV infection reduce, prevention and treatment of HIV and other socially dangerous diseases;

- to ensure confidentiality in the HTS delivery system in accordance with the WHO “5C” principles;

- to carry out regular monitoring of stocks of medical devices for HTS in order to prevent their shortage during anti-epidemic measures and quarantine restrictions related to the COVID-19 pandemic.

Operational objective 2. Reorganization of systems of epidemiological surveillance of HIV and M&E (Monitoring and evaluation) of HTS in the context of reforming the health care system and its financing

The tasks are:

- to implement a system of epidemiological surveillance of new cases of HIV infection based on the established positive HIV status, taking into account international recommendations (HIV Case - based Surveillance);

- to define and introduce effective mechanisms for identifying among new cases of HIV infection belonging of persons with HIV-positive status to KP;

- to ensure the introduction of routine HIV detection and genotyping among new HIV infections cases;

- to ensure the M&E system effective functioning in the field of HTS provision, including monitoring the coverage and effectiveness of index testing for

partners of people living with HIV and KP;

- to conduct operational and special research in the field of HTS in order to identify and effectively address systemic deficiencies, including in emergencies related to the COVID-19 pandemic.

Operational objective 3. Ensuring the quality of HIV testing

The tasks are:

- to develop and approve a long-term plan for the development of the laboratory network and packages of laboratory services in the field of diagnosis and laboratory support of HIV infection in the context of reforming the health care system and its financing;

- to ensure the implementation of the quality management system (QMS), in particular in accordance with the requirements of DSTU EN ISO 15189: 2015, DSTU EN ISO 22870: 2015, in HCFs that provide HTS and laboratories in the field of diagnosis and laboratory monitoring of HIV infection;

- to provide regular conduct of internal quality assessment and external quality assessment (IQA/EQA) of diagnostic tests in the field of HIV/AIDS at the national and regional levels;

- to introduce a system of verification of testing algorithms for HIV diagnosis, monitoring and review;

- to develop a system of supervision of HIV testing for all institutions that provide HTS, and to strengthen the coordinating role of the reference laboratory;

- to review and carry out measures to assess the characteristics of medical devices, confirming their continued suitability for use by the end user for the diagnosis of HIV;

- to develop a system of transportation of biological material from collection points at the primary level to the district, regional and national levels in all regions of

Ukraine in accordance with European guidelines (instructions) on HIV, tuberculosis, viral hepatitis.

Operational Objectives 4: Stigma and discrimination in the provision of HIV testing services reduce

The tasks are:

- to ensure the implementation of measures to reduce the level of stigma and discrimination in the field of HTS, as well as combating violence, including gender-based violence against PLHIV and KP;
- to ensure information campaigns to prevent stigma and discrimination against people tested for HIV, especially KP and PLHIV;
- to arrange monitoring of compliance with the rights of PLHIV and KP representatives to receive HTS and respond to cases of stigma, discrimination and violence, as well as timely monitoring of negative consequences for the provision of index testing services, detection of recent infection.
- to monitor the equality of access of different groups to HTS against the background of the long-term impact of the COVID-19 pandemic on health services;
- to provide psychological support and effective referral to appropriate care services for women who have reported any form of violence by an intimate partner or other family member during HIV testing.

Interdepartmental and intersectoral collaboration instruments

The implementation of the Concept requires an effective division of functions between the parties concerned and responsible authorities, ensuring overall coordination and complementarity of the implemented measures in order to make the most efficient

use of available resources and prompt response to challenges arising in its implementation, including in response to biological threats.

Within the framework of the Concept, it is necessary to use such instruments of interdepartmental and intersectoral interaction as:

- synchronization of HTS tasks, measures and indicators with other components of programs in the field of combating the HIV epidemic, primarily preventive and curative, in the context of health care reform;
- coordination of the implementation of measures to provide HTS within the framework of the work of the National and regional councils on counteracting tuberculosis and HIV infection / AIDS, their working bodies, as well as within the framework of the implementation of activities of local targeted social programs to combat HIV infection / AIDS;
- Coordinating the implementation of HTS providing in response to the challenges posed by the COVID-19 pandemic and in the event of other biological threats.

Data management tools

The effectiveness of the Concept implementation is related to the quality of data used for event planning, collected and summarized during its implementation, used for decision-making and further improvement.

To improve the information management algorithms in the field of HTS it is necessary:

- to introduce electronic systems and tools in HTS providing institutions and medical laboratories in the field of HIV diagnostics and laboratory support to ensure accounting and reporting documentation, preservation of laboratory results in electronic form, data exchange, data collection and analysis;
- to improve the assessment of the number of PLHIV using the computer

program Spectrum / ERP and other modeling programs; to ensure regular (every 3 years) synthesis of data on the estimated number of PLHIV using different sources.

Regulatory tools

Measures to implement this Concept require improvement of the regulatory framework, taking into account the regulatory instruments provided for in the State Strategy, in particular regarding:

- harmonization with the legislation of the European Union (including in the context of compliance with the requirements of the Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their Member States, on the other hand);
- implementation of the WHO guidelines, the Joint United Nations Program on HIV / AIDS (UNAIDS) and other intergovernmental organizations and programs in order to improve the provision and mechanism of service organization;
- alignment of terminology and industry standards in healthcare in accordance with WHO recommendations and international requirements.

The main tasks for regulatory settlement are:

- amending the Laws of Ukraine, which establish the basic principles of HTS;
- systematic revision of normative legal acts of the Ministry of Health of Ukraine, including sectoral standards on HTS provision.

Legal and regulatory framework should include:

- regulatory and legal consolidation of the terms “key” and “vulnerable populations for HIV infection” and the criteria for their definition to replace the term “high-risk populations for HIV infection”;
- determining the procedure for storing confidential information about HIV-

positive people and protecting such information from disclosure and revelation to third parties;

- procedure for access to examination and treatment of persons who do not have identity documents and who have expressed their intention to be examined, examined or receive treatment for socially dangerous infections;

- effective mechanisms for involving PLHIV partners and their biological children in testing with confidentiality;

- implementation of modern approaches to the HTS provision in the HCF, taking into account the additional needs of individual population groups and the peculiarities of the epidemic;

- determining the procedure for registration and reporting of new cases of HIV infection on the basis of positive HIV status;

- expanding the list of health care providers that can carry out medical supervision for PLHIV and ART;

- optimization of the procedure for registration and appointment of ART;

- providing a legal basis for the HTS provision by trained personnel without medical education and organizations without a license to conduct business in medical practice, including in public associations and social service institutions;

- determining the procedure for assessing the characteristics that confirm the further suitability of medical devices for their use by the end user for the diagnosis of HIV, testing algorithms verification to determine HIV status and evaluate their effectiveness.

Financial instruments

Funding of HTS delivery should be provided in accordance with the following principles:

- consistency;
- sufficiency to prevent the deterioration of the epidemic situation ;
- taking into account targets for improving the epidemic situation;
- compliance with Ukraine’s international obligations.

A necessary condition for the implementation of this Concept is to improve the planning and HTS financing through:

- development and approval of methods for calculating the need for medical devices for the diagnosis of HIV at various levels, from national, regional, subregional to the level of HCF; creation of appropriate electronic tools;
- ensuring sustainable financing of activities within the framework of the provision of HTS, including by increasing the contribution of local budgets to regional programs on HIV / AIDS and effective allocation of funds for international technical assistance projects.

Expected results. Monitoring the implementation of the Concept

The implementation of the Concept as a whole, as well as the implementation of measures implemented to achieve its goals and objectives, require systematic monitoring, evaluation and development of a common methodology to improve the process of strategic planning and implementation of multilevel programs, international technical assistance projects and separate events.

Indicators of the effectiveness of the implementation of this Concept are given in the appendix.

The amount of financial, logistical and labor resources

Funding for measures to implement the Concept can be made at the expense of:

- 1) the State Budget of Ukraine, including programs of medical guarantees, public health programs, programs in the field of health care, ensuring the performance of national functions, according to the list approved by the Cabinet of Ministers of Ukraine;
- 2) local budgets, relevant local programs;
- 3) social insurance funds, other special funds;
- 4) charitable assistance (donations), international technical assistance, grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria;
- 5) legal entities and individuals;
- 6) other sources which are not prohibited by law.

Funding of measures for the Concept implementation should include:

- 1) measures to improve and modernize the material and technical base of the HCFs and laboratories;
- 2) measures to strengthen human resources and increase the professional level of HTS providers:
 - constant review, updating and standardization of HTS training programs in accordance with current requirements to ensure early detection and treatment of PLHIV, quality of HTS, involvement in testing partners of persons with a positive test result, combating stigma and discrimination, ethics and confidentiality; development of distance learning courses and HTS practice trainings as for RT;
 - training of medical staff and persons without medical education on the HTS provision on updated and standardized programs, determining the order of

professional training of persons to perform medical procedures that do not require medical education, development of standardized qualification requirements and assessment systems for professionals with medical and non-medical education who are involved in HTS (after amendments to the legislation regarding the provision of HTS to persons without medical education).

The amount of funding, logistical and labor resources required for the implementation of this Concept is determined annually according to needs and taking into account different sources of funding.

TARGET INDICATORS OF THE CONCEPT OF THE NATIONAL STRATEGY FOR HIV TESTING UNTIL 2030

Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
TREATMENT CASCADE INDICATORS					
1. Estimated number of PLHIV	Spectrum or other simulation programs	N - estimated number of PLHIV; D - not used	Age (0-14, 15+), gender (male / female), territory (oblast, city), population group (KP/ total population)	The evaluation result is an Indicator for the first column of the HIV treatment cascade	Not used
2. Proportion of PLHIV who are aware of their HIV-positive status and registered, % (linked to care)	RES data (for the numerator); Spectrum or other simulation programs (for denominator)	N - number of PLHIV who know about their HIV-positive status and are registered (are linked to care); D – estimated number of PLHIV	Age (0-14, 15+), gender (male / female), territory (oblast, city), population group (KP/ total population)	N / D x 100% The obtained result is an indicator for the second column of the HIV treatment cascade. Can be used in absolute values (N) and in percent	2025 – 90%; 2030 – 95%
3. Proportion of PLHIV receiving ART, %	Official statistics or MIS HIV (for the numerator); REN data (for denominator)	N – number of PLHIV receiving ART; D – number of PLHIV who know about their HIV-positive status and are registered (are subject to regular medical check-up)	Age (0-14, 15+), gender (male / female), territory (oblast, city), population group (KP/ total population)	N / D x 100% The obtained result is an indicator for the second column of the HIV treatment cascade. Can be used in absolute values (N) and in percent	2025 – 90%; 2030 – 95%

Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
INDICATORS OF TIMELY DEVELOPMENT OF PLHIV					
4. Late diagnosis of HIV, % (percentage of PLHIV diagnosed and first registered with CD4 level ≤ 350 cells / μ l)	RES (gradual transition to MIS HIV)	N – the number of people with indicators of the number of CD4 cells in the blood ≤ 350 cells / μ l; D – the total number of people living with HIV who were diagnosed with HIV for the first time in their life and their CD4 cell count was determined during the reporting period	Territory (oblast, city/urban-type village/village); CD4 ≤ 200 cells/ μ l, ≤ 350 cells/ μ l	N / D x 100% The indicator is the basis for planning measures for timely placement of PLHIV under medical supervision.	2025 pik $\leq 30\%$; 2030 $\leq 20\%$.
5. Early diagnosis of HIV among newborns, % (percentage of infants born by HIV-infected women tested for HIV during the first two months of life)	M&E data of the PMTCT program on a routine basis; in the future - the electronic data register of the PMTCT program	N – the number of children born to HIV-positive women who have undergone an HIV virological examination during the first two months after birth; D – number of neonates who were born alive of HIV-positive women in	Territory (oblast, city/urban-type village/village); the result of the survey (negative/positive / indefinite)	N / D x 100% Full coverage of HIV-exposed children with early diagnosis is the basis for early detection of HIV and timely appointment of ART	100%

Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
		the reporting year			
INDICATORS OF ACSESSEBILITY, COVERAGE, EFFICIENCY AND QUALITY OF HIV TESTING					
6. Number of sites providing HTS	Operational data on the number of HTS sites on the HCFs, within individual programs and projects. In the future - the National Register of HTS sites	N – number of sites providing HTS; D – the total number of sites that should provide HTS	HCFs by the level of care delivery (primary, secondary, tertiary) and non-medical site; profile of the health care facilities, territory (oblast, city / urban-type village / village)	N / D x 100% Data collected are reported to the database of the European Center for Epidemiological Surveillance - TESSy	100%
7. Percentage of index clients who agreed to provide HTS index, %	MIS HIV (within the project); hereinafter - the national level (development and application of the module for all sites providing HTS).	N - the number of index clients who agreed to provide HTS index D – the number of identified index clients (people with HIV transmission: newly diagnosed; PLHIV who do not receive ART; PLHIV who receive ART but have not achieved VL suppression)	Sex (male / female), territory (oblast, city / town / village), population group (KP / total population); HIV status (newly diagnosed, HIV status previously known as receiving ART / not receiving ART);	N / D x 100% Calculation by automated data processing from MIS HIV	2025 – 70%; 2030 – 95%

Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
8. Effectiveness of HTS in the framework of index testing, % (contact persons who passed the index testing for HIV and received results)	MIS HIV (within the project); hereinafter - the national level (development and application of the module for all sites providing HTS).	N - the number of contact persons who passed the index testing for HIV and received results D - the number of detected contacts from the number reported by index clients	Sex (male / female), territory (oblast, city / town / village), population group (KP / total population); by HIV status (HIV diagnosed for the first time; HIV status known; HIV-negative status established)	Calculation by automated processing using medical information systems. The accounting documentation should document the date of the person's application to the HCF / NGO, the date of the first index test, the date of consent to disclose contacts, partner cards, type of testing (screening, verification), the date of HIV testing and its results.	2025 pik – 70%; 2030 pik – 95%
9. Number of newly diagnosed HIV-positive people who were tested for recent infection with documented results during the reporting period	MIS HIV	N - the number of newly diagnosed PLHIV who have been tested for recent HIV infection D – not used	Sex (male / female); age; territory (region, city / town / village); type of HCF; population group (KP / total population)	The obtained data are the basis for building a cascade of testing for PLHIV for recent HIV infection.	Not used
10. Percentage of people newly diagnosed with HIV who were tested with positive result for recent infection, %	MIS HIV	N – the number of people who received a positive confirmatory testing result for recent HIV D – the number of newly diagnosed PLHIV who have been tested for recent HIV infection	Sex (male / female); age; territory (region, city / town / village); type of HCF; population group (KP / total population)	N / D x 100% The obtained data are elements of the cascade of testing of PLHIV for recent HIV infection and are used to assess the epidemic process.	Not used

Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
11. Coverage of HCF patients with HIV testing at the health worker initiative, %	RES (for the numerator); determination of the data source for the denominator (at the initial stage - the records and reports of the HCF); or the results of special studies (if available)	N – the number of patients who received HTS due to the presence of HIV - indicative conditions and other signs necessary for the appointment of HTS; D – the number of patients with unknown HIV status who had HIV-indicative conditions and other symptoms required for HTS.	HCFs by the care delivery level (primary, secondary, tertiary) and non-medical site; HCF profile, certain categories of population (donors, pregnant women, children, others), territory (oblast, city/urban-type village/village);	N / D x 100%	2025 – 75%; 2030 – 95%
12. HIV testing coverage for pregnant women, %	Monitoring and evaluation data of the PMTCT program and data of prenatal clinics on a routine basis	N – the number of pregnant women tested and received its result; D – the total number of pregnant women who applied for prenatal care during the reporting period (<i>program denominator</i>)	Territory (oblast, city/urban-type village/village)	N / D x 100%	100%
13. HIV testing coverage of sexual partners of pregnant women, % (contact persons who were	Prenatal clinic data: at the initial stage - operational data, later – the records and reports	N – the number of contact sexual partners of pregnant women who have been tested for HIV and received their	Territory (region, city / town / village), population group (KP / total population); by HIV status (HIV diagnosed for the first	N / D x 100%	2025 – 70%; 2030 – 95%

	Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
	tested for HIV and received results)	documentation, and in the future - an electronic data register	results; D – the total number of pregnant women who applied for prenatal care during the reporting period (<i>program denominator</i>)	time; HIV status known; HIV -negative status established)		
14.	HIV testing coverage of KP representatives, %	IBBS data	N – the number of KP representatives aware of their positive HIV status or have been tested for HIV in the last 12 months and received a negative result; D – the number of KP representatives who responded regarding their negative, positive or unknown HIV status	KPs (PWID, SW, MSM, etc.), age (<25, 25+), sex (male / female), gender, territory (oblast)	N / D x 100% It is used to assess the progress in HTS providing to KP representatives	2025 – 90%; 2030 – 95%.
15.	The use of RT in HCFs, % (screening stage of testing except for donors and pregnant women))	SEM results (in the future - MIS HIV)	N – the number of screened persons by using RT (except for donors and pregnant women); D – total number of persons who received HTS (except for donors and pregnant women)	HCFs by the care delivery level (primary, secondary, tertiary) and non-medical site; HCF profile, certain categories of population (donors, pregnant women, children, others), territory (oblast, city/urban-type village/village);	N / D x 100%	> 40%

	Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
16	HIV infection among people tested for HIV, % (confirmatory stage of testing)	SEM data (for the HCFs) and program monitoring data (for non-medical facilities); In the future - MIS	N – the number of persons who received a positive confirmatory HIV testing result; D - the number of persons who have been tested for HIV	HCF by form of ownership (public, municipal, private), by the care delivery level (primary, secondary, tertiary) and non-medical site; HCF profile; certain categories of the population; territory (oblast, city / town / village); age (0-14, 15+), sex (male / female); gender; methods of serological diagnosis (RT, IM).	N / D x 100% The result should be assessed in combination with other indicators and taking into account the regional context	Not used
17	Registered persons with a positive HIV test result, %	RES (more accurate data for N / D can be obtained at the level of the HCF using the primary records and reports documentation). In the future - MIS.	N – the number of PLHIV who received a positive confirmatory testing result, and which are registered during the reporting period; D – the number of people who received a positive confirmatory testing result during the reporting period.	HCFs by the care delivery level (primary, secondary, tertiary) and non-medical site; HCF profile, certain categories of population (donors, pregnant women, children, others), territory (oblast, city/urban-type village/village); age (0-14, 15+); sex (male/female); gender; the time period after receiving a positive testing result (14 days, during the calendar year)	N / D x 100% After 2025, it should show the effectiveness of HTS and redirection, taking into account the reduction of waiting times for ART to 7 days.	90%

	Indicator	Data source	Numerator (N) / Denominator (D)	Distribution	Method of measurement	Target value
18.	Avoidance of the KP members to receive medical care services due to stigma and discrimination	Special studies data, IBBS	<p>N – the number of respondents from among the KG representatives who responded "Yes" to at least one of the four standard questions regarding stigma and discrimination;</p> <p>D – the total number of respondents from among the KP representatives who answered the questions.</p>	KP (PWID, SW, MSM, transgender {TG}), age (<25, 25+)	. $N / D \times 100\%$	0%
19.	Involvement of HCFs providing HTS in external quality assessment programs (EQA) for laboratory tests for the diagnosis of HIV, %	Operational data on the number of HCF-based HTS sites, within special programs and projects. (In the future - the National Register of HTS sites)	<p>N – the number of sites that participate in EQA programs;</p> <p>D – the total number of sites providing HTS.</p>	HCFs by the care delivery level (primary, secondary, tertiary) and non-medical site; HCF profile, certain categories of population (donors, pregnant women, children, others), territory (oblast, city/urban-type village/village);	$N / D \times 100\%$	100%
20.	The level of quality of laboratory tests for the diagnosis of HIV infection according to the results of EQA, %	Operational data on the number of HTS sites that participated in EQA programs and on the number of correct solutions to control tasks	<p>N – the number of HCFs that participated in the EQA program and received the correct test results of control test samples</p> <p>D – the total number of HCFs that participated in the EQA programs</p>	HCFs by the care delivery level (primary, secondary, tertiary) and non-medical site; HCF profile, certain categories of population (donors, pregnant women, children, others), territory (oblast, city/urban-type village/village).	$N / D \times 100\%$	≥ 99%