



**USAID** | HEALTH POLICY  
FROM THE AMERICAN PEOPLE INITIATIVE



# FUNDAMENTALS OF VOLUNTARY HIV COUNSELING AND TESTING

**Guide for Doctors**

**Kyiv 2007**

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- health managers, who will organize VCT services in medical settings;
- lab staff, who diagnose HIV;
- physicians and medical officers, who will work specifically in the field of VCT, during their regular qualification improvement course in the system of post graduate education of Ukraine

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This Guide provides an introduction to the basic HIV challenges, in particular, those, related to Voluntary HIV Counseling and Testing (VCT), and is aimed for doctors. The authors emphasize that VCT is one of the most important services in the country, which provides the population with the access to prevention, diagnostics, medical and social care. Since pre- and post-test counseling in medical settings is a novelty, this Guide will be of a great help to students and doctors of any profile, who work in medical care institutions and HIV services NGOs. It is hoped that a follow-up guide specifically to counseling and testing for those most-at-risk populations will be added at a future date.

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## INTRODUCTION

The Guide «Fundamentals of Voluntary HIV Counseling and Testing» originated from the partnership between the Virology Chair of the National Medical Academy of Post-Graduate Studies of the Ministry of Health of Ukraine (NMAPGS), Ukrainian AIDS Center and USAID|Health Policy Initiative, Task Order 1, Ukraine. The collaboration of the above institutions and organizations in this case proves not only the successful interaction between public and private sectors but also the effectiveness of the use of resources available in Ukraine with the aim to halt HIV, in particular through scaling up the access to most at risk populations to voluntary HIV counseling and testing.

HIV testing has been provided for more than 16 years in Ukraine (of 25 years that the epidemic is known in the world) while counseling has been provided for nearly nine years. The pre- and post-test counseling, envisaged by the laws, has been steadily introduced, however, without any system or standards. International methodologies and individual experience of each AIDS Center were applied in this situation.

Within the last two years Ukraine has made several steps towards scaling up the access to HIV VCT quality services. Under support of the USAID-funded POLICY II Project, public agencies, NGOs and international organizations, engaged in HIV combat efforts in Ukraine, the Procedure of voluntary counseling and testing (VCT) was standardized; the country started establishing “Trust” offices; the Strategy of the HIV Rapid Testing Scale Up was developed and approved; international organizations – partners of the Ministry of Health of Ukraine (MOH) – provided technical assistance to introduce VCT training programs and run trainings in target oblasts.

At the same time, trainings as such can't cover all experts in the country, they can't provide their participants with the certificates approved by the government, finally they can't substitute for the standardized and licensed state training programs. Recognizing this problem, the MOH VCT WG decided to start developing VCT training programs and manuals.

The Virology Chair of the National Medical Academy of Post-Graduate Studies was requested to develop the first training program and fundamental VCT guide for the doctors, who are expected to provide pre- and post-test counseling services at the “Trust” offices and other ancillary clinics. This Guide was developed due to the technical assistance of USAID| Health Policy Initiative and participation of the Ukrainian AIDS Center. Special training programs and materials for psychologists, social workers and NGOs to address specific most-at-risk populations are to be developed in the future.

So, what is VCT and why is it so important now?

VCT is a service, which implies HIV testing, by all means preceded and followed by a voluntary counseling initiated by a patient. VCT contributes to the raising of public awareness of HIV and its prevention, encourages the well-informed voluntary decision related to HIV testing, promotes HIV-risk-free behavior, identifies HIV status of a person, and if found HIV positive, provides the access to ART and prevents opportunistic infections, plus it helps to change behavior in PLHIV, so transmission risk is lowered.

This Guide, which contains modern concepts about HIV, peculiarities of epidemic in the world and in Ukraine, basic counseling and testing knowledge, was developed by a group of authors – the Head of the Virology Chair of the National Medical Academy of Post-Graduate Studies professor I.Dziublyk, the Director of the Ukrainian AIDS Center professor A. Shcherbinska, the VCT Senior Adviser of USAID| Health Policy Initiative, PhD T. Aleksandrina.

The Guide presents in clear language the VCT algorithm, the material on the role of VCT as the effective tool of HIV prevention in Ukraine, specific features of pre- and post-test counseling, testing procedures, parameters of test systems, which provide for the quality serology diagnostics of HIV, definitions of supervision, monitoring and evaluation of VCT. The Guide is attached with test questions, correct answers to them, and case exercises.

This Guide is based on the VCT Protocol, approved with the MOH order of 19.08.2005 No. 415 „On HIV VCT improvement”, WHO/UNAIDS guidelines, VCT materials, developed by PATH for Ukraine. This Guide doesn't contain materials on counseling skills and effective interpersonal communication principles. Since they are set forth in the training guides „Fundamentals of reproductive and sexual health counseling”, prepared by the group of writers under B. Vornik's supervision (Kyiv, 2004) and «HIV/AIDS counseling» (Georgia, 2005), developed by Save the Children and PATH and being adapted by PATH for Ukraine. The MOH WG on 22 November 2006 decided to develop a separate training guide, which will not duplicate the soon-to-be-published PATH guide and for this Guide to focus on fundamentals on testing. It is hoped that a follow-up guide specifically to counseling and testing for those most-at-risk populations will be added at a future date.

The Guide is expected to meet the needs of doctors, who are involved in pre- and post-test counseling, for the lab experts, who do HIV lab tests, health managers, who ensure counseling and testing services. It will be of a great help to students and doctors of any profile during their regular qualification improvement course in the system of post graduate education of Ukraine.

On behalf of the USAID| Health Policy Initiative, Task Order 1 in Ukraine, I would like to express our gratitude to the authors of the Guide, reviewers, other experts of the project, NMAPGS and Ukrainian AIDS Center for their assistance in writing and publishing of the Guide and wish them every success and strong partnership in the field of HIV combat in Ukraine.



## Acronyms

- **ARV** – antiretroviral medicine
- **ART** – antiretroviral therapy/ treatment
- **HAART** – highly active antiretroviral therapy/treatment
- **HIV** – Human Immunodeficiency Virus
- **WHO** – World Health Organization
- **HSV** – Herpes Simplex Virus
- **HEB** – hematoencephalic barrier
- **GC/AR** – group counseling / awareness raising
- **VCT** –voluntary HIV counseling and testing
- **MCI** – medical care institutions
- **RT** – reverse transcriptase
- **PI** – protease inhibitors
- **EIA** – enzyme-immune assay
- **PLHIV** – people living with HIV
- **MP** – medical product
- **M&E** – monitoring and evaluation
- **RTNI** – reverse HIV transcriptase nucleoside inhibitors
- **RTNNI** -- reverse HIV transcriptase non-nucleoside inhibitors
- **UR** – undesirable reaction
- **RDI**- research and development institute
- **PA** – public associations
- **STI** – sexually transmitted infections
- **PGLP** – persistent generalized lymphadenopathy
- **SW** – sex workers
- **RNA** – ribonucleic acid
- **IDU** – injection drug users
- **AIDS** – Acquired Immunodeficiency Syndrome
- **TB** – tuberculosis
- **PTTB** –preventive treatment for tuberculosis
- **ASI** -- area-specific improvement
- **MSM** – men who have sex with men
- **UNAIDS** – Joint United Nations Program on HIV/AIDS



**“Voluntary HIV Counseling and Testing”  
Area-Specific Improvement (ASI) Curriculum**

<b>Code</b>	<b>Title of Course, Section, Thesis</b>
<b>01.</b>	<b>ORGANIZATION OF HIV DIAGNOSTICS LABORATORY OPERATION.</b>
<b>01.01</b>	<b>Organization of HIV Diagnostics Laboratory Operation (for purposes of screening and PCR diagnostics)</b>
01.01.01	Selection of premises. Mode of operation. Equipment.
01.01.02	Logistical support. Personnel. Documentation. External and internal control over the quality of research
<b>01.02</b>	<b>Mode of Treatment of Infectious Materials</b>
01.02.01	Mode of treatment of 1 <sup>st</sup> -to-4 <sup>th</sup> group pathogenic viruses in a laboratory environment.
01.02.02	Biological safety at HIV counseling and testing units
01.02.03	Infectious material selection and transportation instructions. Infectious material receipt and research rules for HIV diagnostics laboratories and counseling and testing units. Research results wording and delivery term. Forms of source accounting records. Methodological techniques guaranteeing the quality of HIV screening and diagnostics
<b>01.03.</b>	<b>Legal Matters</b>
01.03.01	Laws of Ukraine: “On the Prevention of AIDS Incidence and Social Safety of Population” and “On Introduction of Amendments to the Law...”, orders of the Ministry of Health of Ukraine, guidelines and other methodological documents on HIV/AIDS. Order of the Ministry of Health of Ukraine No. 415 “On Improvement of Voluntary HIV Counseling and Testing”, dated Aug. 19, 2005. Voluntary HIV Counseling and Testing Protocol
<b>03.</b>	<b>BASIC PRINCIPLES OF LABORATORY DIAGNOSTICS OF HIV AND VIRAL DISEASES ASSOCIATED WITH AND INDICATING AIDS</b>
<b>03.03</b>	<b>Rapid Diagnostics of HIV and Viral Diseases Associated with and Indicating AIDS</b>
03.03.01	Immunofluorescence Assay (IFA)
03.03.02	Enzyme-immune Assay (EIA)
03.03.03	Immune Blotting (IB)
03.03.04	Immune Blotting (IB)
03.03.05	Polymerase Chain Reaction (PCR): qualitative and quantitative Simple/rapid assays. Immunochromatographic (lateral diffusion) and one-stage methods. The Dipstick method
<b>13.0.</b>	<b>RETROVIRUSES AND DERIVED DISEASES</b>
<b>13.01</b>	<b>General Description of Retroviruses</b>
13.01.01	Classification of retroviruses and their role in human pathology.
13.01.02	Structure and biological properties of retroviruses. Endogenous and exogenous retroviruses
<b>13.02.</b>	<b>HIV/AIDS</b>

13.02.01	Peculiarities of HIV agents: morphology, structure, genome, proteins, physicochemical and biological properties
13.02.02	Pathogenesis of HIV. HIV/AIDS-affected immune system
13.02.03	Clinical presentations of HIV/AIDS. Classification of HIV/AIDS clinical stages. Opportunistic infections and malignant neoplasia in AIDS cases
13.02.04	Specific antiretroviral therapy principles
13.02.05	HIV epidemiology and prevention. Post-contact HIV prevention
13.02.06	Laboratory diagnostics of HIV. HIV diagnostics strategy, tactics and algorithms, and rapid testing for HIV
<b>13.03.</b>	<b>HIV Voluntary Counseling and Testing Procedure. Basic VCT Principles, VCT Protocol, and Organization of Voluntary HIV Counseling and Testing Services Provision</b>
13.03.01	Basic VCT principles. VCT algorithm
13.03.02	VCT protocol, content, general provisions, objective
13.03.03	Other Ukrainian guidelines relevant to VCT services organizing
13.03.04	VCT as an efficient HIV prevention tool. Organization of VCT at Ukrainian medical care institutions
<b>13.04.</b>	<b>Pre- and Post-test Counseling</b>
13.04.01	Pre-test counseling goal, objectives and content
13.04.02	Post-test counseling goal, objectives and content Counseling mistakes
<b>13.05</b>	<b>VCT Supervision, Monitoring and Evaluation</b>
13.05.01	Supervision: goal and objectives
13.05.02	VCT monitoring and evaluation system and techniques
13.05.04	Peculiarities of counseling of various groups of population

## **Section 1. Modern Knowledge of HIV/AIDS**

HIV Etiology

Pathogenesis of HIV disease

HIV Classification, Clinical Presentations and Principles of Treatment

Techniques of HIV Laboratory Diagnostics in Ukraine

Rapid Testing for HIV. Simple/Rapid Assays.

1.6. Strategy and Tactics of HIV Laboratory Diagnostics in Ukraine

### **1.1. HIV Etiology**

The early days of 1980's and mainly the year 1981 witnessed the official recognition of a new illness that one year later was called "Acquired Immune Deficiency Syndrome" of a human being, or it is often abbreviated to AIDS. The discovery of the etiological agent of AIDS was first reported in France by doctors from Dr. Luc Montagnier's team at the Paster Institute in May 1983. It appeared to be a new virus that was defined with a person infected with AIDS and that was examined by using a super microscope, with clinical presentation of lymphadenopathy, which, to some extent, predetermined the first name given to the new virus, i.e. Lymphadenopathy Associated Virus (LAV). It was in May 1984 when a U.S. research team from the National Cancer Institute of the USA headed by R. Gallo, the chief of the laboratory of cellular biology of growths, in its turn, reported the discovery of the virus that caused AIDS and the virus was named a Human T-cell Lymphotropic Virus (HTLV-III). That very year J. Levy, another U.S. researcher, isolated the virus and named it AIDS Related Virus (ARV).

In April 1986 the magazine „Science” published L. Montagnier's report on the discovery of one more new virus isolated from a patient infected with AIDS, an African who was a waiter in Paris and who was an immigrant from West Africa. The new virus was named LAV-II.

In May 1986 at the 2<sup>nd</sup> International AIDS Conference, the International Committee on Taxonomy of Viruses in conformity with the requirements of unification of the international terminology gave the AIDS virus a new name – **Human Immunodeficiency Virus (HIV)**, which in Ukrainian is abbreviated to "BIJ" (HIV).

According to modern knowledge, HIV refers to the family of retro-viruses (Family Retroviridae), of the subfamily of lentiviruses (Family Lent virus). So far, two types of viruses such as HIV-1 and HIV-2 have been identified, which differ distinctly from each other by both the genome and the antigenic structure of their proteins. HIV-I and HIV-2 are the first slow viruses (lentiviruses) causing pathology in the body of a human being. (Fig. 1.1).

### **Figure 1.1 – Place of HIV among the Viruses Pathogenic to Human Beings**

Like other representatives of the family Retroviridae, both of them are viruses of a complex structure. A mature virion is of a spherical form, the diameter of which is about 100 nm (Fig. 1.2). The external glycolipidic envelope of the virus consists of two tiers having 72 prominences formed, for instance, with HIV-I by glycoprotein gp120 and gp41. Glycoprotein gp120 (m.m.120 kDa) is bound to gp41 (m.m.41 kDa) by mobile ligaments, it can easily be isolated from the external envelope of the virus and it can freely circulate in the blood of a person infected with HIV, which in broad terms, may lead to various negative phenomena and after-effects. Below the external glycopidic envelope of the virus there is the so-called matrix protein p17 (m.m.17 kDa) that forms the matrix envelope. In the very center of the virus particle there is a nucleocapsid which is the core of the virus. The main protein forming the nucleocapsid with HIV-I is p24, and with HIV-2 – p26 (Fig. 1.3). In the center of the cone-like core (nucleocapsid) there is a viral genome represented by two independent molecules of DNA, enzymatic molecules of reverse transcriptase (RT), ribonuclease N, integrase (I) and protease (P). In addition to the above proteins, HIV possesses many others. In general, all HIV proteins are divided into structural, regulatory, and supplementary.

**Figure 1.2 – HIV as Seen through an Electronic Microscope (a) and a Schematic Drawing of HIV-1 (b)**

**Figure 1.3 – Schematic Drawing of HIV-1 (b)**

The HIV genome is composed of two independent single-stranded RNA (a diploid genome), each of which has 9 genes: 3 main or structural (gag, pol, env) and 6 regulatory: tat, rev, vif, nef, as well as vpr, vpu (for HIV-1), vpx (for HIV-2), the functionality of which is insufficiently studied. (Fig. 1.4).

**Figure 1.4 - HIV-1 Genome Organization**

The gene tat is the most active regulator that increases the rate of the replication cycle of the virus by 1,000 times. It also regulates the expression of cell-specific genes. The gene rev selectively stimulates the synthesis of structural proteins of the virus. At later stages of HIV infection, the gene rev moderates the synthesis of regulatory proteins. The gene nef, in its interaction with the so-called long terminal repeats (LTR), moderates the rate of transcription of viral genomes ensuring a certain balance between the virus and the human body. A synchronous functionality of tat and nef is responsible for a well-balanced replication of the virus, which does not lead to the death of the infected cell.

The structural gag, pol and env genes ensure the synthesis of viral proteins (Tab. 1.1).

**Table 1.1 – HIV-1 and HIV-2 Genes**

Gene	Function	Proteins encoded	
		HIV-1	HIV-2
1. Structural			
gag	Nuclear Protein	p13, p24, p35	p26
pol	Enzymatic systems (revertase, endonuclease, protease)	p31/33, p34, p53, p64	p36, p68
env	Proteins membranous	p41, gp120, gp160	gp40, gp105, gp140
2. Regulatory			
tat	Positive regulator	p13/14	p19
rev	Selective regulator	p17/18	p15
nef	Negative regulator	p27	p27
vif	Viral infectivity factor	p23	p23

The envelope (env) gene– encodes translation of the precursor protein of the envelope of the virus gp160, which further splits up into gp 120 and gp41.

The group-specific (gag) antigens– encode the inner proteins of the virion. These proteins together with the proteins encoded by the pol gene are read, like with other retroviruses, with a full size RNA with 9,300 nucleotides. The result of transliteration of this i-RNA is that a precursor with the molecular mass of 55 kD is formed. In the process of further proteolytic splitting, this protein splits up into p17, p24, p9 and p7.

The pol gene encodes virus enzyme systems, reverse transcriptase (p66/51), integrase (p31/33), and ribonuclease N (p15).

Virion proteins in the body of HIV infected people determine the immune response with the synthesis of immunoglobulin.

Apart from the structural and regulatory genes, HIV-1 comprises long terminal repeats (LTR), and HIV-2 comprises LTR and one additional X gene.

HIV infection is characterized by a high genetic variability. The frequency of genetic errors during the process of nucleic acid replication is  $10^{-4}$ - $10^{-5}$  errors per gene for a cycle of replication. In other words, not a single fragment of HIV RNA comprising less than 104 nucleotide pairs (n.p.) in length imitates precisely the parent one. The high genetic variability is realized with the variability of antigenic and biological features of isolates. In many cases it is connected with the product of the viral env gene – gp120, the variability of amino acid sequence of which up to 5 - 20% is for isolates of the same sub-type, and from 25 to 35% for different subtypes. The most variable is the area gp120 that forms a button-like domain named V3-loop and which includes 35

amino acids. From 80 to 95% of all neutralizing antibodies are formed in addition to the said domain.

It has been found out that HIV-1 has 9 subtypes that genetically differ in env gene, which are symbolized by the capitalized Latin letters **A, B, C, D, E, F, H, J, I**, and which were combined into one group **M** (main). Besides, a few isolates of the virus that differ distinctly from the known representatives of the group M and were included into the group O (originated from outlier – aside) and the group **N** (non –M, non -O) are described. Scientific studies prove that at the end of the 20<sup>th</sup> century (before 1998), the subtype C ( 48%) prevailed, the subtype A accounted for 25%, the subtype B accounted for 16%, the subtype D and E accounted for 4%, the remaining constituted all other known subtypes (Fig. 1.5).

### **Figure 1.5 - Global Spread of HIV Subtypes (1998)**

As far as HIV-2 subtypes are concerned, this issue is still being under thorough consideration.

The exceptional genetic variability lets the virus survive in the infected body since in a huge pool there can always be found a virus that would be adoptable to the evolution selection.

Describing the agent, it is important to highlight the fact that the structure of the virus and the biological properties are closely connected, including the resistance to physical-chemical factors, disinfectants, aseptics, etc. A complex composition of virus and the presence of the two-tier external envelope containing lipids make HIV vulnerable to many physical-chemical factors of the environment. HIV is thermo labile. At a temperature of 23-27°C in the structure of biological fluids, HIV preserves its infectious activity within 14-15 days, and at higher temperatures (36-37°C) – within 11 days. Its infectious activity is reduced 100 times as much if it is heated at a temperature of 56°C within 30 minutes, and at a temperature of 80-100°C, the virus becomes totally passive within 1-5 minutes. The virus is destroyed by all types of disinfectants used in healthcare practices; however, the most effective of them is a 6% solution of hydrogen dioxide and a 2% solution of glutaraldehyd. HIV is vulnerable to ionizing radiation, ultraviolet light, and artificial freezing at a temperature of 70°C below zero. In the blood intended for transfusion to other person, it may preserve its activity for years, and in human serum or plasma up to 10 years.

## **1.2. Pathogenesis of HIV**

HIV infection is developed after the virus has penetrated into the human body. It has been proved that HIV penetrates into the human body in three ways: sexual contacts, perinatal (from mother to her baby and with mother's breast milk), and parenteral (when the blood or its components containing the virus penetrate into the body of other person or through medical supplies

contaminated with the infected blood of an HIV infected person). Yet, the main “target” of HIV, as well as any other virus, is not only penetrating into the body, but also interacting with a sensitive cell developing its copies in it, and forming of numerous own off-springs -- viral particles. In the human body, only those are sensitive cells that have appropriate CD4-receptors on their surface. Such a cell CD4-receptor is bound to the membrane T-4 lymphocyte (T-helper, Th) in the amount of 7,000 molecules per cell, monocyte/macrophage – up to 200 molecules per cell as well as in some other body cells. Thus, the main target-cells for HIV are the very T-4 lymphocyte and macrophage/monocyte cells. However, HIV is characterized not only by lymphotropy, but also neurotropy – it is capable of penetrating into the CNS cells (astrocytes and neurons) with the help of monocytes/macrophages using the ancient “Trojan Horse” military tactics. (Fig. 1.6).

### Figure 1.6 - Cells – a Target for HIV

The process of virus replication in a sensitive cell (syn.: reproduction, lifecycle of the virus) is of great importance for the pathogenesis of HIV infection. All events taking place at the level of a sensitive cell determine the entire complex chain of pathological processes that occur at the level of the body and are clinically manifested in the form of opportunistic infections and invasions, the CNS diseases and growths.

The whole cycle of in-vitro reproduction of HIV runs for 1-2 days. Within this period, up to 1 billion of virus particles are formed, and a huge number of them are formed and maintained during their long-lasting activity. D. Ho (1996) gives the following dynamics of the lifecycle of HIV under different circumstances (Table 1.2).

**Table 1.2. HIV Lifecycle Dynamics (D. Ho, 1996)**

<b>Description</b>	<b>Duration</b>
Life cycle of the infected cell	22 days
Full HIV -1 production rate	10.3 <sup>10</sup> virus particles per day
Minimal duration of HIV-1 life cycle in vitro	1.2 days
Duration of the virus presence in the plasma (extra-cellular phase)	0.3 day
Intro-cellular phase (i.e. replication of the cell virus)	0.9 day
Average duration of the life cycle of HIV-1 in vitro	2.6 days

The process of reproduction of the virus by the example HIV-1 can be more simply described as follows: glycoprotein gp 120 (or 105 for HIV-2) named „Recognition and fusion protein” interacts with CD4 receptors and with CCR5/ CXCR4 co-receptors on the surface of the sensitive cell (Fig. 1.7).

### Figure 1.7 - HIV Lifecycle

The conformation changes of the superficial proteins and the process of fusion of the outer virus envelop with the membrane of the cell-host further occur. Uncoating of the virus. The transcription stage takes place with the participation of enzyme reverse transcriptase (RT). On the viral (genome) RNA<sup>+</sup>, as on the matrix, a negative strand of DNA is built by the enzyme reverse transcriptase (RT) and a hybrid of RNA-DNA is formed. After joining it, ribonuclease N destroys the RNA genome. The RNA breakdown products become a signal for the following synthesis to start: a complimentary positive strand of DNA on a DNA strand is formed, as a result, a two-strand DNA is formed and migrates to the core of the cell penetrating into the nuclear membrane. The process of integration of DNA into the genome of the cell is performed with the help of the viral enzyme of integrase. The integrated DNA-provirus is accepted by the cell as a group of cell genes and remains in the cell in a latent state until it becomes active. The activated DNA provirus is transcribed by the cell RNA-polymerase II into the viral genome of RNA and iRNA. Several classes of iRNA are synthesized. Also, iRNA comprising the whole genome translates the genes of inner proteins of the virus (gag, pol), and as a result, polyprotein-precursor (protein-precursors) is synthesized and subsequently split up into structural proteins. Such splitting up process is performed by HIV protease. All other iRNA, including those for the env gene, are translated into the precursors of envelope proteins subject to the proteolysis splitting up (processing) for active HIV glycoprotein, however, this time with the help of cellular protease. Then, morphogenesis takes place and the virus leaves the cell. The newly formed viruses abandon the cell by way of gemmation, in which process their full maturing takes place.

The activation of the provirus together with the expression of genes in T4-helpers leads to the burst into thousands of virus particles that leave the cell by way of gemmation through the cytoplasmic membrane and destroy it (Fig. 1.8).

### **Figure 1.8 - T-4 Lymphocytes and Virus Release by Way of Gemmation**

The death of thousands and thousands of T4 helpers results in a sharp decrease of the pool of such cells and the development of T-cell immunodeficiency. It is important to note that among the mechanisms causing the death of CD<sup>+</sup> T-cells there are ones named „direct”, and others named „indirect”. However paradoxical may it sound, only 1% of T-cells die as a result of direct causes, and mainly by reason of reproduction of HIV, and the remaining 99% of T-cells die for other reasons having no relation to the process of reproduction of the virus. In literature, T-cells that die as consequence of „indirect” causes are often called “innocent bystanders”. See the causes of death of CD<sup>+</sup> T-cells as illustrated in Fig 1.9.

### **Figure 1.9 - Causes of CD<sup>+</sup> T-cells Death**

The process of reproduction of HIV with monocytes/macrophages does not lead to the death of cells. The virus only forms persistent infection in such cells. The virus leaves the cells by way of



gemination step by step, in small amounts, specifically on the membranes of the endoplasmic reticulum and the Golgy complex, and the cells do not die in this process, but become a reservoir for the virus in the human body and in this case they play the role of a “Trojan horse” introducing HIV into the CNS as described earlier.

It should be highlighted that the role of monocytes/macrophages in the pathogenesis of HIV infection is of great importance. For example, at the stage of an asymptomatic course of the disease, the ratio of the HIV infected cells in the lungs, lymph glands, the CNS is 1 : 100 and this is the overwhelming majority (up to 90%) of the macrophage, whilst per 100,000 of mononuclear cells of the peripheral blood flow there is only one T-4 lymphocyte infected with HIV.

HIV does not produce any distractive impact on the cells of the CNS. However, 80-90% of PLHIV suffer from CNS disorders as well as degeneracy of the cerebrum and the development of encephalopathy of various degrees, including mental disability.

The process of primary active reproduction of the virus lasts 4-6 weeks after infection, further on, its intensiveness slows down, which means that most of the viruses are grounded in the state of latency. For example, at the stage of acute disease after infection, the level of virus load may be  $10^6$  of copies of the RNA virus and even higher in 1 ml of blood. The reason for that, and mainly for the occurrence and development of the state of latency of HIV infection, can be the following: the continuation of active reproduction of the virus would eventually lead to an abrupt loss of the host, and the mechanisms of HIV transmission require long presence of the agent in the human body to increase the probability of switching off to another host, thus, saving the virus as one representative of all biological species. Bearing this in mind, among the regulatory genes of HIV, the advantage is with negative regulators of the process of transcription, which leads to the suppression of intense reproduction of the agent and its transfer into the state of latency. The duration of such state for various cell-targets of HIV is different. By the way, the transfer into the process of active reproduction is different for various cells as well. Such transfer cannot be synchronized in time since a set of HIV sensitive cells is quite large.

Notwithstanding the fact that the immune system is the main target for HIV's attacks, it is also sensitive to the virus and its antigens by way of forming of specific antibodies and sensibilizing lymphocytes-effectors. After infection, 1.5 – 2 months later, and with some people 6 or 9, or 12 months, antibodies to various virus proteins appear in the human body. At first, the antibodies to the immunoglobulin of the class M (IgM) appear and then the class G (IgG) (Fig. 1.10).

### **Figure 1.10 - Humoral Response to HIV**

However, with almost as many as 10% of PLHIV, it is almost impossible to define the antibodies to the virus or some viral proteins. In many cases, almost at the same time, the antibodies to the core antigen p24 (HIV-1) or p26 (HIV-2) and to the surface antigens gp120, gp41 (HIV-1)

and gp105, gp36 (HIV2) appear. The dynamics of the humoral response to HIV depends on many factors including: infectious doses of the virus, mechanisms of infection, availability of co-factors, which determine the duration of the virus state of latency.

A high level of concentration of the virus during the early months of the disease and during the final terminal stage, when the level of the viral load may account for as many as  $10^6$  of replicas of RNA virus in 1 ml of blood and more, is a very important factor of the pathogenesis of HIV. The immune system, regardless of the suppressive activity of HIV, at the early stages of the disease infection actively suppresses its reproduction, which is why it is difficult to define the virus antigens 8 weeks after the introduction of infection and within months and years of asymptomatic development of the disease. However, since HIV cannot be controlled by normal immune processes, the malfunction of the immune system becomes more and more evident. During the process of HIV infection, the virus contaminates even more new cells of the immune system and exhausts it gradually. A long process of the development of immune deficiency gives way to the activation and appearance of numerous opportunistic infections and invasions, growths, which lead to the death of the HIV infected body.

*HIV is a disease developed as a result of a continuous virus persistence of human immune deficiency in lymphocytes, macrophages and cells of the nervous system and is characterized by slow progressing of infection of the immune and nervous system of the body, which is manifested by secondary infections, growths, sub-acute encephalitis and other pathologic signs.*

### **1.3. HIV Classification, Clinical Presentations and Principles of Treatment**

Since 2006 in Ukraine, to characterize persistent infection of HIV, a clinical classification of stages of HIV among adults and adolescents developed by the WHO has been used. The stages of HIV are determined in accordance with the criteria of assessment according to the WHO guidelines. In clinical practice, it is not recommended to use the term AIDS, the criteria of which could correspond to the 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> clinical stage of HIV depending on the patient according to the WHO classification, since the term AIDS may have a negative influence on the infected person. It should be highlighted that the concept of AIDS being the terminal stage of HIV appeared to be incorrect due to ART, which can help the patient go back from stage 4<sup>th</sup> to stage 3<sup>rd</sup> or stage 2<sup>nd</sup>.

However, the term AIDS is still used in Ukraine in epidemiologic reports that help quantitatively evaluate the evolution of HIV infection epidemics, and it may also be important when PLHIV are enrolled into certain social programs and receive some social benefits. Besides, diseases and conditions, which help detect the 4<sup>th</sup> stage of HIV, are still named AIDS determining or AIDS indicating factors, according to the legislative and regulatory documents of Ukraine.

In Ukraine, it is recommended to use the WHO clinical classification of clinical stages of adults and adolescents living with HIV (Order of the Ministry of Health of Ukraine No. 658 dated October 4, 2006), which comprises 4 stages:

## ANNEX 1. WHO CLINICAL STAGING OF HIV DISEASE IN ADULTS AND ADOLESCENTS

CLINICAL STAGE 1
Asymptomatic Persistent generalized lymphadenopathy
CLINICAL STAGE 2
Moderate unexplained <sup>a</sup> weight loss (under 10% of presumed or measured body weight) <sup>b</sup> Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulceration Papular pruritic eruptions Seborrhoeic dermatitis Fungal nail infections
CLINICAL STAGE 3
Unexplained <sup>a</sup> severe weight loss (over 10% of presumed or measured body weight) <sup>b</sup> Unexplained <sup>a</sup> chronic diarrhoea for longer than one month Unexplained <sup>a</sup> persistent fever (intermittent or constant for longer than one month) Persistent oral candidiasis Oral hairy leukoplakia Pulmonary tuberculosis Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia) Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis Unexplained <sup>a</sup> anaemia (below 8 g/dl ), neutropenia (below 0.5 x 10 <sup>9</sup> /l) and/or chronic thrombocytopenia (below 50 x 10 <sup>9</sup> /l)

CLINICAL STAGE 4 <sup>c</sup>
HIV wasting syndrome
<i>Pneumocystis pneumonia</i>
Recurrent severe bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
Extrapulmonary tuberculosis
Kaposi sarcoma
Cytomegalovirus infection (retinitis or infection of other organs)
Central nervous system toxoplasmosis
HIV encephalopathy
Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacteria infection
Progressive multifocal leukoencephalopathy
Chronic cryptosporidiosis
Chronic isosporiasis
Disseminated mycosis (extrapulmonary histoplasmosis, coccidiomycosis)
Recurrent septicaemia (including non-typhoidal <i>Salmonella</i> )
Lymphoma (cerebral or B cell non-Hodgkin)
Invasive cervical carcinoma
Atypical disseminated leishmaniasis
Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

- a Unexplained refers to where the condition is not explained by other conditions.
- b Assessment of body weight among pregnant woman needs to consider the expected weight gain of pregnancy.
- c Some additional specific conditions can also be included in regional classifications, such as the reactivation of American trypanosomiasis (meningoencephalitis and/or myocarditis) in the WHO Region of the Americas and penicilliosis in Asia.

Source: *Revised WHO clinical staging and immunological classification of HIV and case definition of HIV for surveillance, 2006* (in press).

Following this classification WHO proposed the given below names of the HIV stages

**Table 2. WHO classification of HIV-associated clinical disease<sup>a</sup>**

CLASSIFICATION OF HIV-ASSOCIATED CLINICAL DISEASE	WHO CLINICAL STAGE
Asymptomatic	1
Mild	2
Advanced	3
Severe	4

- a See Annexes 1 and 2 for further details.

**It is important to remember that with ARVs, a person living with HIV can go through the various stages at different times and go from stage 4 to stage 1 with treatment.**

Let us characterize these stages in brief, but we will be bearing in mind the fact that the course of HIV as well as the term and the onset and duration of each stage of the disease may differ

greatly with different people. A huge number of reasons contribute to such differences. Of course, among them there are differences having reference to the virus (virulence, rate of replication, probability of symplast formation, etc.), but also there are those that depend on an individual (state of the immune system, age, conditions of life, sexually transmitted diseases, stresses, risky behavior, etc.).

**Clinical stage 1.** After the incubation period, which for HIV infection lasts 2 to 6 weeks, no symptoms of the disease become apparent with the majority of PLHIV for many years (from 5 to 10 to 20 years or more). However, with a small demographic group of HIV-infected people clinical symptoms of acute viral infection become apparent. These include high temperature, sore throat, weakness, myalgia, arthralgia, sprinkle, enlargement of lymph nodes and other symptoms. All these clinical presentations of acute viral infections are often combined into one group and named “acute retroviral syndrome”, or “acute influenza-like syndrome”, or even “mononucleosis-like syndrome”. Gradually, all these symptoms are fading away, and HIV becomes asymptomatic. During this time, people infected with HIV, as a rule, feel well, live normal life, but the virus, in the meantime, is developed in the human body. Due to having no HIV symptoms, many people do not get tested and can unknowingly infect other people during the unprotected sexual intercourse and sharing of syringes to inject drugs. On the whole, the asymptomatic stage is characterized by a relevant balance between the immune response of the body and activity of the virus: the immune status is normal; the number of lymphocytes including T4-cells is at the lower limit of the norm, EIA and IB - positive.

Asymptomatic stage can be gradually transformed into persisted generalized lymphadenopathy (PGLP). Enlargement of the lymph nodes is identified spontaneously during the medical examination. In many cases, such enlargement does not worry a person infected with HIV. The symptoms are not painful, they are soft, have no implications on the surrounding cellular tissue, the color of the skin over them is unchanged. Later on, the lymph nodes become smaller in shape and tighter (harder), but still they are not painful. Some PLHIV with PGLP have high temperature (39°C and higher), can experience chills and “night sweats” (sweating excessively while sleeping).

**Clinical stage 2.** The disease progresses further. The person infected with HIV can rapidly lose weight - up to 10% of presumed or measured body weight or have recurrent night sweats. The balance between the immune response of the body and the virus activity is offset in the direction of enhancement of reproduction (viral load is increased, EIA and IB - positive) and the reduction of the number of T4-cells. Mucous membranes infection with bacteria is observed, so are herpes viruses, fungus: recurrent bacterial infections of the upper air passages, lichen, angular cheilitis, recurrent aphthous stomatitis, papular dermatitis, seborrheic dermatitis, and fungal finger nail infection.

**Clinical stage 3.** The number of T4 lymphocytes is gradually reduced (< 500 cells per mcl), which leads to the development of bacterial diseases (pneumonia) as well as viral (herpes), fungal (candidiasis of esophagus, trachea, bronchi) infections; oral hairy leukoplakia, pulmonary tuberculosis are defined. Heavy bacterial infections are formed, acute necrotizing ulcerative gingivostomatitis occurs. The person infected with HIV can spend much more time in bed due to lack of energy and symptoms – not less than 50% of the daytime. Considerable loss of weight of body is possible – > 10%, unexpected chronic diarrhea, fever for more than one month. Laboratory researches indicate not only the decrease of the number of T4 lymphocytes, but also the decrease of the ratio of CD4/CD8, anemia, neutropenia or chronic thrombocytopenia.

**Clinical stage 4.** At this stage, the person infected with HIV can spend even more time in bed (> 50% of the daytime). The reduction of the level of T4 lymphocytes from 200 to 50 cells per mcl gives evidence of severe infection of the immune system, which assists in the development of pneumocystis pneumonia, acute and chronic toxoplasmosis, cryptococcus disseminated histoplasmosis, California disease, chronic sporidiosis, micro sporidiosis, pulmonary and extra pulmonary forms of TB, candidiasis esophagitis, etc. Cytomegalovirus and other infections caused by atypical micro bacteria occur when the number of T4 lymphocytes is reduced from 50 cells per mcl to single. Kaposi's sarcoma occurs, so do cervical carcinoma, B-cellular lymphoma and other generalized and severe lesions. At this last terminal stage, the clinical manifestations are most vivid on the background of the developing viremia (viral load is considerable). As many as 80 – 90% of patients at this 4<sup>th</sup> stage experience invasion of infection into the CNS, which causes terrible headaches, darkening of vision, disorientation, mediate neurological symptomatology, lethargy, depression and progressing mental disability – dementia.

Hence, HIV is characterized by a long-lasting course of the disease; it is clinically connected with the progressing decrease of T-cells immune deficiency if not treated adequately, and this decrease eventually leads to the development of severe opportunistic diseases. Tuberculosis is the opportunistic disease that is the main cause of the death of PLHIV. Tuberculosis and other opportunistic diseases are caused by viruses, bacteria, fungus and helminth. The period of HIV disease is closely connected with the level of T-cells when tuberculosis, infection, invasions, malignant growths become clinically apparent.

It is the responsibility of the doctor to be aware of the fact that HIV is a chronic disease. Starting from the point of introduction of infection, the virus is reproduced continuously and rapidly and changes as well. Regardless of the fact that HIV in the human body is characterized by a long period of latency, it never remains in such a state in the body of a person infected with HIV but it actively develops. The level of virus load is the highest in lymph nodes and other organs containing lymphoid tissue. From the very moment of infection, the immune system suffers lesions. Important

components of the immune system of the infected person are ruined gradually but steadily, and at a certain stage, the effective immune response not only to HIV but also to other infections becomes ineffective. This is where the stage of opportunistic infections and malignant growths peculiar to stage 3 and 4 of HIV. The implications caused by tuberculosis and other opportunistic infections and / or malignant diseases may result in death of the person infected with HIV.

Treatment, care and support of the people living with HIV (PLHIV) in Ukraine are based on the following principles:

Administering therapy for all patients who need it according to medical conditions and who expressed their desire to undergo treatment, including injection drug users (IDUs), sex workers and other socio-demographic groups. Neither political nor social factors shall produce any effect on the decisions on ART.

Antiretroviral treatment programs shall include a compulsory complex and all-round assistance and support, including access for IDUs to programs on reducing harm, substitution therapy (ST), narcological assistance, rehabilitation programs with the aim to enroll and retain IDU in the treatment programs, securing adherence to the ART schedule.

Treatment of patients infected with HIV comprises a wide spectrum of types of medical aid. Health improvement of those who, at this moment in time, are not ready to undergo ART or do not have a need to undergo one, shall be achieved by way of prevention measures and treatment for opportunistic diseases and other chronic diseases as well as providing social-psychological support.

Based on an individual's awareness and readiness of each patient to adhere to the ART, the doctor should find out any possible barriers to this adherence, find the best ways to remove them.

Enrollment of PLHIV, who demonstrate high level of adherence to ART, into training other PLHIV and organizing care and support is extremely important to ensure the efficiency of treatment for HIV disease.

**Main principles of therapy for PLHIV are:**

- Prevention or postponement of the development of infection harmful to life at early stages of HIV infection manifestation, during asymptomatic stages and at stage 2 of the disease
- Establishment of favorable psychological conditions, formation of adherence to treatment
- Timely start of antiretroviral viral therapy for stage 3 and 4.
- Timely prevention and treatment for HIV related secondary diseases

Antiretroviral therapy is basic treatment aimed at the suppression of HIV reproduction. As many as 30 medical preparations are available for today on the world's pharmaceuticals market for

treatment for HIV. In Ukraine, according to the Guidelines on ART for adults and adolescents, approved with the MOH order dated 6 October 2006 No. 658, antiretrovirals are divided into three groups considering their inhibitory effect on the stage of HIV lifecycle whatsoever. One more group (fourth) has also been registered in Ukraine recently. However, in the world practice six groups of medications are now being prescribed and new medications as well as treatment guidelines are also being developed.

They all are capable of influencing HIV enzymes – reverse transcriptase (RT), HIV protease (P), and blocking the invasion of the virus into sensitive cells of the human body (fusion inhibitors).

The first group of medications includes inhibitors of reverse transcriptase - nucleoside analog reverse transcriptase inhibitors known as NARTIs (Nucleoside Analog Reverse Transcriptase Inhibitors) - zidovudine (AZT), didanosine (dideoxyinosine), zalcitabine (dideoxycytidine), stavudine (d4T) and lamivudine (RTC) are modified anomaly nucleosides, which after the reproduction cycle into tri-phosphate derivatives are capable of becoming RT inhibitors due to two known mechanisms:

- 1) suppression of HIV RNA on account of the competition with a natural medium;
- 2) suppression of the synthesis of the DNA provirus on account of the termination of DNA chains (since they do not comprise the molecule of the 3'-hydroxylic group needed for elongation of DNA).

Depending on the type of nucleoside, the medications can be combined into subgroups, which are being constantly updated and regularly re-approved with related regulatory documents of the Ministry of Health of Ukraine.

The second group of medications includes non-nucleoside reverse transcriptase inhibitors abbreviated to **NNRTIs**. Unlike **NARTIs**, interfering with the metabolism of HIV infected cell, the medications of this group do not suppress but rather discontinue the activity of RT. **NNRTIs's** group medications bind the RT enzyme and form a stable inactive complex “enzyme-medium”.

Inhibitors of HIV-specific protease (proteinkinase) refer to the third group of antiretroviral medications. Their anti-HIV effect is of a significant selective character due to a high specific interaction with HIV-protease. A protease inhibitor's molecule isolates finite peptide areas of each monomer of enzyme, thus it prevents the possibility of interaction and a fatal compound of active homodimer of HIV protease. By their nature, all HIV protease inhibitors are complex chemical compounds of the group of synthetic oligopeptides, modified by various active substitutes.

The fourth group is the most recent and it comprises fusion inhibitors.



Enfuvirtide (T-20, Fusion) – is the “father” of the group of fusion inhibitor medications. This protein is quite large consisting of 36 amino acids; it is capable of binding to gp41. The medications suppress the earliest stages of HIV reproduction – the stage of fusion of the envelope of the virus with the membrane of the sensitive cell. From the medical point of view, the appearance of the new medication with a novel mechanism of activity has become an important and the only discovery in the last seven years. The firm La Roche received the Galen award for developing this complex medication in 2001. This medication was registered in the USA in March 2003. The forecast is that enfuvirtide will be extremely useful in application for treatment of patients for whom the possibilities of classical HAART have become exhausted (Table 1.3).

**Table 1.3. 2007 Antiretroviral Medications**

Medication Group	Medications
Nucleoside Analog Reverse Transcriptase Inhibitors - <b>NARTIs</b> )	<ol style="list-style-type: none"> <li>1. Zydovudine, azydotimidine, retrovir, tymazide (ZDV, ART);</li> <li>2. Didanosine (dideoxycytosine, ddI, videx);</li> <li>3. zalcitabine (dideoxycytidine, ddC, hivid);</li> <li>4. Stavudine (d4T, zerite);</li> <li>5. Lamivudine, epivr (RTC, )</li> <li>6. Phosphaside, nikavir (F-AZT);</li> <li>7. Abacavir, ziagen (ABC);</li> <li>8. Combivir (CBV), trizivir (TZV), epsicom, cyvexa (ABC+RTC).</li> </ol>
Non-nucleoside reverse transcriptase inhibitors - <b>NNRTIs</b> ).	Delaverdine (DLV), rescriptol; Efavrence (EFV, stocryne, sustiva); Nevrapine (NVP, viramune).
HIV-specific protease inhibitors (protein kinase)	amprenavir (APV, agenarase); atazanavir ( AZV, reatase); indinavir (IDV, cryxivan); nelfinavr (NFV, virasept); ritonavir ( RTV, norvir); squonavir (SQV HGC, INV, invirase; SQV SQC, FTV, fortovase); tipranavir (TPV, antivus); fosamprenavir (FPV, lexyva, telzir); Complex medication – lopinavir+ritonavir (LPV/r, caletra).
Fusion inhibitors	1. Enfuvirtide ( T-20, Fusion)

Zydovudine or AZT (**RTNI**) was the first among antiretroviral medications introduced into clinical practice and one that opened a new era of antiretroviral therapy in 1987, since which time it had been used for HIV mono-therapy, which is known now to be not recommended and harmful.

Since 1992 dual-therapy had been introduced into practice, i.e. two medications of the first group had been used at a time.

Highly effective antiretroviral therapy (HAART, when 3 or more medications are used at a time) for treatment of people infected with HIV was introduced in late 1995 in treatment for AIDS, and the first representative of the HIV protease inhibitors group was produced. It was saquinavir. The introduction of HAART made it possible to reduce virus load extensively— almost to the level that can hardly be defined with the majority of patients.

It is important to note that despite enormous efforts of the world's scientific community, no medication will completely cure PLHIV, or in other words, rid the human organism of HIV, has been developed yet. All the above mentioned medications are capable of:

- Reducing the level of virus in blood (virus load)
- Regenerating T-cells and improving the immune system functions
- Minimizing risks of HIV transmittance from mother to her baby
- Prolonging the life span of PLHIV and improving their living conditions

Plus, it is important to remember that there are other medications that are needed to prevent opportunistic infections. Bearing this in mind, it is necessary to adhere to the principles of continuity of treatment and guidance of the process of treatment, i.e. perform laboratory monitoring of virus load and the quantity of T4-cells during HAART (Fig. 1.11).

### **Figure 1.11.- Treatment Monitoring**

Identification of the level of virus load substantially adds to the existing methods of laboratory monitoring of PLHIV treatment, the key parameters of which in practice are mostly the definition of the quantity of T4-cells, anti-p24 antibodies and the definition of p24-antigenemia. In the world's practice, the test-systems based on EIA are widely used. A virus load (VL) testing is performed by using the polymerase chain reaction (PCR) for the direct quantitative definition of HIV genetic information in human serum or plasma. Unlike the immune enzyme techniques that define the response of the human immune system by way of defining the presence of specific antibodies to HIV, the PCR technique defines the presence of HIV nucleic acid (RNA/DNA in human serum/plasma), which indicates the level of viremia and was named "virus load". The gist of the PCR technique lies in multiple enzymatic replication of the selected area of nucleic acid. Such amplification allows getting and easily identifying of millions of copies of the selected object from the minimum number of copies. The key component of the PCR technique is the nucleic acid of the virus itself, i.e. the RNA HIV1, 2 genome.

The unquestionable fact is that the development and introduction in practice of new anti retroviral medications opened a new page in the history of HIV. HAART gave millions of people

for whom etiotropic treatment became accessible the opportunity to live an active life, prolong life span, work, and be like any other normal people.

Yet, many people in the world have been experiencing problems concerning the organization of HIV treatment and risks of ART:

- Lack of access to medication, including that of opportunistic infections
- High prices of some medications
- Medication is not consistently stocked
- Lack of access to substitution therapy for IDUs
- Homelessness
- Fear of others to find out HIV status when taking pills
- Lack of opportunity to monitor the treatment effectiveness at a required level
- Lack of adherence to treatment,
- Side effects of medications
- Necessity to take ART regularly and constantly during the life span
- Formation of HIV resistant strains to the existing medications

Non-adherence to treatment leads to extremely unfavorable consequences for a person living with HIV: increases the risk of HIV to adapt quickly to medications and further advance of the disease, complicated therapy requiring frequent changes of treatment schemes increases its cost. Resistance to medications is formed when the concentration of medications in human serum is not high enough to discontinue the process of replication of the virus and when HIV mutant strains get benefits over wild-type viruses that do not have mutations of resistance. It is caused by violating of the regime for taking prescribed medications, i.e. interruptions, especially the repeated ones. The development of HIV resistant forms is harmful not only for a patient, but also for health protection and economy. The contagion of the resistant virus enhances the possibility of infection with already resistant HIV forms, which complicates treatment of patients.

It should be mentioned that in Ukraine ART was first introduced in 2001, i.e. 14 years after the beginning of the era of antiretroviral treatment. The beginning of ART for adults and adolescents living with HIV shall be in accordance with the Clinical Protocol approved by the Ministry of Health of Ukraine. The ART Clinical Protocol for Adults and Adolescents takes into account the recommendations of WHO, special features of the healthcare system in the country, spectrum of the antiretroviral medications registered in Ukraine, possibilities of control over the performance of therapy. According to the Clinical Protocol, the tasks of ART are to suppress VL to the level that cannot be defined (best < 20-50 copies HIV RNA /ml in plasma) for a maximum long period of time (years) and increase the number of T4 lymphocytes at least by 50 cells/mcl as much

per year to the level until this indicator considerably exceeds the figure of 200 cells/mcl. The main indicator for making a decision about the commencement of performance of ART in Ukraine is the number of T4-lymphocytes, and VR serves as a supportive factor and is taken into consideration as one more additional criterion for the commencement of ART.

The anamnesis of HIV-indicative diseases, the current fourth stage of HIV in accordance with the classification of WHO is considered to be sufficient grounds for the beginning of the performance of ART when treatment is prescribed. The clinical tasks of ART include preventing or decreasing of occurrences of the disease connected with HIV, reducing of the risk of death caused by HIV. Preventing the occurrence of resistance of HIV to medications or hampering it is yet another task of ART. It is important to remember at all times that ART's aim has been to prolong the adequate lifespan of a patient living with HIV.

In Ukraine, it is recommended that ART be started taking into consideration clinical and immunological criteria, which meets the standards of WHO. (Table 1.4).

**Table 1.4. Recommendations Relevant to Starting ART for HIV-infected People(WHO, 2006)**

<b>Clinical stage according to WHO's classification</b>	<b>Level of CD4 cells</b>	<b>Recommendations</b>
I	< 200 cells/mcl <sup>-1</sup> 200 cells/mcl <sup>-1</sup> - 350 cells/mcl <sup>-1</sup>	Subject to treatment Treatment considered <sup>(1.2)</sup>
II	< 200 cells/mcl <sup>-1</sup> 200 cells/mcl <sup>-1</sup> - 350 cells/mcl <sup>-1</sup>	Subject to treatment Treatment considered <sup>(1.2)</sup>
III	< 350 cells/mcl <sup>-1</sup>	Subject to treatment
IV	Regardless of the level of CD4	Subject to treatment

Note:

- (1)When the number of T4-cells is about 350 cells, it is recommended to start discussing the near perspective of the start of ART with a patient and prepare him or her psychologically. It is necessary to prevent the occurrence of opportunistic infections posing a threat to life. Weighty arguments for the start of treatment include preserving of functionality of organs and systems, reducing of duration of disability due to the hospitalization for treatment and reducing of huge costs for diagnostics and treatment of a person living with HIV.
- (2)The level of VL is associated with the reduction of the number of T4 lymphocytes. If VL is too high (> 100 000 replicas of HIV RNA/ml plasma), there is a very high degree of probability of the decrease of the number of T4-cells. Therefore, if VL is high, it is recommended that ART be started when the number of T4 lymphocytes is < 350/ cells/mcl.

At present, PLHIV can be provided with ART in all regions of Ukraine. As of June 1, 2007, for example, ART has been provided for 5,729 PLHIV including 731 children. The ratio of the Ukrainian patients who survived 12 months after the start of ART is about 85.2%. Among the problems associated with treatment and risks of ART in Ukraine, we can mention late defining and attendance of PLHIV to AIDS centers for hospitalization treatment and observation (at a terminal stage), lack of access to ART in prisons since there is no model of providing complex therapy and mechanisms of receiving medications from the AIDS centers in Ukraine. A separate problem that requires attention is the problem of readiness and compliance to ART of the Ukrainian patients. Compliance is a person's capability to timely take medications as prescribed by the schedule of treatment. To form compliance, the following factors such as motivation, psychological support, clean-cut scheme of treatment, and well-developed schedule for taking medications and, indeed, the family members and close ones' support should be taken into consideration.

If a patient lost faith in positive results, treatment can hardly be a success. Treatment may not be effective if a patient is not happy with the results of HAART and lacks experience in taking medications in time and as prescribed by the scheme and attempts to conceal his or her HIV status from his or her family members and close ones. A recent research demonstrated that it is especially important for positive people to take ART if they drink a lot. Drug and alcohol addiction totally changes peoples' behavior. Yet, research shows with access to specialized support and substitution therapy and monitoring they can be prepared to the correct and timely and continuous use of ART.

#### **1.4. Techniques of HIV Laboratory Diagnostics in Ukraine**

Diagnostics and registration of first occurrences of HIV and AIDS encouraged the development of techniques of HIV laboratory diagnostics of such infections, including immunological (inclusive of serologic), virological, hematological, etc. Modern HIV laboratory diagnostics is based, first of all, on the methods of indication of the virus, its antigens, genetic material, other components and defining of antiviral antibodies.

At the bottom of the virological methods there lies the process of cultivation of lymphocytes taken from a patient or a virus carrier or co-cultivation of lymphocytes with stimulated lymphocytes from non-infected people or sensitive lines of cell cultures. Cell cultures are examined, from time to time, for RT HIV and/or viral antigen. However, to define and identify the virus is not easy in most cases, which is connected with both the transitory character of viremia and the irregular excretion of HIV. The virus and its antigens are easily defined in the areas where their concentration is quite high. Virological methods require long time and special conditions for identification (electronic, luminescent microscopy), personnel possessing the necessary qualifications, specialized and well-

equipped laboratories; these methods are complex and have a restricted effect. Nowadays, the virological methods have been used only for scientific research purposes.

Achievements in the field of molecular biology and genetics have made it possible to use the methods of genetic engineering to diagnose HIV infections. The PLC methods, the method of hybridization of nucleic acids and other molecular biological methods make it possible to define an HIV genome built in the genome of lymphocytes when viral genes are present in one of 5,000 cells amid the absence of antibodies in blood. In some cases, (diagnostics of infection in the seronegative period with children born by mothers living with HIV) genetic engineering methods have become quite effective. Nevertheless, we cannot say for sure that the use of such methods on a large scale for tasks of epidemiological surveillance for HIV have the advantage of the methods intended for defining antiviral antibodies. When using molecular biological methods, erroneous results may occur (false positive and false negative), besides, such methods are expensive to use and require special equipment, different arrangements of the reaction are sensitive to the factors of the environment. Therefore, nowadays, the PCR method is used in many cases as an additional, auxiliary method to help solve tasks of epidemiological surveillance for HIV.

On a general list of laboratory examinations that ensure defining of HIV, the lead, undoubtedly, belongs to the methods of serum diagnostics aimed at the definition of antibodies to HIV by means of diagnostics test systems, i.e. special assay kits for defining infection markers.

According to their intended use, the test systems can be viewed broadly as two types -- screening and confirmatory. To date, more than 40 companies produce over 100 items of screening test-systems throughout the world.

The material for serological studies can be serum (plasma), saliva, lacrimal fluid, cerebrospinal fluid, urine, secreta of genital organs, i.e. all biologic fluids of the body that may contain HIV, but the most appropriate matter for laboratory examinations is considered to be human serum or plasma.

An enzyme-immune assay (EIA) and an immunoblot assay (IB) are used as key methods. According to their diagnostics properties and informative value, EIA and IB have the highest rate of performance.

Most of enzyme-immune test systems for defining of HIV antibodies are based on the principle of the classic Enzyme Linked Immunosorbent Assay (ELISA). Polystyrene or polyvinyl chloride with the immobilized HIV antigen on its surface are used as the solid phase (immunosorbent) in the assay. The enzyme conjugate is antibodies to human globulins (antispecies antibodies), protein A staphilococcus aureus or synthesized or recombinant peptides chrome peroxidase- labeled or alkaline phosphatase-labeled. The chromogen solution (for example, ortophenilendiamin (OPD) solution) is used as an indicator for identifying the antigen-antibody

complex. The higher the presence of antibodies to HIV, the more intense coloring and the higher the value of the optical density (OD), which are examined photometrically. Enzyme-immune test systems can also be designed on the principle of competitiveness of EIA: first antibodies and then the concentrated antigen are immobilized at the solid phase. The decrease of the optical signal that takes place at the phase of blocking of reaction in the course of competition for an antigen between antibodies of serum and the direct conjugant indicates the presence of anti-HIV bodies in the examined sample. However, such systems give way to the test systems built on the basis of the classic EIA principle in terms of sensitivity.

It is worth while mentioning the fact that the first test-system for immune-enzyme defining of antibodies to HIV-1 was patented in the USA in 1985, and in 1988 in that country, 7 commercial diagnostics test-systems for EIA were authorized to use. Concurrently similar test-systems were produced and used in France. The short but rich in events history of the development of diagnostics kits for defining of antibodies to HIV is represented by several generations of test-systems that have been constantly improved in the direction of further improvement of the reagents involved, anti-agents and conjugates, standardization and automation of reactions, more comprehensive and competent interpretation of the results produced.

The creation of conceptually new conjugates (recombined and/or synthetic enzyme labeled) allowed defining of both IgG and IgM, which was introduced into the test-systems of the third generation and the use of which made it possible to shorten the period of “serological window”, on average, down to 20 days. Besides, in the kits of the third generation at a solid-phase, as a rule, fiber-entrapped antigens with determinants that are specific not only for major subtypes of HIV-1, but also for subtypes of O HIV-1 and HIV-2 were sorbed. The factor of sensitivity of the third generation test-systems is 99%. At present, the test-systems of the third generation are the ones that are widely used for screening of HIV as well as for diagnostics purposes in Ukraine.

Yet another success in the development of test-systems based on EIA was the development of test-systems of the fourth generation intended for simultaneous defining of antibodies to HIV and antigen p24 of HIV-1, the so-called multiple-unit test-systems. According to firm-manufacturers, they are capable of defining a marker of HIV 4-8 days earlier in comparison with the use of the third generation kits. EIA tests of the fourth generation make the period of “serologic window” 2 weeks shorter on average. The sensitivity rate of the test-systems of the fourth generation is 99.6%.

After the appearance of antibodies to HIV in the infected person’s blood their quantity is growing within 3-5 months at an early stage of infection until it reaches its peak. At the same time, avidity of antibodies remains quite low and becomes larger in parallel to the advance of HIV. Depending on the number of existing antibodies or their avidity, HIV of a particular patient may be

referred to as “recent” or “established”. Defining of the occurrence of recent HIV has become possible thanks to a new Sensitive/Less-Sensitive Assays, S/LS strategy, which is based on the use of a combination of different generations of enzyme-immune assays. Such S/LS strategy allows defining of possible dates of infection by way of defining of antibody titers to HIV or their avidity using the test-systems of the third generation in combination with modified lysate test-systems of the first generation or rapid assays.

In HIV-1 positive patients’ serum, virus neutralizing antibodies are defined to HIV gene products. The most immunogenic proteins of HIV are surface glycoprotein gp160, gp120 (env gene) as well as trans-membrane protein gp41 (env gene). The antibodies to such proteins are defined with as many as 98% of PLHIV and they are more stable than antibodies to other antigens. The antibodies to major intrinsic proteins of HIV-1 -- p17, p24 (gene gag) are defined with about as many as 75% of patients living with HIV and less than 50% of patients with clinical manifestation of AIDS. The dynamics of the formation of antibodies at HIV is connected with the clinical stages of the disease. The first to appear are antibodies to proteins p17, p24, p55 (gene gag products) with almost two-thirds of patients living with HIV on week 3-6 after infection. Then antibodies to the products of gene pol (p55, p66, p10, p33) and env (gp160, gp120, gp41) occur. In the course of time, the level of antibodies to protein p24 and other products of gene gag is reduced, which correlates with post-primary antigenemia and general advancing of the disease. Thus, at various stages of HIV, antibodies to various antigens of virus can be defined.

HIV is characterized by the presence of the so-called “serological window” period (it is also named seronegative, latent, infectious, diagnostics window), when there are no antibodies to HIV in human serum or their number is so insignificant that they are not defined by test-systems intended for defining antibodies. The period of the “serological window” precedes the occurrence of antibodies in the body of a person infected with HIV. As a rule, the first to occur are immunoglobulin of class M (IgM) to proteins encoded by gene gag, which circulates during the viremia. Five-seven days after the occurrence of IgM-antibodies, antibodies of class IgG to p24 and gp120 are synthesized. While analyzing the occurrences of HIV with the exact date of infection (for example, due to infusion of the infected blood), it was found out that sero-conversion may take place 3-12 weeks later. Information about a long seronegative period with PLHIV has been lacking support from any known evidence in the literature over recent years.

To maximize the process of defining of infection in the course of laboratory examinations, it is necessary to decide what test-system to use. Based on modern knowledge, scientific, medical, and economical criteria are applied to assess the quality and suitability of test-systems. Scientific criteria of the method choice comprise defining of sensitivity rates, specificity values, and the production of results by test-systems.



Sensitivity (%) is an index that describes the ability of a test system to define a maximum quantity of truly positive serums and reflects the number of infected people who can be examined by means of a certain test-system.

Specificity (%) is the ability of a test-system to define the needed component it is capable of defining of, i.e. it is the index that describes the possibility of the diagnosticum to register the minimum available quantity of false positive serums.

The interconnectivity between sensitivity and specificity is that the improvement of one index triggers the degradation of the other one.

According to the recommendations of WHO experts, the indicators of sensitivity and specificity of the diagnosed specimen should meet the minimal requirements – at least 99% and 95%, respectively. Depending on the target of testing, more or less sensitive special test-systems may be used. HIV diagnostics is based on the ground of phases and succession of the EIA performance: the first test-system should have the highest sensitivity rate (to keep the number of false negative analysis data as low as possible), and the other ones should have a higher level of specificity compared to the first test-system (to reduce the number of false negative results of examination).

According to the recommendations of WHO, USA CDC (Centers for Disease Control and Prevention), and USA FDA (USA Food and Drug Administration), the rate of sensitivity is defined on the basis of the produced results in the course of testing of a static true quantity of serum of patients living with HIV at different stages of the disease, patients with the pathology inherent to certain area, patients with acute viral infections, people with a high risk of HIV; commercial sero-conversion panels (for example, BBI, NABI). The definition of the specificity of a test-system is based on the test results of an ample quantity of randomly selected healthy donors taking into account the initial (IR – initial reactivity) and repeated (RR – repeated reactivity) reactivity of the received positive samples with further validating of the results. While estimating sensitivity and specificity, the indeterminate results are not taken into account.

Sensitivity and specificity of test-systems may be near or equal to 100% when they are defined on standard panels, which can hardly ever be actually achieved in an HIV diagnostics laboratory setting. There is no diagnostic that would ensure a 100% sensitivity and specificity of examination. For example, according to the world's literature, the risk of not defining serum of a person living with HIV is 1 instance per 493,000 donor blood tests. One of the reasons of false positive results may be the presence of the serological window. As said earlier, depending on the ability of the diagnosticum to define antibodies to HIV, the test-systems are grouped according generations.

The reasons for false positive reactions in EIA may include:

- Presence of certain cross-reacting leucocytic antigens in the body of a patient
- Presence of autoreactive antibodies
- Presence of antibodies to rheumatoid factors
- Antibodies to Epstein-Barr virus
- Injections of immunoglobulin medications (full-transistorized sero-conversion)
- Vaccination against any viral disease (influenza, hepatitis B, etc.)
- Presence of growths in the body of a patient
- Immune deficiency of any other nature (not HIV).

False negative results of EIA, as a rule, can be produced when the human blood is examined (tested), which is in the period of “serological window” (see above) and antibodies to HIV, the number of which is small. In social groups with a low risk of HIV, false negative results may be produced in 0.001% of occurrences.

However, beside biological factors, the reason for producing of false results during examinations for HIV may be the examinations held in the places where HIV is not widely spread among people. In such case, the number of false positive results, sometimes, may be even higher than the number of truly positive results. It is a fact that the number of false positive results is notably higher in socio-demographic groups with a low level of risk of HIV in comparison with those of a high risk of HIV.

Sensibility and specificity values of test-systems are constant and preset and do not depend on the contagion of HIV. However, on the whole, the ultimate results of examinations are influenced by both the contagion of HIV and the qualitative characteristics of the test-system, which reflects values as a predictive value of assay. A positive prognostic value of an assay (PPV - positive prognostic value) – is the prediction of the fact that people with a positive result of EIA truly have antibodies to HIV in the blood. A negative prognostic value of an assay (NPV - negative prognostic value) – is the prediction of the fact that that people with a negative result of EIA do not have antibodies in the blood.

The higher the level of contagion of HIV among people, the higher the level of prediction that a human being with a positive result of EIA is truly infected (i.e. the higher is EIA). With the spread of HIV, the part of serum specimens with false positive results of the assay is reduced, and the prediction that a human being with negative results of the assay is not truly infected, is reduced (i.e. the lower is EIA). Thus, during the examination of the socio-demographic groups among which HIV is widely spread, the most effective are the test-systems with a high value of EIA. If the prediction of HIV is low, then the test-system with high EIA is more useful. Table 1.5,

conventionally titled “Two by Two”, shows the relation between the features, which include: sensitivity, specificity, prognostic value of the results of assay, both positive and negative.

**Table 1.5 “Two by Two”**

HIV status of patient		Assay results:	
		positive	negative
Confirmed HIV status of patient	positive	positive	false negative
	negative	false positive	negative

**Note:** The table shows the relation between the features, which include: sensitivity, specificity, prognostic value of the results of assay, both positive and negative.

Sensitivity

= number of positive results / (number of positive results + number of false negative results)  
 = probability of a positive result if HIV is defined

Specificity

= number of negative results / (number of negative results + number of false positive results)  
 = probability of a negative result if HIV is not defined

Predicted positive result

= number of positive results / (number of positive results + number of false positive results )  
 = probability of HIV at positive results of assay

Predicted negative result

= number of negative results / (number of negative results + number of false negative results )  
 = probability of a negative result of assay if HIV is not defined.

Thus, EIA being an up-to-date method of laboratory diagnostics for HIV is characterized by certain values and has a number of advantages and disadvantages, which the doctor should be aware of, especially when he or she is involved into pre-assay and post-assay counseling, since the diagnostics and reliability of its results are of great interest to a patient (Fig. 1.12). The main disadvantage of EIA, among others, is the probability of producing a “false positive” result and the necessity to perform additional verification (confirmation) examinations.

### **Figure 1.2. EIA Advantages and Disadvantages**

At present, the “Golden standard” for confirmation of the specificity of the produced positive results of an HIV assay using the EIA method is immune blotting (Western Blot – WB),

established on the basis of a combination of electrophoresis in gel and the antigen-antibody reaction. In poly-carbamid gel, the distribution of pre-cleaned antigens of HIV in accordance with the molecular mass takes place; then, they are gathered on a nitrocellulose membrane and cut into strips. The material under examination (human serum or plasma) is placed on the strip, if the sample contains specific antibodies, they are bound with corresponding (complimentary to them) strips of antigens. The result of such interaction is determined by way of successive adding of the conjugate, labeled enzyme and reducer. The interpretation of the results of investigation is performed in accordance with the guidelines of a particular test-system. In addition, there are unified evaluation criteria for the examined results produced with the use of the immune blotting method (IB) (WHO, CDC). For example, experts from WHO (1998) recommend using the following criteria:

- positive result – defining of antibodies of two of the following three groups of virus proteins in serum – env, gag or pol.

- negative result – antibodies to virus-specific proteins are not present;

- indeterminate result – defining of antibodies in serum only to proteins of one group – either gag or pol. As a rule, the indeterminate reaction is associated with the presence of product-proteins of the expression of genes gag HIV-1 p15/17; p24 and p55 and it may produce both a false positive reaction and the probability of HIV.

Commercial test-systems intended for examinations using the IB method differ by the nature of viral antigens, methods of distribution of proteins in gel and transmittance of antigens onto the nitrocellulose membrane, as well as by kinds of conjugate and chromogenic substrates. On this basis, test-systems for IB as well as test-systems based on EIA have different sensitivity. The doctors should bear in mind that for IB as a confirmatory assay, the problem of the “indeterminate result” is essential. One of the potential reasons may be the examination performed during the period of acute infection (early sero conversion) when antibodies to HIV are not represented for all main antigens. False positive results are peculiar to IB, too. False results in IB occur:

1. at infection of viral lizyte by cell antigens when transferred on strips
2. during pregnancy of a woman under examination;
3. at a high level of bilirubin in the examined specimen of serum or plasma;
4. at haemolysis of the specimen of serum or plasma.

It is a known fact that as many as 20%-33% of negative results in EIA of serums in IB (WB) give an indeterminate result. Besides, almost as many as 20% of serums that have been under multiple examinations in EIA, each giving a positive result, can also be evaluated in IB (WB) as a negative result.

Such patients with an indeterminate result in IB (WB) should undergo a repeated assay within next 2-3 months, which means quite a long period of doubts and unrest for a patient, and an additional pre-test and post-test counseling.

Along with the diagnosticum based on the classic IB (WB) method, there also are the so-called “linear assays” that are used to validate primary positive results of EIA as well. These assays differ from classic ones by the use of recombinant or synthetic peptide antigens transferred onto nitrocellulose strips (sheets). These linear assays are considered to be more specific in comparison with the classical IB method since they do not contain cell components capable of cross-reacting with the components of the examined samples of serum. For today, such diagnostics assays have been registered in Ukraine.

A procedure for record-keeping, registration of diagnostics aimed at defining antibodies to HIV are performed in conformity with the “Guidelines for Establishing of HIV Diagnostics Laboratories”, 2002.

### **1.5. HIV Rapid Assay. Simple /Rapid Assays.**

To perform examinations aimed at defining of antibodies to HIV using EIA and IB, the availability of present-day laboratories with all necessary equipment – HIV diagnostics laboratories – should be secured. However, quite frequently, performing of such examinations is difficult or impossible, mainly in small hospitals or laboratories on the periphery. In such cases, for urgent examination of pregnant women, a small number of patients, especially in emergency, and private individuals with the aim to define the level of HIV, it makes sense to use the so-called simple/rapid assays. They are often called “assay in pocket”, “lab in pocket”, “test in situ”, “test at patient’s bed”, and “basic rapid-test”.

Simple/rapid assays for defining antibodies to HIV are simple sets of diagnostic tools (test-systems) the use of which makes it possible to produce the overall result without using special equipment for EIA within a short period of time – within 2 minutes or one hour. Minimum requirements to the equipment and technically simple procedures for their performance as well as interpretation of the results of examinations are promote their extensive use.

Most of simple/rapid assays are ready for use instantly, provided with an internal procedure control system that confirms the quality of performing assays to make sure that all components and reagents worked correctly and that the material for examination was used in the right way, accordingly.

Samples of the peripheral blood, serum or plasma can be used as a material for examination. Rapid assays for defining of antibodies to HIV in the samples of saliva and urine have also been developed and used. Modern rapid assays are conditionally divided into two groups depending on

which method is used for performing an assay. The first group (“dot blot” or “flow through”-assays) comprises diagnostic kits in the course of which use the examined biological substrate is placed on the surface of the solid-phase, the overall result is produced in the form of a blot or strip. The second group, called “lateral flow” assays, comprises diagnostic kits in which the membrane (for example, plastic Gabel-Top or nitrocellulose strips) with antigens are sopped into the examined sample, which diffuses in the membrane. Most rapid assays allow defining of antibodies to HIV-1 and HIV-2. The assays also presume the formation of a control dot or strip (so-called test area – T), which allows to check if the assay was performed correctly.

There also is another distribution group for simple/rapid assays for HIV. They are:

Dot-blot or flow-through assays

Rapid agglutination assays

Immune-chromatographic assays

The rate of sensitivity of most of these assays is about 99% and specificity is 98%.

When taking decisions on assays for rapid defining of antibodies to HIV, one should take into consideration a number of factors, and mainly:

- declared characteristics of a rapid assay, i.e. ability to selectively define antibodies to HIV-1, HIV-2, group O HIV-1, overall antibodies;
- diagnostics characteristics of an assay;
- simplest algorithm of performing an assay;
- time needed for examination and period of validity of a rapid assay;
- cost of a rapid assay;
- personnel possessing the necessary qualifications to perform an assay;
- possibility of further verification of the results of a primary assay in the laboratory authorized to perform confirmation assays.

It ought to be remarked that even though the use of rapid assays does not require special equipment for performing the assay, the cost of a single examination is higher than the use of the traditional EIA method. Moreover, the results produced are visualized, i.e. their results are interpreted subjectively (doctors have an individual approach to interpret the results) and there is no confirmation of the results of the assay in writing at that. Bearing this in mind, the situation needs to be considered when a rapid assay is used to make sure that the level of qualifications of experts is high enough to perform such examination.

***Dot-blot or flow-through assay*** – makes it possible to produce the results in 5-10 minutes. Usually, in such assays, antigens are lacking vitality to adsorb on a nitrocellulose membrane in the form of a patch or dot, sometimes in the form of a stripe. The testing procedure starts with the introduction of the buffer solution to moisten the membrane, then 1-2 drops of blood are taken

(from the finger or black blood), plasma or serum, for some HIV assays even saliva can be used. After that, a conjugate and a substrate are gradually added within very short intervals and the reaction is stopped by a stop-reagent. Most dot-blot assays have internal control systems – control dot that confirms correctness of the reaction, and that all reagents worked properly, and that all components were added successively in the course of examination.

One of the most rapid, reliable and economically accessible methodologies of the dot-blot testing is ORGANIC's kit - the ImmunoComb. In the past twenty years, this technology has not only made a lodgement in the leading world's countries including USA, France, Japan and others, but also has been used according to the WHO recommendations, in international programs on control over sexually transmitted diseases and AIDS.

In addition to test-systems devoted to defining antibodies in serum and plasma, the same firm ORGANIC has developed test-systems intended for defining antibodies in other biological fluids, specifically in saliva.

ImmunoComb II HIV-1 and 2 Saliva is a system that includes a diagnostic kit for rapid quality and selective defining of Ig antibodies to HIV-1 and HIV-2 using human saliva. Like any other testing technologies, the ImmunoComb II HIV-1 and 2 Saliva testing system is a kit of assays for the EIA indirect solid-phase. The solid phase is represented by a comb with 12 teeth. Unlike other testing, each tooth has 3 positions of application:

Upper dot-blot -- goat's antibodies to human immunoglobuline (internal control system),

Middle dot-blot -- HIV-2 synthetic peptides,

Lower dot-blot -- HIV-1 synthetic peptides.

The starting procedure for the assay is analogous to a standard methodology of use of the ImmunoComb test-systems intended for defining of antibodies. The difference is that human saliva is used as the biological object for the assay, and for sample collection of which the tanks of SALIVA COLLECTION KIT are used.

With the pupose of confirmation of the proper operation of the kit and correctness of the results produced, the following three conditions should be observed:

Positive control should lead to the formation of 3 blots on the tooth of the comb.

Negative control should lead to the formation of the upper blot (internal control system) and not any other.

Each examined sample should lead to the formation of the upper blot (internal control system). This confirms that the sample was introduced. Should one of these three conditions be not observed, the results shall be considered incorrect, samples and control sampling should be examined one more time.

The appearance of only the upper blot (internal control) shows that there are no antibodies to HIV-1 and HIV-2 in the sample. The middle blot with distinct color shows that there are antibodies to HIV-2. The lower blot with distinct color shows that there are antibodies to HIV-1. Sometimes, high concentrations of antibodies to HIV1 or HIV-2 lead to the formation of a blot with pale or dim color as compared to more intense color of the homologous antigen. In case of co-infection of HIV2 and HIV-2 , both blots have the same depth of color.

It is worth mentioning the fact that the presence of antibodies to HIV-1 or HIV-2 in the examined samples should be confirmed by verification examinations. Any indistinct coloring should be considered a positive reaction and subject to further examinations.

In this manner, we may say that dot-blot testing can be performed in a laboratory of any level, it does not require expensive and complex equipment to produce testing results. At the same time, the results produced by the ImmunoComb kit are considered to be highly specific and correct, because for the arrangement of assays, the same components and biotechnologies for other enzyme-immune assays are used.

**Rapid agglutination assays.** As is clear from the name of the tests, they are based on the principles of agglutination of particles of latex or gelatine covered with antigens HIV 1/2 and the time needed for such a test is from 10 to 60 minutes. Plasma or serum are the materials for examination. If virus-specific antibodies are present in serum, then the interaction between antigens and antibodies takes place with the formation of a specific complex visualised as “stitching” or agglutination of the particles of latex. The presence of agglutination is considered to be a positive result. And, vice versa, the absence of agglutination is considered to be a negative result (Fig. 1.13).

### **Figure 1.13. SFD HIV 1/2**

**Immune chromatographic tests.** At the bottom of the immune chromatographic tests (ICT) there lies a specific interaction of antigens and antibodies on a chromatographic membrane after its moisturizing with a fluid of the examined sample or buffer solution. Such interaction takes place due to diffusive transfer of the ICT indicator component colored with collaurin, which was applied on the membrane in advance and antigens or antibodies of the examined sample after the latter had been applied on the membrane. To visualize a specific immune reaction, in a certain area-strip of the chromatographic membrane, the fiber-entrapped components introduced in advance of additional immunological reaction enable concentrating of the coloring material in the form of a stained strip. Inserted into the system (slightly oversized), the colored immune component indicator diffuses in the chromatographic membrane further from the place of manifestation of the immune reaction and stops at the control area-strip due to the immunological interaction with the fiber-entrapped component of different specificity there. The coloring of the control strip shows that the testing took place correctly. When there is a testing for HIV, on a certain area of the



chromatographic membrane (zone S), whole blood, or serum or plasma are applied. Further on, mixing with corresponding components of the specific immune reaction, they diffuse on the membrane. In the areas where there are tightly sorbed antigens of HIV-1 and HIV-2, if antibodies are present in the biological material, specific immune complexes are formed and manifested due to the presence of collaurin, in the form of a strip. In some ICT assays, only antibodies to HIV-1 can be defined, and some other assays are intended to define antibodies to HIV-1 group M or group O and HIV-2. The results of the assay are considered correct when the control strip appears. The time needed for testing is 15 minutes.

If the assay is designed to define antibodies to HIV-1, 2, the data measuring should be as follows: Positive test – the appearance of two legible lines of red color. One of the lines should be in the test area T, the other one in the control area C. The positive result shows the presence of antibodies to HIV1, 2 in the examined sample of blood. (Fig. 1.14).

### **Figure 1.14 - ICT Testing Results**

The intensity of the strip in the area T may vary depending on the concentration of antibodies in the sample. Therefore, the appearance of any intensity of the tint of red color in the area T should be considered to be a positive result.

Negative test: only one red strip appears in the control area (C). There is no strip in the test area (T). The negative result shows that there are no antibodies in the examined sample of blood.

Invalid test: The control strip does not appear.

While using tests intended for selective defining of antibodies to HIV-1 of a certain group and HIV-2, when the result is positive, the strips should definitely appear in the control area (C), and one or several distinct strips should be available in the test area T, correspondingly.

It is the ICT assays that are most often used in Ukraine for rapid diagnostics of HIV infection with pregnant women.

The rapid DoubleCheck test for quality defining of antibodies, especially to HIV-1 and HIV-2 using human serum or plasma, can serve as an example of a combination of two technologies of rapid assays.

Unlike the above described ImmunoComb methodology, the DoubleCheck methodology is built on the principle of dual recognition established on a specific definition of antibodies to HIV by antigens that bind two sides of antibodies. The assays use a combination of immunochromatography and immunopreception. The diagnostic kit consists of two parts: the round port intended for introducing a sample, and the oval port, in which the reaction with the applied HIV antigens and internal control take place. (Fig. 1.15).

### **Figure 1.15 - Simple/Rapid “DoubleCheck” Tests**

At the beginning of the assay, the dissolved sample is introduced into the port A. The components of the solution move along the chromatographic strip and are collected in the reaction port B. This results in a specific binding of anti-HIV-antibodies with immobilized HIV antigens. The complex antigen-antibody makes it possible for the biotinylized HIV antigen to get bound at the stage of dual recognition, which is followed by a coupling reaction of the conjugate of streptavidin/alkaline phosphatase (AP). The result is the manifestation of grey-green blots after the reaction with the chromogen substrate. The overall results are shown in Fig. 1.16.

### **Figure 1.16. Recording of “Double Check” Testing Results**

Only rapid assays registered in Ukraine are used for examinations.

Warning on the performance of simple/rapid assays for HIV:

- examinations should be performed using rubber or latex gloves with strict adherence to the anti-epidemic regime;
- at the places of examination (ward, admission room or any other premises) there should be no containers with hydrogen peroxide, chlorine containing compounds or any other strong oxygen carriers;
- prior to examination, familiarize yourself with the instructions for use and the period of validity of an assay;
- it is forbidden to use assays after the expiry date of their validity;
- it is forbidden to use any assay component of different kits and product lines;
- it is forbidden to smoke, take a meal, drink, use cosmetics or make manipulations with contact lens in the premises (areas) where the preparation of samples take place and test-diagnostic procedures are performed;
- it is forbidden to freeze the assays;
- the sample that was examined with the use of a rapid assay, regardless of the result produced, should be forwarded within 3 days to the laboratory for verification using the EIA, PCR or another method;
- the assay result, according to the instructions for use of rapid assays, should be registered in Form No. 498/o “Register of Protocols on the Performance of Laboratory Diagnostics for Infectious Diseases with the Use of Rapid Assays”, which should be kept in the laboratory or the department of a medical and preventive treatment facility, hemotransfusion stations located at the place of assay;
- if a negative result is produced, Form No. 209/o “Assay Result” should be filled out and forwarded to the corresponding department to be attached to “Inpatient’s Medical

Record” – Form No. 003/o or “Delivery History” – Form No. 096/o, or “Donor Medical Chart”;

when a positive or indeterminate result of an assay of samples with the use of rapid assays is produced, further actions should be taken in accordance with a relative order of the Ministry of Health of Ukraine. For example, if a positive result using rapid assays for HIV is produced, further actions should be taken as designated by the Order of the Ministry of Health of Ukraine No.120 “On Improvement of Medical Services Provided to PLHIV”, dated May 25, 2000.

Thus, rapid/simple assays are intended for examination of both single samples of blood (serum, plasma, other biomaterials) for HIV, and simultaneous examination of a combination of any number of samples. Most of simple assays do not require special conditions of storage. They can be kept in the laboratory setting at an environmental temperature from 2 to 30° C. Within a short period of time without using special equipment and medical installations, it is possible to produce reliable and accurate high quality results, which actually can compete with the traditional EIA methods. Even though the methods and technologies intended for performing rapid/simple assays have been constantly improved, new conformational diagnostics kits have been developed, all of them having more sensitive and specific features, possessing a high level of displaying of results. Still, it should be taken into consideration that there is a possibility to produce both false negative and false positive results and confirmation (verification assays). The main problem with the use of rapid/simple assays (without taking into consideration the training courses held for doctors and nurses) is that there is still a necessity of mandatory counseling of the patient prior to testing, receiving his or her voluntary agreement to undergo testing.

### **1.6. Strategy and Tactics of HIV Laboratory Diagnostics in Ukraine**

The spread of HIV, the index of infection among certain socio-demographic groups under examination is determined on the basis of the results of screening assays. Screening is a methodological approach used for examination of socio-demographic groups or their certain cohorts to diagnose a certain disease, its evolution, and factors enhancing its occurrence and advancing. The screening examinations are of multi-stage character and their target can be not only defining of the disease, but also an in-depth examination with the aim to determine more exactly the diagnosis and take a decision concerning the needed medical intervention.

In Ukraine, those to be subject to screening examinations are designated pursuant to the Law of Ukraine “On Prevention of AIDS and Social Security of Population ” (1991), amendments

to this law (1998), “Rules on Medical Inspection Aimed at Defining of HIV Infection, Registration of PLHIV and People with AIDS and Medical Surveillance for Them” (1998). In these documents, the demographic groups that are subject to serological examination are determined according to the target of examination, the possibility of realization of the manner of infection transmission, as well as in conformity with the approved classification of demographic groups by the levels of risk of infection.

To date, there exist a number of methodological approaches to HIV screening examinations. According to the recommendations of WHO and UNAIDS (1997), examinations are performed to ensure transfusion/transplantation arrangements (safety of donor blood, its products, tissues, organs, sperm, and ovum), diagnostics, epidemiological surveillance, and scientific researches of the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> strategies. These strategies designate a certain order authorizing the performance and heredity of primary, validating and confirming examinations when testing different groups of people depending on the target of the examination and the level of spread of HIV. The 1<sup>st</sup> strategy of the WHO and UNAIDS recommendations is that the samples of blood are examined according to the method of EIA solid-phase or the simple/rapid assay: serum that reacted positively is considered to contain antibodies to HIV. This strategy is used for examination of donors. The 2<sup>nd</sup> strategy: serums that are positive after the first EIA are subject to repeated examination by means of EIA or the simple/rapid assay based on the alternative antigenic preparation (EIA + EIA). Serums that reacted positively in both assays are considered to contain antibodies to HIV. If the examined sample is positive in the first assay, but negative in the second one, it is subject to verification using two diagnosticums. If the results remain ambiguous, serum is considered to be unidentified regarding anti-HIV. The 3<sup>rd</sup> strategy of the WHO and UNAIDS recommendations stipulates the same approach as the previous one. However, depending on the target of the assay and the level of spread of the infection among the people of the examined demographic group or on a certain territory, the indeterminate results are subject to one more assay with the use of an additional test (PCR, immune blotting -- IB). Serum samples that are positive to HIV after the first EIA are subject to repeated assay in two “wells” of the same diagnosticum. All the positive samples are subject to the next reference stage – examination by means of other two EIA-test-systems with a higher level of specificity. HIV examination algorithm is shown in Fig. 1.17. Repeated blood sampling in Ukraine is practiced if a positive result of EIA is produced. Such practice dramatically increases the time of waiting for the overall result of HIV assay.

### **Figure 1.17. HIV Examination Algorithm**

All the above mentioned strategies of HIV laboratory diagnostics stipulate the performance of several stages of examinations. This is accounted for the fact that on the basis of the results of the

primary examination, it is impossible to determine for sure if a patient is infected with HIV. As stated above, in the course of EIA, the possibility of false results of the examinations, both false negative and false positive, is taken into consideration. The laboratory diagnostics strategy selection is dependant on the target of the examination of a particular group of people, sensitivity and specificity of the test-systems, level of spread of HIV among the examined groups of people, and economic opportunities. The strategy that stipulates EIA + IB is the most effective in case of a low level of HIV in a certain area. If the ratio of PLHIV is below 10%, the diagnostic approach that comprises three tests is considered optimal: two alternative EIA and IB assays (EIA + EIA + IB). When the spread of the infection is in over 10%, two-stage diagnostics is sufficient: EIA + alternative EIA. The order of validating of controversial results of diagnostics is designated according to the anamnesis data, social behavior characteristics of the person under examination as well as determination of feasible realization of any way of HIV transmission. As regards defining of anti-HIV agents with children born by infected mothers, it is advisable and necessary to use PCR regardless of the level of the spread of the infection. The patients are advised of the results of the assay. When providing information about the negative result of the assay, one should bear in mind the following:

negative result shows that antibodies to HIV are not defined;

negative result shows that the person may not be infected with HIV;

negative result shows that the person could be at the stage of “serologic window” at the moment of the assay.

When providing information about the indeterminate result of the assay, one should bear in mind the following:

- necessity of the performance of a new assay in 2-3 weeks;

Communication of data about the positive result of the assay takes place after all the stages of the laboratory diagnostics and its validation by confirmation assays are over. The positive result shows that the person might be infected with HIV. Diagnostics of HIV is based on defining of antibodies to HIV, data of clinical, immunological, and epidemiological examinations.

However, the issue on the presence of HIV in the body of a human being under the examination cannot be resolved only on the basis of the serological assay results. It is necessary to take into account a complex of clinical, immunological, and epidemiological data.

According to WHO, the “AIDS-indicating” clinical factors include: pneumocystic pneumonia, Kaposi’s sarcoma, cytomegalovirus infection, etc. (26 names in all), which, together with positive HIV results of the serological diagnostics, make diagnosis setting possible.

Immunological markers include the level of T4-lymphocytes and the index of T4-lymphocytes-T8-lymphocytes ratio (CD4+/CD8+): in parallel with advancing of the infectious process, the number of T4-lymphocytes is reduced and the number of T8-lymphocytes increases, thus, the index CD4+/CD8+ becomes lower.

In-depth clinical-laboratory examinations in Ukraine are performed in special in-patient facilities, provided that the person was found out to be infected with HIV in the course of primary screening.

## **Section 2. HIV Epidemics in Ukraine and the World**

- 2.1. History of the Spread of the HIV Pandemic
- 2.2. General Overview and Peculiarities of the Spread of the HIV Pandemic at the Onset of the 21<sup>st</sup> Century
- 2.3. Ways of HIV Transmission and People Vulnerable to HIV
- 2.4. Description and Stages of HIV in Ukraine
- 2.5. National Strategy of Reduction of the Spread of HIV in Ukraine
- 2.6. Prevention of Infection with HIV

### **2.1. History of the Spread of the HIV Pandemic**

The first cases of AIDS were registered by the US Center for Disease Control and Prevention (CDC) in 1981. It was in the USA where a rare disease was diagnosed among young homosexuals (men who have sex with men (MSM)), such disease is clinically represented as opportunistic pneumonia caused by *Pneumocystis carini*, Kaposi's sarcoma, as well as some opportunistic infections that are usually formed on the background of immunodeficiency. In 1982 Dr. M.S. Gottlib, in collaboration with other co-authors gave a clinical chart of this disease and proposed introducing in clinical practice the conception of Acquired Immune Deficiency Syndrome (AIDS). Since the identification of the first cases of AIDS, the number of cases had been growing rapidly, thus a year later an estimated 711 AIDS-positive people were registered in 16 countries worldwide, in another five years the total of 72, 504 AIDS-positive people were registered in 113 countries worldwide. The pace of spread of AIDS is so fast that it has acquired the features of a pandemic spread and become one of the greatest threats to mankind ever, evolution and survival of each and every nation.

In 1985, it was identified that the AIDS causative agent can be present in the biological fluids received from of a sick human being and is transmitted through blood, semen, mother's breast milk and vaginal secretion. The same very year, the first EIA test system intended for defining specific antibodies to HIV for screening donor blood was developed by ABBOT, a US company. First testing of blood preparations for HIV started in the USA and Japan, and in another year such testing got underway in almost all other countries of Western Europe.

In 1987, the WHO Global Program on AIDS was established and the World Health Assembly adopted a resolution on global strategies for fighting AIDS. The same year, the first antiretroviral medication called zidovudine or azidothymidine (AZT), the produce of the company currently known as GlaxoSmithKline, was introduced into clinical practice, which opened a new era of antiretroviral therapy (ARV). The first cases of AIDS in the Soviet Union, including Ukraine, were identified and registered in 1987.

In 1988, the first day of every last month of the year – December 1 - was proclaimed World AIDS Day.

In 1989, over 200 children infected with HIV were hospitalized in the cities of Elista, Volgograd, Nizhniy Novgorod, which encouraged establishing a network of AIDS Centers in the Soviet Union.

In 1990, a new antiretroviral medication called didanosine (videx) was introduced into clinical practice in the USA. According to the World Health Organization (WHO), a total of 10 million people were living with HIV (PLHIV) in the world.

In 1995 in Germany, four people were taken to prison on the charge of selling HIV-infected donor blood. The first Federal Law on HIV/AIDS in Russia became effective.

In 1996, the WHO Global Program on AIDS gave place to the Joint United Nations Program on HIV/AIDS (UNAIDS), in the activity of which all six UN agencies such as: WHO, UNICEF, UNESCO, UNFPA (UN Population Fund), UNDP (United Nations Development Program) and the World Bank take part. The Eleventh International Conference on AIDS was held in Vancouver (Canada), at which, for the first time, it was announced “Hit Hard and Early” and that a new third group of ARV medications – HIV protease inhibitors -- had been developed.

By the end of 2000, the total number of PLHIV worldwide had reached a record 36.1 million people, and 21.8 million died from AIDS.

Taking into account different HIV prevalence rates, WHO and UNAIDS experts determined the following stages of the HIV epidemic:

1. Primary stage of the HIV epidemic
2. Concentrated HIV epidemic stage
3. Generalized HIV epidemic stage

**The primary stage of the HIV epidemic** is characterized by the fact that a long presence of HIV notwithstanding, it never spreads beyond the boundaries of certain groups of the population. The registered cases, as a rule, concern those who belong to most at risk populations – sex workers, men who have sex with men, and injection drug users (IDUs). The quantitative equivalent – under 5% in any population.

**The concentrated HIV epidemic stage** is characterized by a rapid spread of HIV in separate population groups, such as sex workers, injection drug users, men who have sex with men, however, HIV has not yet “rooted” among the general population. This stage of HIV is also characterized by the presence of very high risks among certain population groups. The spread of the HIV is defined by the frequency and manner of contacts among people within the population groups having high rates of infection and the general population. The quantitative equivalent – the rate of spread of infection is steadily over 5% at least within one population group, however, it remains below 1% among pregnant women who live in cities or in a suburban area.



**At the generalized stage of HIV epidemic** the so-called “rooting” of HIV among the general population is observed. Regardless of the fact that the most at risk populations contribute a lot to the spread of HIV, the level of sexual contacts among the general population is fairly high to maintain the epidemic without any interference of vulnerable groups. The quantitative equivalent - the rate of spread of HIV among pregnant women is above 1%.

To resolve the issues of planning of prevention programs in the countries with the spread rate of HIV above 15%, recently a fourth epidemic scenario was offered by experts – **hyper endemic epidermis as the fourth stage of the HIV epidemic**.

„AIDS is an extraordinary issue worldwide, indeed. The AIDS pandemic is potentially the gravest environmental tragedy in the history of mankind. In the first instance, AIDS kills adults who are a driving force of economic growth, but also, which is equally important, the force that creates new generations. Many economists, political analysts, experts in the sphere of healthcare and state policy are mistaken. They consider AIDS an issue for healthcare experts but not a serious crisis in resolving of which they themselves should contribute to using their own skills and weight. There is only one choice for us – to fulfill our duties today no matter where we are or who we are...” (Peter Piot, Executive Director, UNAIDS, 2005).

## **2.2. General Overview and Peculiarities of the World Spread of HIV Pandemic at the Onset of the 21<sup>st</sup> Century**

At the onset of the 21<sup>st</sup> century, according to WHO/UNAIDS data (Global HIV/AIDS Pandemic Summary: Number of Adults and Children Living with HIV/AIDS as of the End of 2006) of Dec 2006, promising developments have been seen in recent years in global efforts to address the AIDS epidemic, including increased access to effective treatment and prevention programs. However, despite a significant increase of the level of political tendency in the direction of fighting HIV, accelerated activity and an increase of material resources to fight the pandemic evolution of HIV, the number of people living with HIV continues to grow. As of the end of 2006 the estimated total number of people living with HIV worldwide reached a total of 39.5 million people (Fig. 2.1a). In 2006, as many as 2.9 million estimated people, among whom 380 000 children, died from AIDS, and 4.3 million people were HIV infected for the first time. (Fig. 2.1b)

As compared with 2004, the estimated number of people living with HIV has increased considerably, especially in Eastern Asia, Eastern Europe and Central Asia. For example, in Eastern Europe and Central Asia, the estimated number of those newly infected with HIV has increased by 70%, mainly because of Russia and Ukraine, in South and South-East Asia – by 15%, in Middle East and North Africa – by 12%, while in Latin America, Caribbean and North America this number almost hasn't changed. Nevertheless, HIV has spread widely across Africa, especially sub-Saharan Africa. It is the very region where there is almost 63% of the total number of PLHIV and

59% of the total number of women living with HIV. According to statistics,  $\frac{3}{4}$  of the total number of AIDS-caused deaths occurs in Africa (Fig. 2.1c). At the same time ART helped prolong the lifespan of PLHIV by nearly 834 000 extra years.

HIV epidemics in Eastern Europe and Central Asia are still relatively “young” and continue to grow, especially in Ukraine, which shows the highest prevalence and incidence rates in Europe.

In June 2004 UNAIDS and WHO presented the new policy in the field of HIV testing and counseling with the focus on the awareness of one’s HIV status, which is crucial for scaling up access to HIV prevention, treatment and support. This document contains two most important models, which are supposed to improve the identification of one’s HIV status and scale up access to HIV prevention, treatment and support. The first model is VCT and the other – HIV testing and counseling initiated by a health care provider (WHO/UNAIDS Guidance on provider-initiated HIV testing and counseling in health facilities, 2007). Perhaps these two models and other efforts will help halt HIV and slow down the new incidences rate.

### **2.3. Ways of HIV Transmission and At Risk Populations**

The source of HIV is the person infected with HIV with or without clinical presentations. In the body of such a person, HIV is present in all biological fluids without any exceptions (blood, urine, sweat, semen, vaginal discharge, breast milk, etc.). The highest concentration of the virus is defined in blood, semen, vaginal discharge and breast milk (in that order), which are the fluids which transmit HIV to another person. In other biological fluids, the level of concentration of the virus is insignificant, and if one adheres to the hygiene requirements during everyday communication at home, work, in school and other institutions, HIV infection does not occur.

It has been proved that the ways of HIV transmission from a person infected with HIV to other person are:

- through sexual intercourse, including anal, vaginal and oral;
- parenterally (injection therapy), including blood products, blood, sharing contaminated syringes and other medical instrument;
- perinatally from mother to child (during pregnancy, birth, feeding breast milk).

Sex or the sexual way of HIV transmission prevails throughout the world. However, the prevalence of any way of HIV transmission depends on each country’s social, cultural, ethnic circumstances and ways of life. Considering the ways of HIV transmission, there are certain most at risk populations, such as injection drug users, men who have sex with men, sex workers, people who have spontaneous sex with strangers, children born by mothers infected with HIV, blood and blood products recipients (see Fig.2.2)

Figure 2.2 - Proportions of HIV infections in different population groups by region, 2005 (WHO/UNAIDS, Global summary of the AIDS epidemic, December 2006).

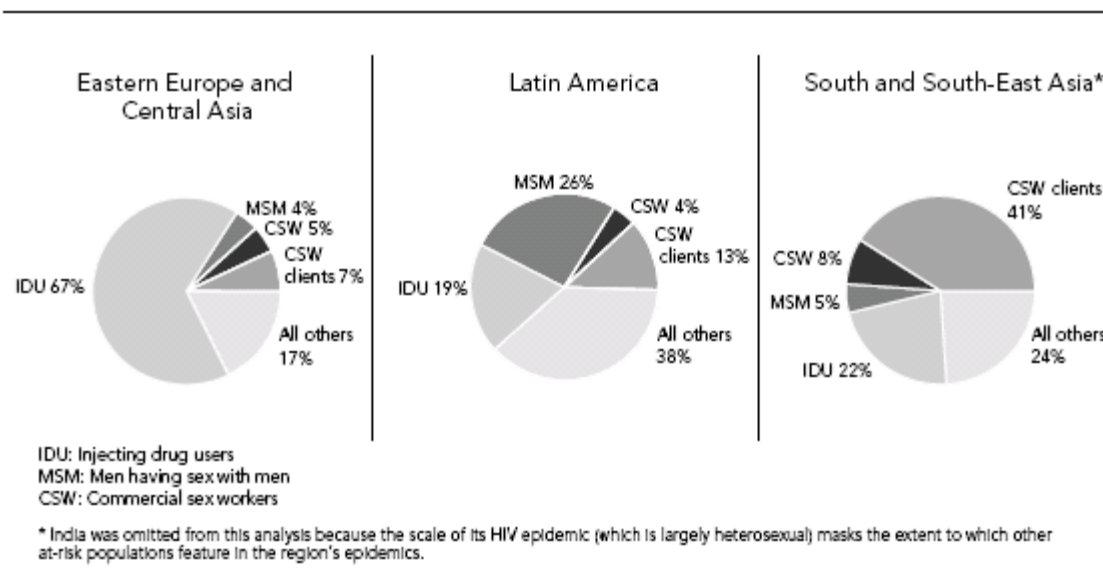
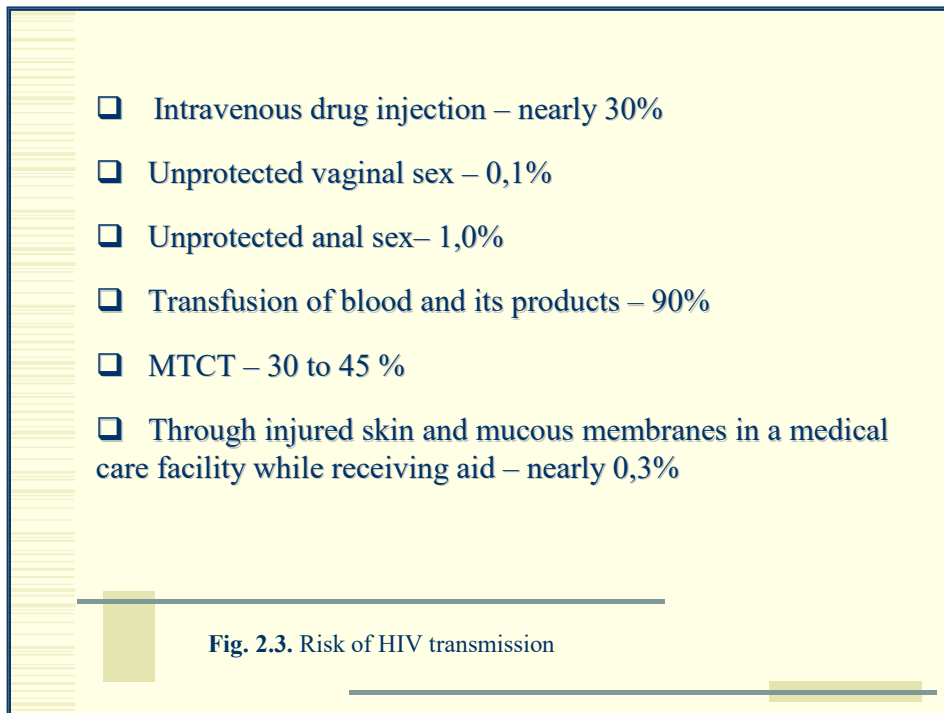


Figure 2

The risk of being HIV infected depends on how big the virus dose is. The infectious dose for HIV is 0.01ml of blood. It is important to remember that even large concentrations of the virus frequently lead to infection of a human being. Healthy and uninjured areas of skin integument constitute effective barriers against HIV infection. However, any injuries, affections, maceration may become “open gates” for HIV infection to invade the blood flow and thus a sensitive cell, respectively.

Whatever the case, there is a certain risk of HIV transmission. According to researchers, the risk of HIV transmission during a single intercourse (unprotected vaginal sex) is 0.1%, and unprotected anal sex – 1.0% (Fig. 2.3.).

Figure 2.3. Risk of HIV Transmission («HIV/AIDS counseling», PATH training guide, Georgia, 2005).



The “feminization” of HIV is observed in the world today. For example, from 1998 to 2006, the share of women among adults living with HIV increased from an estimated 42 to 48%. The highest risk of HIV infection worldwide is with young women 15-24 years of age. Owing to an active involvement of women into the epidemic process, the number of children born by infected mothers has also increased worldwide. The frequency of HIV MTCT in various regions of the world ranges from 30% up to 45 % if no prevention is provided (during pregnancy 5% - 10%, during birth – 10% - 20%, during breast-feeding – 10% - 20%). In the countries where certain prevention programs are introduced the frequency of HIV transmission is below 10% - 5 % and in some cases 2% or less. And vice versa, in certain countries of the African continent this index reaches 50%, which depends on a number of medical and biological factors.

Researches are confident about the fact that, in general, HIV transmission from mother to child takes place during birth. Feeding breast milk duplicates the risk of HIV and the frequency of HIV transmission to a newly born baby. In the breast milk of an infected mother there is a huge number of viruses and cells in which the process of virus reproduction takes place. Therefore, the virus can be transmitted to a child through micro injuries and disruptions of a baby’s mouth cavity.

HIV is not transmitted through:

- respiratory routes
- fecal-oral routes
- vector-born ways (by insect-bloodsuckers and epizoic parasites)
- physical contact
- eating utensils

- everyday communication

HIV does not have characteristics of periodicity and seasonal prevalence.

As said above, the ways of HIV transmission and vulnerable demographic groups usually influence the population structure by age and sex. Young people and adolescents are the “favorite” target for HIV. However, in the countries where the mechanism of HIV transmission is concentrated it is among the injection drug users and men who have sex with other men, and women who have relations with these men or injection drug users.

## **2.4. Description and Stages of the Spread of HIV in Ukraine**

In Ukraine, the HIV epidemic has been spreading for at least twenty years now. In Ukraine, according to the Ukrainian AIDS Center, **the initial stage of the epidemics of HIV** began in 1987, when the first incidences of HIV were reported. As many as six citizens of the then Ukrainian Soviet Socialist Republic and a total of 75 foreigners infected with HIV, who later were deported from Ukraine in accordance with the existing legislation in effect that time, were diagnosed for HIV as of the end of that year. Before 1994, the spread of HIV in Ukraine could be described as slow in terms of the rates of infection (nearly 40 incidences per year), with the way of heterosexual HIV transmission prevailing and which was a virtually equal correlation between women and men infected with HIV. In total, as many as 183 citizens of Ukraine infected with HIV were registered during 1987 through 1994. Two incidences of brothers infected with HIV, who lived in Mykolayiv and were injection drug users, were registered in late 1994. It was most likely that one of the brothers had been infected in Poland where he used to live for some time and where the rate of IDU-related HIV had already been quite high.

**In 1995 Ukraine reached the stage of the concentrated HIV epidemic.** The first incidences of IDU-related HIV were registered in Odesa in early 1995. As of the end of 1995, nearly 1,000 IDU-related PLHIV were registered in Mykolayiv and Odesa regions, and by 1997, the incidences of IDU-related HIV were registered in the rest of the regions of Ukraine. According to statistics, a total of 8,934 PLHIV were reported in 1997. Thus, the deterioration of the epidemiological situation in Ukraine that was observed in 1995 was associated with the growth of the number of IDUs infected with HIV. It should be highlighted that almost a quarter of the total number of PLHIV fell on women of a fertile age. In 1997, when the total number of IDUs infected with HIV during the period of the epidemic spread was registered, a share of women of a fertile age among IDUs infected with HIV reached its highest rate – 85.2%.

In 1998, the number of annual registered incidences of HIV dropped a little bit and neared the figure of 8,590 people, in 1999 – 5,830 people, however, since 2000 it has started growing again (in 2000 – 6,216 people, in 2001 – 7,009 and so on, see Fig. 2.4).

Fig. 2.4. HIV Incidence Registering Dynamics (progressive total for 1987-2006)

However, the fact that the number of officially registered PLHIV over the years has slightly decreased, there has been no evidence of improvement of the epidemiological situation, though, in fact, the number of IDUs infected with HIV has decreased by 23% as compared with 1997. The analysis has revealed that such a decrease resulted in a revised Law of Ukraine “On Acquired Immunodeficiency Syndrome (AIDS) Prevention and Social Security of Population” (March 1998) in force, where the principle of voluntary HIV testing was declared for the first time, as well as in the decrease of the number of diagnostic studies, including the number of testing among such demographic population as IDUs. The spread of AIDS and AIDS-caused deaths from 1987 to 2001, when no special antiretroviral therapy was available, was constantly increasing, as shown in Fig. 2.5 and 2.6.

Fig. 2.5 AIDS Incidence (progressive total for 1987-2006)

Fig. 2.6 AIDS-caused Death Toll in Ukraine (progressive total for 1987-2006)

The highest rate of HIV during this period was registered in South-Eastern Ukraine (Fig. 2.7). Meanwhile, the lowest rate of HIV was reported in Western Ukraine and the Sumy region.

Fig. 2.7. Spread of HIV among the regions of Ukraine (per 100,000 citizens as of 2006)

The epidemiological analysis of the ways of HIV transmission also revealed the changes in the prevailing ways of HIV transmission in Ukraine from 1995 – from the sexual way (heterosexual), which prevailed during the first 7 years of the epidemic (80-90%), to parenteral, and the use of injection drugs from 1995 to 2000, and again the sexual way started to prevail in early 2001 until now (Fig. 2.8a and 2.8b).

Fig. 2.8a Ways of HIV Transmission (1987-2004)

Fig. 2.8b Ways of HIV Transmission (2007)

Thus, one-time instances of HIV infection among Ukrainian citizens gradually developed into a full-scale epidemic in Ukraine that had already passed the initial and concentrated stages and reached the third stage – the stage of the generalized epidemic. For example, quite frequently, experts point out the increase of rates of HIV among the citizens of Ukraine, but Ukraine rated first among the countries of Eastern Europe by this factor (according to experts, the number of PLHIV in Eastern Europe is over 1 million people). According to the Ukrainian AIDS Center of the Ministry

of Health of Ukraine, as of early 2007, over 104,000 PLHIV were officially registered in Ukraine. According to WHO and UNAIDS estimates, a total over 377,000 PLHIV lived in Ukraine in late 2006, i.e. as many as 1.46% of adults of Ukraine. The 2000-2006 statistics analysis revealed that the rate of HIV infection was twice as much, the number of PLHIV increased by 7 times as much, and AIDS-caused death toll – by 5 times as much.

The most at risk to HIV have become people living in the southern and eastern regions of Ukraine. These are the regions where HIV transmission is 3-4 times as much higher than the average index across the country. These regions include the Dnipropetrovsk, Donetsk, Mykolayiv, Odesa oblasts, the Autonomous Republic of Crimea and the city of Kyiv.

At the third phase of its spread, the HIV epidemic proliferates in Ukraine due to the combination of extremely important ways of HIV transmission, such as parenteral and sexual. The results of epidemiological studies concerning the role of IDU at this stage of the epidemic spread show that in as many as 70% of incidences it is them who have become the source of infection for their partners in sex and will remain to be the factor of the spread of HIV in Ukraine (National AIDS Centre Bulletin, 2007).

The largest number of PLHIV is in the age-group of people who are 20-39 years old.

The number of PLHIV among blood donors increased: from 800 PLHIV in 1998 up to 1067 PLHIV in 2006. From 2001 to 2006, a total of 15 incidences of the transfusion of blood or its components from the donors being at the stage of the so-called “serological window” at the moment of such transfusion were registered.

The leading cause of death with as many as 50% PLHIV at the third stage of the epidemic has appeared to be tuberculosis (TB), which is yet another big issue for Ukraine -- HIV-associated TB. Among other opportunistic infections, which most frequently are developed with PLHIV in Ukraine include herpes simplex virus infections (HSV), parenteral viral hepatitis B and C, candidiasis, pneumocystic pneumonia, mental disability and growths.

## **2.5. National Strategy of Reduction of the Spread of HIV in Ukraine**

Over all these years Ukraine has been taking much effort to fight HIV, demonstrating political will to intensive activity, consolidation of efforts of the state, international and non-governmental organizations, and people living with HIV. Ukraine signed the Declaration of Devotion to Combating AIDS, adopted by the UN General Assembly in 2001, which defined the ways of implementation of its decisions. The experience of many countries of the world and Ukraine’s own experience show that we already have had the tools to fight the threat. First of all, these are preventive programs aimed at making changes in risky behavior of the youth and vulnerable groups of people. Their economic effectiveness has been proved: for example, the cost

of prevention of one incidence of IDU-related HIV is nearly 1,030 hryvnias, the cost of treatment of a patient infected with HIV is 7,900 hryvnias (on condition that the purchasing price of medications for a one-year course of treatment is minimal). The basic principles of fighting HIV and its consequences are built on the state policy of fighting AIDS in Ukraine, as well as legislative and statutory acts. They lie in the background of the Concept of Strategy of Governmental Efforts to Prevent the Spread of HIV/AIDS by 2011 and the National Program to Ensure HIV Prevention, Support and Treatment of PLHIV for 2004-2008, endorsed by the Resolution of the Cabinet of Ministers of Ukraine No. 264 dated March 4, 2004.

Given below, for descriptive reasons, is a list of dates and events associated with fighting HIV in Ukraine, and the national strategy of reducing the spread of HIV in Ukraine.

- **1987** – The first instances of HIV in Ukraine were registered.
- **1989** – The Republican Center for AIDS Prevention was set up; the first regulatory documents (guidelines) were developed.
- **1990** – Special government authorities (bodies) were set up to fight AIDS.
- **1991** – The first year of independence marked the adoption of the Law “On Prevention of AIDS and Social Security of the Population”, which recognized that the spread of AIDS jeopardized private, civil and state security, that fighting AIDS is one of the priority assignments of the state, that the state guarantees accessibility, quality, and effectiveness of medical examination aimed at defining HIV, provision of means of prevention, social security of PLHIV, including monthly governmental allowance to children living with HIV.
- **1992** – The National Program for 1992-1994 was endorsed. The President’s National Committee for Fighting AIDS was set up. Amendments to the Crime Code were adopted abolish criminal liability for homosexuality.
- **1993** – National manufacture of medical disposable instruments and latex products was developed.
- **1995** – The National HIV Program for 1995-1997 was endorsed. Scientific research on production of domestic antiretroviral medications began.
- **1996** -- The first prevention programs on “harm reduction” for IDUs were put into operation.
- **1998**- A new edition of the Law on AIDS, in which conscious voluntary HIV testing is declared, was adopted.
- **1999**- The Program on Prevention of AIDS and Drug Abuse for 1999-2000 was endorsed. Newly developed epidemiological surveillance techniques were endorsed.



- **2000** – The President’s Decree “On Urgent Measures to Curb the Spread of HIV/AIDS” was issued. Strategic planning of national programs to counter the epidemic was launched. The PMTCT program was introduced. The manual “Epidemiological Control” was published. Centralized purchase of ART medications began.
- **2001** – The HIV Program for 2001-2003 was endorsed. The Governmental Commission to Fight AIDS was set up. Ukraine initiated the convocation of the UN General Assembly Special Session on HIV/AIDS in New-York on June 25-27. The President’s Decree on proclaiming the year 2002 the Year of Fighting AIDS in Ukraine. Ukraine contributed to establishing the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The Ukrainian Fund to Fight HIV/AIDS was established. The All-Ukrainian Network of People Living with HIV was established.
- **2002** – Ukraine joined the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria. The ‘Memorandum of Understanding’ was signed as part of the Program to Accelerate Access to ART; the agreement to reduce the purchasing prices by 75-85% was achieved. The Board of the Global Fund made a decision to extend a grant (financial assistance) for provision of medical treatment, care and support to PLHIV. The mechanisms of implementation of the facilities of the Global Fund to Fight AIDS, TB and Malaria were developed in association with the Governmental Commission to Fight AIDS and the Ukrainian Fund to Fight HIV and AIDS. UN Secretary-General Kofi Annan participated in the activity of the Governmental Commission to Fight AIDS and the Enlarged Board of the Ministry of Health of Ukraine.
- **2004** – The Three Ones principle of combating HIV in Ukraine and the strategy of universal access to treatment, care and support of PLHIV, developed by UNAIDS and the Ministry of Health, were put into operation. The first report on the implementation of the resolution of the UN General Assembly was prepared by Ukraine. The Fifth National HIV Program was launched. Implementation of the GFATM grant in Ukraine (92 million US dollars) started through the International Charitable Fund “International HIV/AIDS Alliance in Ukraine”. Antiretroviral therapy was introduced for PLHIV on a large scale.
- **2005** – The President’s Decree of Nov. 30, 2005, concerning additional financing (totaling 17 million hryvnias) to insure the implementation of the National HIV Program. The National HIV Coordination Council, an advisory body at the Cabinet of Ministers of Ukraine, and corresponding regional councils were set up.
- **2006** – Ukraine participated in the First AIDS International Conference of Eastern Europe and Central Asia Countries held in Moscow on May 21-23. First experience was

gained in the implementation of substitution therapy using buprenorphine in pilot oblasts of Ukraine. Up-to-date techniques of laboratory diagnostics for HIV were introduced: defining of the number of CD4-lymphocytes, viral load in PLHIV, DNA diagnostics of younger children born by infected women. The second report on the implementation of the resolutions of the Declaration of the UN General Assembly was prepared. Acknowledgement for presenting the report was received from Dr. P. Piot, UNAIDS Executive Director. Amendments to the Fifth National HIV Program were developed in view of a critical situation with the incidence of HIV.

## **2.6. Prevention of HIV**

A preventive trend is prioritized to fight HIV. It is a common knowledge that it is easier and more prospective to prevent infection than conducting treatment for it afterwards. Traditionally, prevention of HIV is carried out at three levels. Primary, secondary, and tertiary preventions are assumed.

Primary prevention of HIV can be conducted by changing a person's (people) behavior with the goal of mitigating the impact or reducing the risk of infection, as well as by way of development and introduction of specific prevention, i.e. HIV vaccines.

Secondary prevention is aimed at detection of PLHIV and their post-test counseling, in particular for the purpose of changing their way of life and behavior, and counseling on the issues of family planning, etc.

Tertiary prevention is aimed at prevention of the development of clinical presentations of HIV, opportunistic infections and invasions, improvement of conditions of life, care, social support, etc. An example of such prevention may be vaccination for opportunistic agents of infections, influenza vaccination, nutrition education, care, treatment and support of PLHIV. It should be noted that vaccines for PLHIV should not be live. Only inactivated, subunit or split types of vaccines can be used.

Let us consider some approaches to prevention of HIV by sexual contacts, injective drug use and post-contact prevention of HIV.

One of the techniques of prevention, known as "mitigation", is generally based on the fact that the risks of HIV transmission can be defined and certain methods of protection that have already given a good account of themselves can be applied. For example, use of condoms; donor blood screening; thermal treatment of blood factor VIII; cessation of breast-feeding; application of well-known preventive measures of HIV in medical facilities while carrying out invasion manipulations, etc. In other words, the theory of "mitigation" adds up to health protection, defining

of factors of risky behavior and their complete elimination. Such risk factors of HIV infection include unprotected sexual contacts, sexual contacts with many partners, especially with the partners whose HIV status is unknown, and the presence of sexually transmitted infections in the body of a sex partner. The risk of HIV infection occurs during transfusion of blood and its products, conducting of invasion manipulations, transplantation of organs and tissues, and use of biological materials and fluids at work. Drug injections, application and sharing of syringes and needles for drugs and psycho-stimulants injection by some people should be considered risky. Generally speaking, there is no doubt that if someone's HIV status is ignored during family and pregnancy planning, it is considered risky. It seems that according to the theory of "mitigation" the best way of mitigation is to eliminate the impact completely. For example, abstinence from any sexual relationships is the best way to avoid HIV. However, sometimes such approach seems to be impossible and even harmful. The approach that a person is aware of risks and uses the ways of their elimination appears to be more reasonable. That is, there is no need to refuse from sexual relationships completely; it is enough to use condoms or other individual protective devices during sexual contacts. Condoms should be used during any sexual contact, both homosexual and heterosexual. Condoms should be used during every sexual contact! Of course, different sexual contacts present different risks.

The highest risks of HIV infection are for receptive anal sex without using condoms, for receptive vaginal sex without using condoms, insertive anal sex without using condoms, insertive vaginal sex without using condoms with a partner infected with HIV.

It is important to note that being aware of your own HIV status and the HIV status of your partner in sex does reduce the risk of HIV infection during sexual relations. Sex with partner not infected with HIV is in theory safer, though even the negative result of testing for HIV does not guarantee 100% protection from the risk of HIV infection (think of the "serological window"-phase).

A very important approach to HIV prevention when drugs are used is to cope with drug use as a phenomenon. In some countries of the world the use of drugs is strictly forbidden by laws. However, it does not mean at all that there are no IDUs or IDUs living with HIV in those countries. The model of "mitigation in reducing illicit drug use" or the harm it causes means that prevention of HIV are more important than the process of elimination of drug addiction. A radical approach to the elimination of drug addiction from the life of society, time and again, leads to backing the problem into a corner where neither law nor special services are able to help reduce the risks of HIV infection. In this case, the optimal approach seems to be the one, alongside with which there are steps relating to efforts to combat drug trafficking, this gives access to treatment IDUs and makes it possible to arrange various substitution therapy techniques on the basis of medications that affect

the opiate receptors of the brain. For example, in USA for more than 20 years, substitution therapy methadone is given to help heroin drug users to stop using drugs and reduce sharing syringes. In UK, Greece and many other countries of Europe, within the frameworks of prevention “mitigation” programs on reducing the harm, injection opiate drugs are substituted by methadone to be used orally. The efficiency of such prevention programs is based on the fact (evidence as a result of research for more than 20 years) that the people involved in such programs, alongside with substitution therapy, can receive HIV counseling, testing, medical and psychiatric aid and reduce their use of injection equipment.

The counseling principle “Peer to Peer” makes it possible to reduce the risk of HIV effectively. The lead of such people often encourages or to certain extent, even makes IDUs seek medical assistance and treatment. Working in the street among IDUs is not only a chance to share one’s own experience, tell about the ways of HIV transmission, prevention of HIV, but also to distribute among people condoms, disinfectants, alcohol soaked napkins. Voluntary counseling (either individual or group) and voluntary testing for HIV of IDUs can radically improve the situation in such population and reduce the risks of HIV infection.

The International HIV/AIDS Alliance has offered a new form of prevention among vulnerable groups and subpopulations. It is called “Assessment Criteria for Involvement” and is based on three important aspects:

Emphasis on participation: interactive tools and methods allowing people to more actively participate in providing and discussing information are recommended instead of conducting questionnaire surveys;

(Combination) Simultaneous gathering of information and conducting of testing: involvement in the process of gathering information and its processing in contrast to the procedure when only experts are involved in conducting analysis;

Assessment as activity: emphasis on the involvement of a group in the process of assessment of the situation and its analysis. The opportunity to find out “What kind of problem is it?” and answer the question “What can be done to resolve it?”

The realization of such preventions in Ukraine has revealed certain features of the epidemic situation in the country and a new group of an increased risk of HIV infection, to which students having their midyear exams (use of drugs for stress release or to reduce its level), military men (use of drugs to reduce emotional pressing), musicians and artists (they use drugs to regain creativity resources), police officers (they have extensive access to drugs, may be infected with HIV if injured or get traumas while conducting searches), teenagers from rural areas who arrive for study in a big city (they are often used as drug traffickers, and the extra money they earn is a financial opportunity

for them to get first experience with drugs), migrant workers (unscrupulous sexual relations, use of drugs, cheap sex services, alcohol abuse) were included.

In different countries of the world, there are different approaches to solving problems associated with the spread of HIV among those who are serving their sentence. In some countries, the convicted inmates should undergo testing for HIV involuntary, and in some other countries no testing for HIV is conducted but special prevention programs are used instead. Such programs as “Peer to Peer”, “Health Support”, “If You Love Him, Love Yourself”, etc. can serve as an example. By 1997, the policy of mandatory testing of convicted inmates for HIV had been pursued at the state correctional institutions in Ukraine. In 1997, the penitentiary system of Ukraine renounced mandatory testing and isolation of people infected with HIV, and instead, since then, the state has been involved into extensive educational and prevention activities among convicted inmates and personnel of such institutions guided by the principles of VCT, including affordability of condoms, disinfectants, and accessibility of programs, etc.

Under rapid spread of HIV among the population, the issue on prevention of HIV at medical and prevention institutions and post-contact chemoprevention of HIV has become extremely important. In Ukraine, this issue is regulated by the Order of the Ministry of Health of Ukraine No. 120 dated May 25, 2000, which endorsed the Guidelines on Intrahospital Infection and Occupational HIV Infection. According to the Guidelines on Intrahospital Infection and Occupational HIV Infection, a safety control system for HIV infection of medical personnel in the course of fulfillment of their duties should be the responsibility of a security commission of a medical and prevention facility; the membership of the commission should be approved by the chief doctor of the facility. Work places of medical staff should be provided with first-aid kits for urgent prevention in emergency situations, kits of disposable medical instruments, and disinfectant materials to be used for disinfection. Each and every subdivision should be provided with a first-aid kit. The kit should contain fingerstalls (1-2 items for each employee), an adhesive plaster (1 coil), a pair of scissors (1 item), potassium permanganate in portions weighing 0.05 (3 items), a vessel for potassium permanganate solution 1 liter label, 70% ethanol (50 ml), a dropping tube with a 30% strength sulfacetamide solution (1-2 items), a 5% strength iodine solution, a 3% strength hydrogen peroxide solution, a few pairs of rubber or latex gloves (3 pairs), a few portions of disinfectants - 3 items of each (chloramines 30 g, chlor zink 30 g), and a vessel for a disinfectants solution. Medical instruments, as well as ware, linen, devices, etc. infected stained with blood and other biological fluids (except urine, saliva, excrement, in which the concentration of the virus is not high) and things stained with mucus should be disinfected according to the normative acts to eliminate the risk of occupational infection. It is suggested that a disinfection regime similar to the one applied to prevention of infection with viral hepatitis B be established.

The highest risk of HIV infection for health care workers takes place when they manipulate with blood or its components (plasma, concentrated red cells, thrombocyte mass, leukocytal mass, blood factors VIII and IX), male semen and vaginal secretion. These are the very biological fluids that contain the highest concentration of the virus. For example, it has been defined that 1 ml of blood of a person infected with HIV may contain from 100 to 1,000 or even 10,000 infectious doses of the virus.

The risk of infection for health care workers depends not only upon the infectious dose of the virus, but also upon the frequency and type of contact with blood. Infection may occur after receiving injuries ranging from hits to cuts, penetration of a biological material into the unprotected schneiderian membrane, conjunctiva, tunica mucosa of mouth, the affected areas of skin integument (cuts, dermatitis, eczema, etc.). In the course of prospective studies among health care workers, it has been established that the risk of infection caused by the penetration of HIV through the skin is 0.3% (0.2-0.5%), and if it reaches mucosal tunics, the risk rate is 0.09% (0.006-0.5%). Yet, even though the risk is low, transmission to health care workers does happen; in 2000, CDC registered 56 incidences of seroconversion with health care workers connected with the fulfillment of their occupational duties, and in 138 incidences of HIV infection, contacts with blood were considered to have been a highly probable cause of infection (CDC, 2000). In addition, Hepatitis C is epidemic and is much easier to be transmitted than HIV. Health care workers need to practice universal precautions, which is the international and MOH standards to prevent Hepatitis and HIV. A risk of intrahospital infection of a patient is quite often connected with transfusion of blood and its components, transplantation of organs and tissues, artificial fertilization, application of non-sterile instruments during invasion manipulations.

Health care workers should be careful while working with cutting and piercing instruments (needles, scalpels, scissors, etc.) during manipulations. It is also recommended to carry out manipulations in the presence of other expert who can continue the manipulation in case of a rubber glove gets ruptured or cut; do not rub your mucosal membranes with your hands; in case a patient's blood or other biological materials get on a smock or clothes, it is recommended to take them off and soak them in any disinfectant solution; in case hands or other body areas get contaminated, it is recommended to wipe them out with a 70% strength ethanol solution, slush them with soap and wipe them with a 70% strength ethanol solution again; contaminated shoes should be wiped out twice with a wiper moisten in a disinfectant solution.

If there was a contact with blood, biological fluids or biological materials, and it caused harm to skin integument, then the medical personnel should be aware of the procedure established by the Instructions and act as follows:

- Turn the gloves inside out while taking them off;
- Press out blood from the affected area;
- Rinse the affected area using one of the disinfectants (a 70% strength solution in ethyl alcohol, a 5% strength tincture of iodine (for cuts), a 3% strength solution in hydrogen peroxide);
- Wash hands carefully with soap using flushing water and then use a 70% strength solution in ethyl alcohol;
- Put a plaster on the affected area and put on a finger stall;
- Put on new gloves if you are going to continue your work;
- Immediately inform the management of the medical and preventive treatment facility about the emergency situation so that it can be recorded and prompt HIV prevention measures can be taken.

In case blood, biological fluids or biological materials have caused contamination without affecting the skin, it is recommended to:

- Use one of the disinfectants (a 70% strength solution in ethyl alcohol, a 3% strength solution in hydrogen peroxide, a 3% strength solution of chloramines);
- Rinse the affected area with water and soap and use alcohol solutions twice;

If blood, biological fluids and biological materials have got on a fine mucosal tunic, it is recommended:

- For the mouth cavity – to rinse with a 70% strength solution in ethyl alcohol;
- For the nasal cavity – to use a 30% strength of solution;
- For eyes – to rinse with water and instill, using a 30% strength of sulfacetamide;
- For the nose and the eyes – a 0.05% strength solution of potassium permanganate can be used.

In all medical and preventive treatment facilities, Form No. 108-0

“Logbook on Incidents during Provision of Medical Assistance to PLHIV and Manipulations with HIV Infected Materials” is maintained. Registration of incidents is performed according to the established procedure by voluntary agreement of an injured health care worker. After registration of the emergency situation, the injured health care worker is offered to voluntarily undergo an examination for defining of antibodies to HIV. At first, blood for testing according to code 115 (medical contact) is collected immediately after the emergency situation but no later than 5 days after it. A positive

result shows that the medical care worker has been infected prior to the emergency situation, and such situation was not a cause of HIV infection. If the result is negative, the next testing should be conducted in 3.6 months and the next one in a year.

If the incident occurred during manipulations with biological materials the presence of HIV in which was known in advance, then the injured medical care worker, for the period of medical supervision, is prohibited from donating blood (tissue, organs) and prevention in emergency settings shall be conducted, i.e. antiretroviral medications are prescribed upon consent of the injured person. It is advisable to conduct prevention as soon as possible but no later than 36 hours after the emergency situation. If the injured medical care worker appeared to be infected with HIV according to Form No. 108-0, further acknowledgment of the disease shall be in accordance with the procedures established by the current legislation of Ukraine.

### **Section 3. VCT as an Efficient HIV Prevention Tool in Ukraine**

- 3.1. Basic VCT Principles
- 3.2. VCT Protocol, Content, General Clauses, Goal
- 3.3. Other Ukrainian Guidelines Relevant to VCT Services Organizing
- 3.4. Organization of VCT at Ukrainian Medical Care Institutions

#### **3.1. VCT Protocol, Content, General Clauses, Goal**

Since recently, a tendency toward an increase of the level of political will, intensification of activity and increase of the volume of material resources allocated to fighting the HIV pandemic have been observed on a global scale. In June 2004 UNAIDS and WHO proclaimed a new policy regarding the issues on testing and counseling for HIV, which highlights the importance of awareness of one's HIV status for broadening access to HIV prevention, treatment, care and support. The document clearly defines two strategies, the implementation of which may broaden access to HIV prevention, treatment, care and support. These include voluntary HIV counseling and testing (VCT) and HIV provider-initiated testing and counseling (PITC).

Again, in 2006 the UN General Assembly upheld the course for stepping-up efforts concerning prevention and treatment of HIV as well as care and support of people who need it.

Outlining the role of VCT for people and society, one may emphasize the fact that the implementation of the VCT strategy promotes the level of HIV informational content for people, minimizes the level of stigmatization and discrimination in society, forms safe behavior, assists in PMTCT, encourages treatment and prevention, prevents the spread of HIV infection among people in general and especially among the vulnerable groups and subpopulation. In other words, it is an effective tool for prevention of HIV infection.



In Ukraine the VCT strategy is guided by “Procedure for Voluntary HIV Counseling and Testing”, developed in accordance with the Law of Ukraine “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Protection of the Population” and the Resolution of the Cabinet of Ministers of Ukraine No. 264 “On Approval of the Concept of the Strategy of Government’s Effort to Prevent the Spread of HIV/AIDS Infection to 2011 and the National Program “Ensuring Prevention of HIV, Care and Treatment of PLHIV and People with AIDS for 2004-2008”, dated March 4, 2004.

The procedure for voluntary HIV counseling and testing (hereinafter referred to as “Protocol”) embraces state and communal medical care facilities, medical care institutions of other forms of ownership, public associations (PA) including international ones, other institutions, organizations and establishments in the sphere of prevention of HIV, care and support of people living with HIV. It is expected that successful cooperation of the said institutions and establishments in this direction will ensure the effective use of existing resources in the country to prevent the spread of HIV and broaden access to voluntary HIV counseling and testing for various populations in each administrative region of Ukraine.

The Report includes the following sections:

Order of the Ministry of Health of Ukraine No.415 “On Improvement of Voluntary HIV Counseling and Testing” of August 19, 2005, registered with the Ministry of Justice on 22 November 2005 under entry file No. 1404/11684

- General Clauses;
- Goal and Objectives of VCT;
- Principles of VCT;
- Counseling Procedure;
- Organization of Pre- and Post-test Counseling;
- Supervision, Monitoring and Evaluation of VCT.

The “Protocol” has appendices and reference materials.

The goal of VCT is providing counseling assistance to population in respect of the ways of HIV transmission and prevention, ensuring that voluntary informed decisions are taken as regards testing for HIV, definition of a person’s HIV status, maintenance of safe HIV infection behavior, timely receiving of medical assistance, i.e. examinations for tuberculosis, sexually transmitted infections (STI), opportunistic infections and treatment for them, timely start of ART, PMTCT, family planning services and all-round support (including the principle “peer to peer”).

VCT is considered to be the key component of the programs on prevention, treatment and care for PLHIV.

The objectives of VCT are as follows:

1. Slowdown the pace of HIV among the most at risk and general population by way of explaining the mechanisms and factors of HIV transmission, risks of infection, measures and means of reducing the risk of HIV infection, assessment of an individual risk, formation with a person his or her own assessment of the risk of HIV infection, procedure for testing and the interpretation of the results, providing all-round support, information about the existing state medical care institutions and other establishments, organizations, public associations that provide different kinds of assistance to those who need them, and ensuring that voluntary informed decisions are taken as regards testing for HIV.

2. Providing information on legal issues in relation to HIV.

3. Ensuring improvement of health of people, including their lifespan extension and standards of living of those living with HIV.

### **3.2. Basic VCT Principles**

In conformity with the VCT Protocol drawn up on the grounds of the recommendations of WHO and UNAIDS, the main principles of VCT are:

voluntariness

confidentiality

anonymity

accessibility

non-discrimination

reliability and completeness of information

occupational and technical perfection

mobilization of all resources

These are the compulsory minimum requirements to the procedure for voluntary HIV counseling and testing. Let us consider each separate principle.

The principle of voluntariness has been effective in Ukraine since 1998 and is outlined in Article 9 of the Law of Ukraine “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population”. The criterion of this principle is obtaining of informed consent of a patient to undergo testing during the pre-test counseling model. Testing for HIV can be conducted only after conscious and voluntary consent of the patient. It means that information to him or her was delivered in plain language and in a simple manner for him or her to be aware of positive and negative outcome of testing defining his or her HIV status. Moreover, the patient is expected to confirm his or her consent in writing to undergo testing or refuse to undergo it. The patient also can postpone for some time his decision on testing without any pressure placed on him or her. No pressure or unlawful application of force!

Voluntariness also assumes the absence of pressure on the person who attends a clinic to receive VCT in relation to changing his or her risky behavior. Only by way of motivation of the patient about the importance of learning his or her HIV status, it is possible to obtain his or her informed consent. In the event that a positive HIV status of the patient is produced during testing for HIV, this principle is most important to form a positive attitude with the patient to prevention and treatment.

Confidentiality is a principle according to which the person who attends a clinic to receive VCT provides the consultant with his or her personal details, and the consultant should not infringe on the right of the person for private life nor disclose the information obtained.

Anonymity is a principle according to which a person does not provide personal information, including their name, and the person remains anonymous (cannot be identified).

The information that becomes known in the course of VCT services to the consultant or the person who conducts testing (set of facts of the person's referrals, content of services received, personal background of the person, contact details, results of testing) is considered confidential. This information may be forwarded to the legal representatives of a child-patient or a patient who is under a disability, medical care institutions, prosecution agencies, investigation agencies, inquiry bodies, and court only in cases stipulated by the Ukrainian laws. Pre- and post-test counseling, as well as notification of the outcome of testing should be made maintaining confidentiality. "The disclosure of information by the employee of the health care facility, or an auxiliary staff, who, all by himself/herself or through a health care provider, obtained the information about conducting examination of the person for HIV or AIDS and its results, which became known to him or her during his or her course of duty, entails criminal liability" (Art. 132 of the Crime Code of Ukraine, 2001).

At the patient's will, HIV counseling and testing may be conducted anonymously, i.e. without keeping any records which may be used to identify the PLHIV (passport details, place of residence, etc.). In such a case, VCT is conducted using a code that is given to the patient for HIV counseling and testing and according to which the patient can receive the results of testing.

Accessibility and non-discrimination: VCT services should be accessible to all those who need them without any discrimination. We include both physical and economic aspects into the concept of accessibility. Physical accessibility implies that each person should be provided with information about the agencies that provide VCT services (addresses, phone numbers, and their office hours). With that end in view such information should be available at all medical care institutions, irrespective of the form of ownership. Such information should also be available at comprehensive and vocational schools, universities, enterprises, organizations and medical care institutions; and be distributed by mass media. Economic accessibility implies that testing should be

free of charge for all patients. Involving of state and municipal institutions, establishments and organizations, medical care institutions of other forms of ownership, public associations engaged in activity with different groups of population, including high-risk groups of HIV infection (harm reduction programs, etc.), facilitates broad access to VCT services.

The principle of non-discrimination is one of the most important in organizing of VCT services, since the people who are living with HIV experience the highest pressure of discrimination worldwide, including discrimination on the part of health care workers during medical examination for defining their HIV status.

Let us consider the concepts of stigma and discrimination.

Stigma (“label”, “brand”) is preconceived, unfavorable opinion about somebody or action against somebody, which radically changes the attitude to him or her of other people. It is a judgment. Discrimination is a behavior that shows prejudice and is against the rights of the individual. Discrimination needs to be addressed by documentation of the act and many times by involving the judicial services.

Stigma and discrimination has existed for prior to HIV against certain groups or people that practice behaviors that others do not understand, are afraid of, find unacceptable, or illegal. Even without HIV, many people practice stigma and discrimination against people who are physically or mentally disabled, have darker skin color, immigrants, people with TB, prisoners, drug users, men who seem “gay” and sex workers. In Ukraine and other countries, HIV has affected many injection drug users (IDUs), sex workers, both males and females. This has facilitated the discrimination of PLHIV as those referred to the categories of immoral characters – “pariahs”. The consequence of stigma and discrimination is that a person is unlikely to return for services since the experience has been humiliating and demoralizing. Unfortunately, stigma and discrimination against people living with HIV is still practiced worldwide. HIV education and information and people publicly speaking about living with HIV has made a difference, especially in urban settings. Yet, much stigma and discrimination still exists, including in health care settings, against people who inject drugs, sex workers, men who have sex with men, prisoners and others, which leads to the most at risk people being very reluctant to receive any services for fear of being humiliated and treated badly.

Besides “external stigma”, often people most at risk to HIV have their own “internal stigma”, their own shame about themselves. This internal stigma is important to recognize since it often leads to reluctance to receive VCT services and if a positive test result, internal stigma can be the factor that prevents a person to follow through with referrals or receive other services, including vital medical treatment. Health care workers who become infected with HIV (normally through practice unsafe sexual behavior) often have internal stigma since they are a “professional” they believe they “should have known better” and have much fear that others will find out about their

status and they will lose their job. Peer support has been shown to be an effective intervention to reduce internal stigma.

Reliability and completeness of information: everyone who is going to undergo testing should be offered pre- and post-test counseling, during which information about the goal and procedure, ways of HIV transmission, measures and means of prevention of HIV infection, existing opportunities of receiving medical, psychological and social assistance, etc. should be provided. The volume and form of the information delivered should be complete for the person so that he or she can realize the necessity and consciously decide to undergo such testing. The patients with both positive and negative results of testing for HIV, during notification of the results of testing at the state or any other medical care institution, should also be provided with information about medical, psychological, social and legal assistance centers open for them to attend, if need be.

Occupational and technical perfection: The doctor is required to possess relevant occupational qualifications – he or she is expected to have taken the training courses to improve his or her theoretical knowledge of VCT aspects, be familiar with the Protocol and regulatory system (Curricular and programs of such modules at the virology department of P. L. Shchupryk National Postgraduate Academy of Medicine are given in supplements). The issue of technical perfection, first of all, concerns workrooms for conducting counseling and all other aspects of laboratory diagnostics for HIV, which include the aspect of quality of diagnostics systems intended for defining antibodies to HIV, the use of only those testing methods, equipment, etc. that have been registered and certified in Ukraine.

Mobilization of resources: establishments, organizations and medical care institutions providing VCT services should be aware of the existence of other additional resources and cooperate with other establishments, organizations and medical care institutions providing medical, psychological, social legal and all other types of assistance.

### **3.3. Other Ukrainian Guidelines Related to Administering VCT Services**

Working experience and long-term teaching activity in the system of postgraduate training of doctors at the medical institutions of the 3<sup>rd</sup>-4<sup>th</sup> levels of accreditation show that doctors do not know much and quite understand the Ukrainian legislation, articles relevant to human rights, human health care. As a rule, paying attention to modern occupational information regarding medications, their side-effects, pharmacokinetics and pharmacodynamics, clinical presentations of illnesses, etc., they are less interested in the fundamentals of the Ukrainian legislation on health care, do not know the Law of Ukraine “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social

Security of the Population”, and it is on rare occasion that they refer to normative acts established by the Ministry of Health of Ukraine.

At present, the Ukrainian legislation on HIV meets the requirements of the European legislation norms, takes into consideration the recommendations of the United Nations in the sphere of ensuring human rights and is represented by a number of articles in the Constitution of Ukraine, laws, codes, normative acts of the Cabinet of Ministers of Ukraine and the Ministry of Health of Ukraine.

Providing VCT services with regard to the goal and the main principles of VCT is completely impossible without having knowledge and understanding of the regulatory and legal framework of the aspects of VCT.

Voluntary HIV counseling and testing is a key component of the National Program “On Ensuring Prevention of HIV, Care and Treatment of PLHIV and People With AIDS for 2007-2008” (hereinafter referred to as “Program”), endorsed by the Resolution of the Cabinet of Ministers of Ukraine No. 264 of March 4, 2004.

The introduction of the VCT component into the Program was based on the Articles of the Law of Ukraine “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population”, first adopted by the Verkhovna Rada of Ukraine in December 1991, and in August 1992 by the Resolution of the Cabinet of Ministers of Ukraine No. 460 “Rules of Procedure for Medical Examination Aimed at Defining Human HIV, Registration, Medical Inspection and Prevention Supervision of PLHIV”, which determine the subpopulation groups subject to mandatory medical examination (laboratory blood or other biological fluids tests aiming at defining of HIV). Practically, most of such subpopulation groups should have undergone mandatory testing (injection drug users, sex workers, etc.).

In 1998, some positive changes in the Law of Ukraine “On Prevention of Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population” were made, which made it possible to switch from mandatory to voluntary informed HIV testing along with the creation of relevant conditions for this purpose.

It is important to note that providing VCT services should be in full compliance with the Protocol of Voluntary HIV Counseling and Testing (Protocol) approved by the Order of the Ministry of Health of Ukraine No.415 of August 19, 2005, registered with the Ministry of Justice of Ukraine under entry file No. 1404/11684 on November 22, 2005, and shall be conducted provided that the main principles established by the Protocol are observed. At the patient’s will, HIV counseling and testing may be conducted anonymously, i.e. without keeping any records of personal data which may be used to identify the PLHIV (his or her last name, first name, middle name, date

and place of birth, place of work or study, etc.) and ensuring the confidentiality of medical examinations and their outcome.

Let us take a brief look at some of the most important normative acts adopted by the Verkhovna Rada, resolutions of the Cabinet of Ministers of Ukraine and those adopted by the Ministry of Health of Ukraine as well as other central agencies of the executive power.

The Constitution of Ukraine ( 254k/96-VR), Article 49. Contents: Everyone has the right to health protection, health care and health insurance. The State creates conditions for effective medical service accessibility to all people. State and communal medical care institutions provide medical care free of charge.

Civil Code of Ukraine.. Chapter 20. General Provisions on Personal Non-property Rights of Natural Persons. Article 284 “Right to Medical Assistance”. Contents: A natural person has the right to confidentiality of his or her state of health, set of facts of referrals for medical assistance, diagnosis, as well as information obtained during a medical examination.

It is forbidden to demand and deliver information about the diagnosis and methods of treatment to the management at the place of work or study. A natural person is obliged to refrain from the disclosure of the information set forth in Paragraph 1 of this Article, and which became known to him or her in the course of fulfillment of his or her occupational duties or from other sources.

Civil Code of Ukraine. Paragraph 20. General Provisions on Personal Non-property Rights of Natural Persons. Article 301. “Right to Privacy and Secrecy”. Contents: A natural person has the right to confidentiality of his or her private life. A natural person’s private life details may be disclosed by other people provided that such details do not contain signs of violation of law, established by a court decision.

Civil Code of Ukraine. Paragraph 20. General Provisions on Personal Non-property Rights of Natural Persons. Article 302. “Right to Information”. Contents: Gathering, use, and disclosure of information about a natural person’s private life without his or her consent is forbidden, except otherwise stipulated by the legislation and only in the interests of the national security, economic wealth and human rights.

The Law of Ukraine “Fundamentals of the Legislation of Ukraine on Health Care”. Article 39. “Obligation to Provide Medical Information”. Contents: A doctor is obliged to explain to the patient in an appropriate way the objective of offered examinations and measures of treatment, prognosis for advancing of the disease, including the risks to his or her life and health. A patient has the right to familiarize him or herself with his or her case history and other documents that can be used for further treatment. On special occasions, when complete information may cause harm to a

patient's health, a doctor may provide him or her with only part of such information. In such a case, a doctor should inform the members of a patient's family or his or her legal representative taking into account private interests of the patient. A doctor acts this way when the patient is unconscious.

Article 40. "Medical Secrecy". Contents: health care workers and other people, to whom such information about a disease, medical inspection, examination, and their results, private and family life of a person became known in the course of fulfillment of their occupational duties, shall not have the right to divulge this information, except otherwise stipulated by the acts of law. When using the information considered being a medical secrecy during training, scientific research, including its publication in special literature, the anonymity of a patient's data should be ensured.

Article 43. "Consent to Medical Intervention". Contents: Informed consent of the patient, according to Article 39 of these Fundamentals, is required for application of methods of diagnostics, prevention and treatment. As regards a patient under 15, as well as the patient who is legally incapable, according to established procedures, medical intervention shall be performed by consent of their legal representatives. In emergency, if there is an actual threat to a patient's life, his personal or his or her legal representative's consent for medical intervention may not be required. If no consent is given and this may result in serious consequences for the patient, a doctor is obliged to explain this to the patient. If no consent to treatment is given after such explanation, the doctor has the right to require that the patient should present his or her refusal in writing, and if there is no opportunity to obtain it, he or she shall confirm such refusal by drawing up a report in the presence of witnesses.

If such refusal is provided by a legal representative of the patient, and it may result in serious consequences for the patient, the doctor shall give patronage agencies a notice to that effect.

The Law of Ukraine "On Acquired Immunodeficiency Syndrome (AIDS) and Social Security of the Population". Contents: This Law defines the procedure for legal control of the activities aimed at the prevention of the spread of HIV in Ukraine, and appropriate measures of social protection of PLHIV, in accordance with the standards of international law and recommendations of WHO.

The Law consists of 7 sections comprising 34 articles.

Rights of people to a medical examination are defined by the following articles of the Law: In Section I "General Provisions", Article 4 defines state guarantees concerning accessibility, quality, and effectiveness of medical examinations aimed at defining of HIV, including the anonymous one, providing preliminary and further counseling assistance; -- ensuring of the activity aimed at the formation of stereotypes with the population of a safe sexual behavior and awareness of a high risk of HIV during the use of injection drugs;



-- safety of treatment and the diagnostic process for patients and medical personnel at the state medical care institutions, state sanitary-and-epidemiologic control over safety of such process at medical care institutions of all forms of ownership, as well as the performance of measures aimed at the prevention of the spread of HIV infection in the course of private medical practice.

In Section II “Conditions and Procedure for Medical Examinations Aimed at Defining of HIV Infection. Registration of PLHIV and people living with AIDS, providing them with medical care and medical supervision” Articles 7, 8, 9, and 12 contain certain information about the organization of VCT services.

Article 7. Citizens of Ukraine, foreigners and people without citizenship who permanently reside or are lawfully temporarily residing in the territory of Ukraine have the right to a medical examination for HIV, obtain official results of such examination and qualified recommendations concerning the prevention of the development of HIV. Only state and communal medical care institutions with adequately equipped and accredited specialized laboratories have the right to produce the official results of such examination. A medical examination is voluntary and free of charge.

A medical examination of children under 18 and those who are legally incapable can be conducted on request or consent of their legal representatives who shall have the right to be present during such examination. Those who have been examined have the right for a repeated medical examination to be conducted at any time, at their choice, at the same or at any other medical care institution accredited according to the established procedure.

Article 8. At the will of a person who visited a medical care institution for a medical examination, such medical examination may be conducted anonymously. Information relevant to the medical examination, the presence or absence of HIV with the patient shall be considered confidential and constitute medical secrecy. Such information may only be disclosed to the person concerned, and in other cases stipulated by the legislation, also to legal representatives of the person, a medical care institution, prosecution agencies, investigation agencies, inquiry bodies, and court.

Article 9. According to the results of a medical examination, the person infected with HIV infection shall be notified about this by an authorized medical worker of the medical care institution in which such medical examination was conducted in full compliance with the Law on confidentiality of such information... If HIV is defined with young children or incapable people designated as such in accordance with the established procedure, an authorized medical worker of the medical care institution where the medical examination was conducted, shall notify about this the family members or other legal representatives of such people.

The rights of PLHIV are allowed for in the fourth section of the Law – “Social Protection of People Infected With HIV”.

Article 12. Medical care of PLHIV and people living with AIDS – residents of Ukraine, non-residents and people without citizenship shall be provided under general conditions in accordance with the established procedure and in compliance with international agreements of Ukraine. Records, registration of people living with HIV (PLHIV) and medical supervision shall be conducted in accordance with the principles of confidentiality and respect of their private rights and human liberties.

Article 17. People living with HIV (PLHIV) shall enjoy the rights and freedoms stipulated by the Constitution and laws of Ukraine.

Article 20. The people who became infected with HIV as a result of medical manipulations shall have the right to be reimbursed for the harm caused to their health at the expense of the person at fault according to the judicial procedure.

Obligations of PLHIV are stipulated by the following Articles of the Law:

Article 9. ...A PLHIV shall be simultaneously notified about the necessity of adherence to prevention measures aimed at prevention of the spread of HIV, guarantees of adherence to the rights and freedoms of PLHIV as well as criminal liability for knowingly putting at risk of infection or infection of other people.

Article 14. If information from a medical care institution about HIV and warning about the necessity to adhere to prevention measures aiming at the prevention of the spread of HIV and criminal liability for knowingly putting at risk of infection or infection of other people is received, PLHIV shall be obliged to confirm the receipt of such information and warning in writing.

Article 15. PLHIV are obliged to take measures aimed at the prevention of the spread of HIV, shall notify those who had had sex with them prior to infection about the risk of being infected and they shall refuse from any types of donor activity.

The rights of medical care institutions are set out in the following articles:

Article 7. Only the state and communal medical care institutions shall have the right to perform a medical examination and produce official conclusions on its results.

Also, in Chapter 5 “Social Protection of Health Care Workers...”

Article 25. If health care workers (HCWs) and pharmaceutical industry workers get infected with HIV at their work place, HIV in this case shall be considered an occupational disease.

Article 26. The health care workers (HCWs) involved in laboratory examinations and scientific researches in relation to HIV issues...are subject to compulsory state insurance against

HIV infection during the fulfillment of their official duties at the expense of the owner of the medical care institution (MCI).

Article 27. Health care workers who were infected with HIV in the course of fulfillment of their occupational duties, have the right to annual free sanatorium-and-spa treatment, annual holidays of 56 calendar days that can be used by them at any time that is most convenient for them.

Article 28. Health care workers, who were infected with HIV in the course of fulfillment of their occupational duties, have the priority right to improvement of their housing conditions.

Article 29. The health care workers (HCWs) providing services for PLHIV, using laboratory diagnostics of HIV ...shall have salary bonuses and the right to pension on a preferential basis as well as an additional annual holiday...

Article 30. The owner of the medical care institution (MCI), the personnel of which are involved in diagnostic studies and provide medical aid to PLHIV, is obliged to ensure that the personnel are provided with necessary means of protection.

Liability of medical care institutions is set forth in the following articles and sections:

Article 18. A medical care institution's refusal to admit and/or provide medical aid, denial of other rights of people with reference to the fact that they are PLHIV as well as the denial of the rights of their family members and close ones, is forbidden thereupon.

Article 19. Illegal actions of officials who infringe on the rights of PLHIV, their family members and close ones, may be challenged in court;

Also, in Section VI "Liability for Violations of Law in the Sphere of Fighting AIDS".

Article 31. The refusal of officials in the realization of a person's right to a medical examination for HIV, or conducting such examination without the person's prior consent, or inappropriate discharge of officials' duties, which led to HIV infection, as well as disclosure of information relevant to the medical examination and its results, entails liability as established by the Ukrainian legislation.

In the last seventh section of the Law, Article 37 says that the official documents containing confidential information, personal data specifying the details of peoples' private life, which shall not be subject to disclosure pursuant to other legislative and normative acts, may not be obligatory submitted.

The Resolution of the Cabinet of Ministers of Ukraine No. 264 "On Approval of the Concept of the Strategy of the Government's Effort to Prevent the Spread of HIV for the to 2011 and the National Program on Ensuring Prevention of HIV, Care and Treatment of PLHIV and People Living with AIDS for 2004-2008", dated March 4, 2004. The VCT issues are covered in the Section "Arrangements to Implement the Program", paragraphs 9,14,18,21. Contents: Extend the

potential of access of various population categories to the system of voluntary HIV counseling and testing. Create conditions for providing psychological, social, legal, medical and counseling services to reduce the risk of HIV infection and adopt a policy to avoid the discrimination against PLHIV, including those in the sphere of human activity. Ensure free access to voluntary HIV counseling and testing for pregnant women as well as information about the issues of HIV disease in general. Ensure voluntary HIV testing services for different categories of the population to be provided free of charge.

The regulatory base of the Ministry of Health of Ukraine contemplates the approval of methods and procedures for both counseling and testing, including instructions on the organization of work of laboratories for HIV diagnostics, guidelines for the use of rapid blood tests to define antibodies to HIV, maintenance of records and reporting documents, etc.

### **3.4. Organization of VCT at Ukrainian Medical Care Institutions**

According to WHO and UNAIDS, voluntary HIV counseling and testing (VCT) is a general model of ensuring testing and counseling on the client's (patient's) initiative. Following this model's criteria, separate individuals (clients or representatives of public HIV-service associations) should take the lead in the issues on testing for HIV. Yet, VCT services, provided on the initiative of the patient, cover a limited number of population categories that can have access to such services because of a high level of stigmatization and discrimination, as well as a low level of awareness of the availability of such services and risks of infection among people.

To avoid the aforesaid negative factors, in 2007 WHO/UNAIDS established a new model of the organization of voluntary HIV counseling and testing under the title "Guidelines for HIV Counseling and Testing at Medical Care Institutions on the Initiative of the Providers of Health Care Services", which contemplates scaling up access to the procedure for HIV counseling and testing of the population including the population groups vulnerable to HIV infection.

In this country, the procedures for the organization of counseling and testing services with reference to the methodological aspect are established by the August 19, 2005, with the Order of the Ministry of Health of Ukraine No. 415 "On Improvement of Voluntary HIV Counseling and Testing" drawn up on the basis of a multi-sectoral approach and involvement of all state structures concerned, state and non-state social organizations. This Order was registered with the Ministry of Justice under entry file No.1404/11684 on November 22, 2005, which allows using it across Ukraine and for establishments and organizations of different forms of ownership.

The Protocol Section “Peculiarities of Counseling of Various Groups of Population”, which determines the procedures for counseling pregnant women, family members, adolescents, blood donors, medical care workers, military men, as well as inmates and convicts, sex workers, injection drug users, TB patients, etc., gives evidence of the normative regulation of the issues on scaling up access to counseling and testing services for the population.

The idea of scaling up access to the VCT services for most at risk populations was supported by the President of Ukraine by way of endorsing his November 30, 2005, Decree No. 1674/2005 „On Improvement of State Administration in the Sphere of Fighting HIV/AIDS and Tuberculosis in Ukraine”, which provides for establishing a network of offices for provision of adequate services within the system of medical care institutions. The June 27, 2006, Order of the Ministry of Health of Ukraine No.421 “On Approval of the Draft Regulations of the “Trust” Office set the procedure for opening and operation of such offices not only in the oblast centers and large cities, but also all across administrative regions of the country.

With aim to scale up access to HIV counseling and testing for the population most susceptible to the risk of HIV infection -- injection drug users, TB patients, people with STI, and those who attend a medical care institution for assistance in the country, an additional procedure was developed and established by the Order of the Ministry of Health of Ukraine “On the Approval of the Instruction on the Introduction of the Procedure for Voluntary HIV Counseling and Testing (Protocol) at TB, STI and Drug Rehabilitation Clinics”.

Therefore, access to the VCT services for the entire population in the country has been formalized. The organizational procedure for providing such services is stipulated by the relevant Order of the Ministry of Health of Ukraine (dated 19 April 2006 No. 236 “On the Organization of Implementation of the Procedure for Voluntary HIV Counseling and Testing (Protocol) at Medical Care Institutions”. The plan of action on organizing the implementation of the Protocol points out the necessity of taking such measures as follow:

- issue of an organizational order to be operative in the territory of the country, oblast and town;
- establishment of a network of trust offices in accordance with the adherence to relevant requirements and confidentiality for conducting quality HIV counseling and testing;
- appointment of responsible people to be involved in the organization of HIV VCT services in the administrative territory;
- organization of an ongoing system of learning the VCT Protocol for medical care workers involved in providing VCT services;

-- assistance in the involving of psychologists, social workers, workers of civil and charity organizations, religious confessions in pre-test counseling and ensuring access to a relevant teaching process;

-- carrying out of a prompt review of the activities of medical care institutions concerning the issues of VCT including further discussions at conferences and board meetings.

One of the most important items of the plan of action is the necessity to define and approve the scheme of cooperation between medical care institutions and organizations providing HIV VCT services in the territory where such services are provided, since the Protocol contemplates a system of cooperation between medical care institutions and organizations of different forms of ownership including public associations (PA) in providing such services. It provides for scaling up access to VCT services for the population including the representatives of groups most vulnerable to HIV infection by way of entering into agreements on cooperation between a regional AIDS center, other state or communal medical care institutions and public associations (PA), other establishments that are involved in this sphere and that possess relevant experts providing counseling services.

The cooperation of state, communal medical care institutions, PA, religious and other associations involved in the sphere of providing HIV services and their prevention, providing services for people living with HIV will ensure the rational use of the existing resources for providing VCT services. It is necessary to ensure ongoing information sharing among people about the availability of such institutions and the scope of services provided by such institutions. The regional AIDS centers are responsible for gathering and distributing such information.

If pre-test counseling is conducted at medical care institutions and establishments and organizations other than the state and communal medical care institutions, PA and the patient expresses his or her desire to undergo testing, the counselor directs the patients to undergo HIV testing at a territorial polyclinic, AIDS center or any other state or communal medical care institution where the aforesaid testing can be conducted.

The system of cooperation between the aforesaid entities should ensure, depending on the needs of the patient, access to HIV counseling, reproductive health, STI, TB, other opportunistic infections counseling, receiving medical, psychological, social, legal, other types of assistance.

Pre- and post- HIV testing and counseling services can be provided by counselors of the state and communal health care institutions, as well as the state non-medical institutions (centers for social services to family, children, and youth, etc.), medical care institutions of other forms of ownership, representatives of religious associations and PA providing services in the field of HIV issues, FBOs that support PLHIV, groups of PLHIV (upon one's consent).

Only the counselors who have participated in special training programs, according to the requirements of the Protocol, are allowed to do HIV counseling and testing.

According to the existing legislation in Ukraine, only the state and communal medical care institutions that possess adequately equipped special laboratories and that are accredited in accordance with the procedure established by the Cabinet of Ministers of Ukraine shall be entitled to carry out a medical examination aimed at defining of HIV and prepare the official medical report about the results of such examination.

A medical examination for HIV is conducted by way of sampling of blood or other biological fluids that are forwarded to a specialized HIV diagnostics laboratory. The person defined as the one infected with HIV, according to such examination, shall be notified about this by an employee of the state or communal medical care institution following the principle of confidentiality of such information.

Pre- and post- HIV testing counseling can be provided by HCWs of the state and communal medical care institutions, organizations, and establishments, as well as by HCWs of establishments, organizations, and institutions of other forms of ownership, and representatives of PA, in accordance with the requirements of this Procedure, motivating the patient to undergo testing for HIV and referring the patient to the state and communal medical care institutions to undergo such testing.

After primary post-test counseling at the state or communal medical care institution, the patient may, at his or her will, visit other institutions, organizations, establishments, and PA for further post-test counseling.

To ensure the effective cooperation of institutions, organizations, and establishments of different forms of ownership, as well as PA, it is advisable to make a list of services that patients may be provided within the framework of the agreement and mutual obligations of the organizations and institutions in relation to the performance of this work.

What organizations and institutions can provide counseling services? They are:

- medical care institutions of other than the state and communal forms of ownership;
- centers for social services to families, children and youth;
- educational institutions;
- public associations working with IDUs, SWs, prisoners, men who have sex with men;
- PLHIV support groups;
- religious societies, etc.

An important point in the process of organization of high-quality VCT services is planning, provision of diagnostic laboratories with test-systems, and their efficient use. At present, planning and purchasing of the test-systems for donors and pregnant women is centralized and

financed via the state budget based on the number of donations of blood and deliveries during the previous year, taking into account the correcting factor.

The purchase of test-systems for the general population, according to the Law of Ukraine “On the State Budget of Ukraine”, shall be carried out at the expense of local budgets, as well as following the analysis of the number of testing sessions conducted during the previous year, the number of the population vulnerable to HIV, and the peculiarities of the region.

A considerable contribution to implementing measures of regional HIV programs on VCT services is the realization of international programs and projects. These involve teaching counselors, trainees and supervisors, providing technical assistance in the publication of the relevant information for the population, and purchasing the needed testing models most frequently used at mobile VCT units, which make VCT services more accessible to the most at risk groups to HIV (e.g. IDUs, SWs, MSM, prisoners) and where the cooperation between the medical workers of the communal medical care institutions (doctors and laboratory technicians) with psychologists and social workers of PA promotes the expansion of counseling and testing services and improves their quality.

Consequently, the regulatory framework enabling the use various models of providing VCT services is substantiated in this country:

- model on the basis of specialized centers (centers for prevention and fighting AIDS, “Trust” offices);
- combined model (special departments at medical care institutions, where separate VCT offices/units were organized);
- model in relation to the activity of PA (counseling only);
- model in relation to the activity of private medical care institutions (counseling only);
- models in relation to the joint activity of PA and state and communal medical care institutions (during the operation of mobile VCT units or VCT offices at the AIDS centers and other medical care institutions established by non-governmental organizations).

All the models above have advantages and disadvantages; therefore, none of them may be defined as a standard one. Each model may be used depending on the needs and peculiarities of the region.

While talking about the organization of HIV counseling one should primarily focus on confidentiality, which is stipulated in Ukrainian laws and is an integral part of human rights guarantees.



The process of counseling and HIV testing is complicated by the people's fear of disclosure of information about their private life, the fear of alienation and discrimination in their families and in the society.

Ensuring confidentiality of VCT information shall be mandatory for the facilities, institutions and organizations (hereinafter - organizations), that provide VCT services. "The disclosure of information by the employee of the health care facility, or an auxiliary staff, who, all by himself/herself or through a health care provider, obtained the information about conducting examination of the person for HIV and its results, which became known to him or her during his or her course of duty, entails criminal liability" (Art. 132 of the Crime Code of Ukraine, 2001).

The aforementioned employees shall observe the rules of processing, the use, and the storage of documents that contain confidential information, take into account that personification of PLHIV is prohibited when one is making national, departmental and other reports, presents information on HIV, gives information to mass media; it is also prohibited to use other characteristics that make possible the identification of a PLHIV.

Managers of organizations where pre- and post-test counseling is done shall be responsible for complying with information confidentiality requirements and shall control compliance with confidentiality requirements.

The manager's main confidentiality responsibilities are the following:

- creating conditions that would ensure confidentiality in a counselor's work;
- preventing access to confidential information by any official or staff member, except the staff responsible for pre- and post-test counseling and testing.

In implementing the aforementioned tasks, the organization manager shall:

- issue an in-house order that would name the counselors responsible for pre- and post-test counseling;
- ensure the adequate level of their professional training, their familiarizing with laws and legal acts on HIV, including those on issues of confidentiality assurance;
- organize official investigations of cases of the disclosure of confidential information about patients, who came to receive counseling and/or to have a test done.

Another important component of VCT confidentiality is the record keeping procedures ensuring the patient's right to medical secrecy of his/her personal information.

Access to all patient information shall be restricted; the restriction status shall be set by the manager.

The access status shall ensure that unauthorized persons (support staff, relatives of the employees, etc.) do not have access to the information. It means that the following documents containing the patient's personal data shall be kept in safes: logbooks of voluntary pre- and post-test counseling for HIV testing (form #503-/o); logbooks where PLHIV are registered; information kept in accounting departments of the regional AIDS centers on babies born to infected mothers, which is used for social welfare purposes.

Confidential information shall be handled in such a way that would make impossible for unauthorized persons to have an access to it; archiving of the information and maintenance of the archives, the outpatient medical records of PLHIV shall be kept in the office of the authorized physician or infectious disease physician at the facility.

System of coding of HIV status (diagnosis) in medical documentation should comply with requirements of MOH Order #120 of 05/25/2000 "On improvement of medical care services provided to PLHIV," registered at the Ministry of Justice of Ukraine on 11/14/2000, #819/5040. There shall be no codes indicated on the cover of an outpatient or inpatient medical record or a child's medical record. Health personnel shall be informed where the code is to be entered into the medical records.

The information about a person seeking VCT, including PLHIV, shall remain confidential for an unlimited time. When employed, and annually thereafter, medical setting employees (both medical personnel and support staff) shall become familiar (and confirm it with their signature) with the requirements of the Law of Ukraine "On AIDS prevention and social security of the population" regarding the confidentiality of information about HIV test results, and their criminal responsibility for any unauthorized disclosure of information learned while performing their duties.

While working with computer databases containing information on PLHIV, it is necessary to make sure that it is impossible to have an access to personal databases through the Internet. The database should be in a separate computer that isn't connected to the Internet. Personal databases should be protected by a password known only to the health provider designated by the order of the manager. Personal data are removed when the database is sent via e-mail. Computers with confidential information can't be used for non-related database maintenance purposes or for personal use.

### **Requirements to the counseling stations**

The counseling can be provided both by the detached VCT settings (“Trust” offices, needle exchange points, mobile VCT vans for hard-to-reach groups and rural population etc.) and by medical settings, if under VCT guidelines.

Counseling stations may be either stationary or mobile. When organizing and deciding on the location and the work hours of the counseling stations, it’s necessary to take into account the needs of the potential clients (pregnant women, youth, IDUs, SWs, MSM, etc.).

Since, according to the Art. 7 of the Law of Ukraine “On AIDS prevention and social security of the population”, medical examination (testing and lab tests) to detect HIV and issue official results of the examination may be done only by public or municipal medical institution, the counselor in an NGO or private clinic after pretest counseling is expected to offer the patient testing at the public or municipal medical institution. Nowadays, the amendments to the Ukrainian legislation are negotiated, which would enlarge the list of organizations authorized to provide HIV rapid testing, however, there are still no official documents regulating this issue.

#### **Stationary counseling facilities standards**

Counseling shall be provided in a separate room that is not a connecting one.

During the counseling, the door of the room shall be closed to prevent anyone walking in and interrupting the counseling. The counselor shall not be disturbed by telephone calls.

The room shall be big, light, clean, with fresh air, and well-furnished. The interior of the room shall be comfortable and pacifying.

It is advisable to have next to the counseling room a waiting area with an adequate number of chairs, a table with info-literature on HIV. When inviting a patient to the counseling room, it is necessary to ensure confidentiality regarding the patient’s name and the fact that he/she seeks VCT services (give no names or other information that might be used by the other patients to identify the patient).

In the public and municipal medical settings, it is advisable that the counseling room is located next to the manipulation room.

#### **Mobile counseling facilities standards**

Mobile counseling facilities can be created to provide VCT services to hard-to-reach and most at risk groups (IDU, SW, homeless and street children, men who have sex with men, ex-prisoners, rural population etc.).

The “mobile” counseling may be provided in any place that is safe both for a counselor and for a patient and that ensures confidentiality.

Mobile facilities can be organized by both medical/non-medical public/community-based organizations, institutions, settings, private settings and NGOs. When a mobile counseling facility is established, confidentiality of its work shall be ensured. Counseling services shall prevent any stigmatization of the patients who seek them.

Forms of mobile VCT facilities:

- a mobile laboratory that goes directly to the places where certain categories of patients can usually be found, to harm reduction sites<sup>1</sup>, to places where SW<sup>2</sup> usually work, etc. to take blood samples for HIV test or provide HIV rapid testing. Such a laboratory can be a part only of a public or community-based mobile medical unit.
- counseling units of NGO or other institution/organization where employees provide pre- and post-test counseling services.

### **Requirements to the counselors**

Pre- and post-test counseling can be carried out by health professionals (doctors and nurses), psychologists, social workers, or NGO members, who work in the field of HIV disease prevention (including PLHIV groups), and who had special training.

During the period of time needed to train adequate number of counselors, counseling may be carried out by specialists, who have a good knowledge of this Protocol and can ensure the implementation of all requirements.

### **Training of counselors shall be carried out:**

- by educational institutions with highly qualified teaching staff and VCT training programs, which train health managers, psychologists, and social workers – if the HIV training course with basics of VCT is included in the educational institution’s curriculum, according to the Protocol and this Guide;

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<sup>1</sup> The USAID| Health Policy Initiative does not condone or promote the use of illegal drug use and U.S. Government policy prohibits the use of federal funds for the purchase or distribution of needles and syringes for the purpose of injecting illegal drugs. USAID is, however, committed to supporting effective strategies to prevent the spread of the HIV epidemic. Risk for HIV infection is one of the harms associated with injecting drug use. There are many challenges in changing addictive behaviors; thus “harm reduction” programs are designed to reduce the harmful impact of drug use on the user, his/her partner(s), and the community. Comprehensive harm reduction programs encompass a range of interventions, including voluntary HIV counseling and testing, information on the risks associated with injecting drug use, referral services, demand reduction programs, and substance use treatment, as well as needle and syringe exchanges in some cases.

<sup>2</sup> The USAID| Health Policy Initiative does not support the legalization of prostitution or sex trafficking. It is, however, committed to supporting effective strategies to prevent the spread of the HIV and other STIs and mitigate their impacts. The use of the terms “sex work” and “sex worker” does not imply support for prostitution as a legal form of employment; rather they are used as a way to reduce stigma and discrimination faced by sex workers, who may be vulnerable to exploitation and lack access to health-related and other types of information and services.

- by projects of international technical assistance, that act on the basis of MOU in the field of health care;

- through continuous guidance and supervision of counselors by qualified specialists.

**To provide high-quality and effective assistance, the counselor shall:**

Have:

- an adequate bulk of up-to-date information on HIV, practical skills of counseling, self-control, coping with stress and psycho-emotional exhaustion;

Be able:

- to establish positive, trust-based relations with a patient, to understand the patient's feelings, his/her problems, and to take into account the patient's individual character, psychology, age, gender, and social particularities; to separate and overcome one's own feelings, attitude, and biases; to improve the patient's awareness, and, by means of his/her assessment of his/her own risk of getting infected, encourage the patient's decision to reduce his/her own risk; to use language that is easily understood by the patient; to identify the most common psycho-social and clinical complications related to HIV: anxiety, depression, obsessional ideas, suicidal ideation, need in and seeking for revenge, etc.; to maintain tactful and friendly contacts with various people, who are different by their background, education, and lifestyle;

Know:

- about particularities of the lifestyle of PLHIV, people with high risk behaviors, and be able to tactfully discuss with them intimate issues related to risk of infection, including motivations for risky behavior; about available services and organizations that provide support to PLHIV and to people with high HIV risk behaviors;

Constantly improve one's professional level and skills, attend specialized conferences, trainings, and seminars, if possible – to take part in discussion of clinical cases.

Not exceed one's authority during counseling, not provide information or recommendations that exceed one's level of training and professional competence. In case of a lack of special knowledge, the counselor shall recommend a relevant specialist to the patient.

Also, when doing a group counseling/informing, the counselor shall be able to cope with difficult situations that might occur in a group: be able to communicate with peremptory persons, who would tend to dominate in the group; be able to engage into discussions those who are quiet, shy, but attentive; let all the participants express their thoughts; be able to handle people who lose control of their emotions in front of others; be unbiased and sensitive to any beliefs (religious, cultural, medical etc.) of group members; refrain from "lecturing" to the group, let the

participants, in the process of communication, learn something new from the experience of other group members; behave as one of the group members, not as a teacher in the class.

### General requirements to the counselor's pre- and post-test counseling skills and behavior

COUNSELING ABILITY	COUNSELING SKILLS
<p>1. Ability to establish positive rapport with the client, which implies: creation of an atmosphere that ensures comfort, conditions for privacy and confidentiality; interest and sympathy, ability to react to the patient's emotional condition (possible nervousness and confusion); unbiased attitude, active listening (verbal and nonverbal), emotional warmth and support.</p> <p>2. Ability to collect information, which includes:</p> <ul style="list-style-type: none"> <li>- correct use of close-ended and open-ended questions;</li> <li>- silence and active listening for the patient to be able to speak his/her mind;</li> <li>- specifying the patient's expectations.</li> </ul> <p>3. Ability to provide the patient with necessary information: the counselor's ability to convey information about HIV disease in a clear and distinct way; ability to repeat and to highlight important information, ability to check how the patient understood information he/she was provided with and level of its generalization.</p> <p>4. Ability to cope with complicated situations arising during counseling sessions, which includes:</p> <ul style="list-style-type: none"> <li>- ability to talk about intimate topics, taking into account cultural particularities, education, religious and other beliefs of the patient;</li> <li>- ability to identify and take into consideration the patient's typical psycho-emotional response to the</li> </ul>	<p><b>Verbal communication skills:</b></p> <ol style="list-style-type: none"> <li>1. Sympathize and understand the patient's situation, recognize the patient's feelings, accept his/her words, expressions and gestures;</li> <li>2. Respect the patient's views, opinion, and traditions, even if they have nothing in common with the counselor's;</li> <li>3. Ask, specify and retell the information provided by the patient, using different words and expressions so that the patient could identify his/her own resources and seek positive solutions with the counselor;</li> <li>4. Repeat information that, due to emotional shock or rejection, was not perceived or clearly heard;</li> <li>5. Summarize key points of the session to focus attention on decisions that have just been made.</li> </ol> <p><b>Nonverbal communication skills:</b></p> <ol style="list-style-type: none"> <li>1. Talk with the patient in the similar tone and in the similar tempo.</li> <li>2. Maintain eye contact;</li> <li>3. Show attention with facial expressions, posture and gestures.</li> <li>4. Remain at an appropriate distance from the patient.</li> <li>5. To ease up tension, use appropriate humor and gestures</li> </ol>

<p>diagnosis (emotional shock, suicidal ideation, rejection, exasperation, etc.);</p> <ul style="list-style-type: none"> <li>- ability to calm down and soften the patient's emotional reactions, upon patient's consent, engage in counseling another specialist (if it is appropriate and necessary);</li> <li>- understand the patient's colloquial flavor, be able to adapt to it;</li> </ul> <p>5. Ability to role play with the patient (on informing the partner about positive result of HIV testing, promotion of safe sex, etc.)</p>	
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To ensure monitoring of the effectiveness of counseling at all institutions and establishments providing VCT services, it makes sense for the interested parties to conduct an analysis of further referrals to medical care institutions for examinations aimed at defining of HIV, as well as social, psychological, legal services for assistance and support.

The procedure for sharing information about the existing resources for the organization of counseling for different populations in connection with HIV testing may be approved with the decision of the local HIV Coordination Councils established at local state administrations.

To monitor the effectiveness of the system of cooperation, it is required that a register of voluntary pre- and post-test HIV counseling be maintained (No. 503/o) and records of referrals and their outcomes be kept.

## **Section 4. VCT Algorithm. Pre- and Post-test Counseling**

- 4.1. VCT Algorithm
- 4.2. Pre-test Counseling
- 4.3. Post-test Counseling
- 4.4. Peculiarities of Counseling of Some Certain Populations
- 4.5. Peculiarities of Counseling of MARPs
- 4.6. Counseling Mistakes

### **4.1. VCT Algorithm**

Let us try to establish an algorithm for voluntary HIV counseling and testing considering the forms, goal, objectives and content of pre- and post-test HIV counseling and relative results of testing and then consider each element one at a time. (Fig. 4.1).

Figure 4.1 VCT Algorithm.

### **4.2. Pre-test Counseling**

Pre-test counseling is an interview conducted between a doctor and a patient with only one clearly defined **goal** to provide a patient with the maximum amount of precise and reliable information relevant to prevention of HIV transmission and, at the same time, to provide psychological and emotional support to a person to help him or her make an informed decision relevant to testing and undergo testing to define his or her HIV status.

Efficient pre-test counseling helps a patient raise his or her awareness, uptake information about the main issues of HIV disease and various aspects of prevention of this disease. Such information should be complete so that the person himself or her self could evaluate the risks of his or her behavior, which may lead to HIV infection. The information obtained about the capabilities of modern laboratory diagnostics of HIV; about the methods of defining antibodies to HIV using special test-systems including simple/rapid tests (testing) and the meaning of the results of such testing should help the person make his or her final voluntary decision to undergo testing.

Pre-test counseling may be conducted for an individual or a group of people at a time, i.e. there are individual and group level sessions of pre-test counseling/informing.

An individual counseling session is a more patient-centered approach, it is provided to all who want it including a post-test group session. The goal of conducting such counseling is not only to provide the aforesaid general information relevant to HIV disease given in Section 1 and 2, but also to evaluate an individual risk of infection, the development of an individual plan to decrease the risk of infection and find out the consequences of defining an HIV status for such person under specific conditions of his or her life.

Individual counseling is conducted solely and exclusively in full compliance with the



Procedure for Voluntary HIV Counseling and Testing (Order of the Ministry of Health of Ukraine No. 415 of August 19, 2005).

While providing individual counseling, a doctor should tactfully explain to his or her patient the reason why he or she asks intimate questions. The doctor should assure the patient that the person's answers are kept confidential!

For the process of counseling, it is best to break down the process into stages and conduct counseling step by step as if you went upstairs. (Fig. 4.2).

#### Figure 4.2 Counseling Stages

As an illustration of such individual counseling, refer to the material given in Table 4.1.

Table 4.1. Content of Individual Pre-test Counseling

Introduction to the content of counseling	<p>Explain:</p> <ul style="list-style-type: none"> <li>• voluntariness, confidentiality of HIV counseling and testing and that the latter is free of charge;</li> <li>• VCT procedure;</li> <li>• Goal and objectives of HIV pre-test counseling;</li> <li>• Possible results of testing, their evaluation;</li> <li>• Ways of HIV transmission;</li> <li>• Behavioral risks of infection;</li> <li>• Measures relative to prevention of HIV infection.</li> </ul>
Evaluation of an individual risk of HIV infection	Evaluate an individual risk of infection (behavior related to a high risk of HIV infection)
Formulation of ways to decrease the risk of HIV infection	<p>Draw up an individual plan in relation to the ways of decreasing the risks of HIV infection and prevention of HIV transmission. Provide information about relevant medical, psychological, social, legal, and other services. Tell where and how more detailed information can be obtained and what other opportunities are to receive additional counseling.</p>
Decision support to undergo testing	<p>Evaluate the patient's level of readiness to undergo testing. Discuss with him or her the advantages of being aware of his or her HIV status. Evaluate the consequences of being aware of his or her HIV status and its impact on the patient's further lifestyle. Give him or her some time to think over the questions discussed. Make sure that the patient understands the information provided to him or her. Provide any further information, if required.</p>

	Find out how strong the patient's desire is to undergo HIV testing.
Suggest undergoing testing at a state or communal medical care institution	The patient who gave his or her consent to undergo HIV testing: The doctor should suggest that he or she fill out Form No. 503-1/o, and direct the patient to a manipulation unit for blood sampling and fix up the date of next appointment with the patient <sup>+) </sup> .

NOTE: +) During the anonymous session, form No.503-1/o is not filled out.

**Introduction to the content of counseling** contemplates only one goal, i.e. reaching understanding with the patient in relation to the goal of counseling. The attitude to the patient should be benevolent and tolerant at that. This first stage of counseling should include the following:

- Greeting the patient;
- Explaining the principle of confidentiality and advantages of anonymous HIV counseling and testing;
- Description of the VCT procedure;
- Providing information on the content of pre-test counseling;
- Explaining the procedure for HIV testing;
- Answering the patient's questions.

**When evaluating individual risks of HIV infection** it is important to question the patient and define the factors producing an impact on episodic or systematic patterns of his or her behavior. For this purpose, the doctor asks the patient questions, in a purposeful and consistent manner, about the reasons of his or her referrals for counseling, the recent occurrence of his or her risky sexual behavior, defining of the factors and circumstances that influence the risk of HIV infection, evaluation of the risk of his or her partner, etc. The doctor, together with the patient, analyzes and studies the particular aspects of the patient's risky behavior: the presence of a casual sex partner/partners, experience in frequent changes of his or her sex partners, offering paid sex services, drug and alcohol abuse, etc. The doctor, together with the patient, defines the priority level of such risks and other issues to be discussed.

**Formulation of ways to decrease the risk of HIV infection** provides for strengthening of motivation and the patient's efforts relevant to the necessity to decrease the risks of infection. At this stage of an individual pre-test counseling session, it is advisable to consistently consider the previous attempts to decrease such risks, experience in safe sexual relations, and obstacles on the way to decrease the risk of infection, study the influence of taking psychoactive substances,

presence of social factors that increase the probability of high-risk behaviors; the doctor should provide the patient with alternatives to decrease his or her risk of infection, and if required, develop skills for using condoms.

**Decision support to undergo HIV testing.** It is the fourth step of an individual pre-test counseling session. It is nothing else than a remedial influence on the patient with the only purpose to help him or her make a voluntary informed decision on being tested for HIV. (Table 4.2)

Table 4.2 HIV Counseling Session Sequence

Discussion of his or her previous experience in testing and changes in his or her behavior after the result of testing has been received	Clarify the details of his or her undergoing HIV testing before, what such experience was like, if any changes in his or her behavior relevant to decreasing of the risk of HIV took place
Discussion with the patient how he or she feels about undergoing HIV testing	Ask the patient to tell you about his or her feelings, find out whether the patient's husband/wife/partner, boy friend/girl friend, family members knew about his or her decision to undergo testing for HIV and what their reaction was on such a decision.
Discussion of the meaning of positive and negative results of testing for the patient	Find out what the patient understands by a positive and negative HIV testing result, provide relevant explanations.
Evaluation of the level of his or her readiness to undergo testing and accept its results	Discuss with the patient his or her probable reaction to a positive or negative result. Find out what his or her expected result might be, and who the patient can tell about his or her testing result and who he or she can receive support from.
Discussion of his or her lifestyle should the patient's HIV-positive status be defined	Discuss possible changes in the patient's lifestyle in case of a positive result. Explain to him or her that such lifestyle provides for rational nutrition, periodical medical examinations, receiving of further medical assistance, support and the presence of sense of optimism
Evaluation of the risk of possible negative consequences of a positive result of testing	Find out if there is a possibility of committing suicide, aggressive reaction towards himself or herself and other people, his or her auto-aggressive behavior in the past and identify a psychiatric anamnesis. Give advice according to his or her needs.
Discussion of the advantages of being aware of his or her HIV status	Specify the advantages of the patient's awareness of his or her HIV status, and namely: <ol style="list-style-type: none"> <li>1. Get treatment, including access to ART free of charge;</li> </ol>

	<ol style="list-style-type: none"> <li>2. Protect his or her partners and future children against HIV infection;</li> <li>3. If a negative HIV status is defined, get additional stimuli relevant to the use of the necessary means of HIV prevention.</li> </ol>
Discussion with the patient of the difficulties connected with the awareness of his or her HIV status	Ask the patient about the negative aspects of being aware of his or her HIV status. Discuss ways of influencing such circumstances.
Suggest undergoing testing for HIV	<p>If the patient has made a decision to undergo testing for HIV, suggest that he or she fill out Form No.503-1o and direct him or her to a manipulation unit for blood sampling and its testing.</p> <p>Offer a repeated counseling session for those who refused to undergo testing for HIV.</p>

**Completing a counseling session.** The process of counseling is completed at the last fifth step, when the doctor and the patient fix up the date of next appointment.

Group counseling/awareness raising (GC/AR) is also provided to those who want it, and can be conducted when defining of a patient's HIV status is not the main goal of the examination. For example, if a person attends a clinic for a certificate, or visits a donor center or a blood transfusion station for blood donation, etc. GC/AR can also be conducted when, under certain circumstances, a shortage of counselors occurs.

GC/AR is conducted in accordance with the VCT Protocol at only oral consent of all people involved in counseling. GC/AR does not contemplate evaluating an individual risk of HIV infection or defining individual consequences of a positive result of testing. It is important that each patient who takes part in GC/AR should be offered an individual counseling session prior to testing for HIV. The crew strength for GC/AR should not exceed 16 people.

The crew for GC/AR should include those who have a shared goal of testing, for example, blood donors represent one group, pregnant women represent another group. At the same time, each group should be informed adequately according to the features it possesses. The counseling doctor should make sure that all members of the group arrange for confidentiality of private information, if such information is disclosed in the course of a counseling session by one of those counseled. Measures on GC/AR should also be adapted to the features of the medical care institution where a counseling session takes place. The following information is provided during GC/AR:

- What HIV disease and AIDS, acquired immunodeficiency syndrome, are;
- How HIV infection may occur (ways of transmission, factors of transmission, source of infection);
- What risks of infection, methods and means of protection against infection exist;

- What “prevention of transmission of HIV from mother to child” stands for and what measures are taken in this respect, how efficient they are (when counseling pregnant women);
- In what environment HIV testing is conducted and what the target is, voluntariness and confidentiality of testing;
- Procedure for testing and receiving results;
- Importance of receiving an individual counseling session and further testing;
- Legal effect of a defined HIV status;
- Where, when, and how psycho-social support and medical aid can be received.

The content of a group pre-test counseling session is shown in Table 4.3.

Table 4.3. Content of a Group Pre-test Counseling Session

Introduction to the content of counseling	<p>Explain:</p> <ul style="list-style-type: none"> <li>• The goal and objectives of counseling;</li> <li>• Procedure and principles for counseling and testing (voluntariness, confidentiality, free of charge);</li> <li>• Possible results of testing, their evaluation</li> </ul>
Providing the patients with information for them to evaluate their own risks of infection	<p>Tell about:</p> <ul style="list-style-type: none"> <li>• Ways of HIV transmission;</li> <li>• Behavioral risks of HIV infection;</li> <li>• Measures and means of prevention (for this particular group undergoing counseling);</li> <li>• Consequences of defining an HIV status, including legal aspects.</li> </ul> <p>Offer those who are counseled to evaluate their own risks of HIV infection, taking into account the presence or absence of behavioral risks, including those among sexual partners. Offer individual counseling for those who so desire</p>
Providing information about other forms of assistance	<p>Inform about:</p> <p>sources of infection in greater detail and an opportunity of receiving HIV counseling;</p> <p>opportunity to receive psycho-social and medical aid</p>
Making a decision on undergoing testing	<p>Inform about the advantages of being aware of his or her HIV status. Answer questions, if any. Offer individual counseling, if required. Offer a repeated counseling session and hold a discussion about risks of infection to those who refused to undergo testing</p>

Suggest undergoing testing at a state or communal medical care institution	The patients who gave their consent to testing: Suggest that they fill out Form No.503-1/o, direct them to a manipulation unit for blood sampling and fix up the date of next appointment +).
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NOTE: +) In case of an anonymous session, Form No.503-1/o is not filled out.

### 4.3. Post-test Counseling

Post-test counseling is a confidential dialogue between the doctor and the patient, the goal of which is to discuss the results of testing for HIV, provide relevant information and psychological support.

A notification about the results of testing should be followed by post-test counseling.

No time gap between the notification about the results of testing for HIV and post-test counseling is admissible!

Post-test counseling should be conducted immediately after the notification of the results of testing only at state and communal medical care institutions (MCI). It is initial post-test counseling.

It is to be desirable that post-test counseling of a patient be conducted by the same doctor of the medical care institution who conducted his or her pre-test counseling. If pre-test counseling was conducted by a different expert and even at a different medical care institution, then during post-test counseling, the doctor should find out all information about the place of pre-test counseling, its content and what kind of equipment was used, what information about HIV the patient was provided with.

Disclosure of information about a medical examination for defining HIV and its results that became known in relation to the fulfillment of occupational duties, entails criminal liability!

Considering the fact that information about the results of testing for HIV, the presence or absence of HIV in the body of the person who underwent the medical examination, shall be kept confidential and constitute medical secrecy, such information may be disclosed only to the person concerned, and in cases stipulated by the laws of Ukraine also to legal representatives of such a person, medical care institutions, prosecution agencies, investigation agencies, agencies in charge of preliminary investigation and court.

Such data shall not be disclosed to the state or non-state medical and non-medical care institutions, organizations, establishments, PA, even though pre-test counseling was conducted at such institutions. However, if the patient himself or herself refers to such institutions or establishments in person and at his or her will provides information about the results of his or her testing for HIV, then additional supportive (not primary) post-test counseling may be conducted at

the aforesaid institutions. As state above, post-test counseling should be conducted immediately after the notification of the results of testing for HIV. However, the results of testing may appear to be negative, which means that the antibodies to HIV1/2 in the tested samples of blood (serum or plasma) are absent and, accordingly, positive results mean that the tested sample contains antibodies to HIV1/2 or they are undetectable (questionable).

If the result is negative, it is important to discuss with the patient the ways of decreasing the risk of HIV infection in the future. It should also be highlighted that the results of testing show that the patient is not infected with HIV, but bearing in mind the so-called “serological window” and a risky behavior during the last three months, convince the patient of the necessity of undergoing repeated testing for HIV. According to the “Procedure”, counseling is conducted as follows:

- Notification of the patient about his or her results
- Study the patient’s reaction to the result of testing
- Emphasis on the necessity to consider the result in relation to the risk within the “serological window”
- Expressing anxiety in relation to the risk of HIV infection if the patient does not pay due attention to a decrease of his or her risky behavior.

The latter means that the doctor should help the patient develop a clear and specific plan to decrease the risk of infection, which would be most suitable to skills and capacity of such a patient, his or her motivation in relation to changes in a certain type of his or her behavior. At that, there is no need to maintain his or her plans of unreasonable or radical nature regarding changes in his or her lifestyle!

The doctor and the patient together should determine the term of the implementation of the patient’s plan of action and consider all opportunities of receiving support from the side of family members, friends, with whom the patient would be able to discuss his plan and even report to them about its fulfillment.

It is important to note the significance of this stage of counseling, since past experience shows that there is a very little chance that such patient will ever visit a doctor once again to analyze with him or her the fulfillment of such plan.

Initial post-test counseling if the result is considered positive contemplates **crisis counseling**, psychological support in accepting the diagnosis and support in planning his or her future.

Ensuring the awareness of the patient of his or her results of testing, providing him or her support in defining the opportunity of assistance and resources not to fall apart and overcome the situation, should be a task of priority.

Counseling is conducted as follows:

- Notification about the results of testing. At the patient's request, issue him or her a reference about the results of testing (Form No. 503-2/o);
- Analysis of the meaning of the results;
- Providing an opportunity for the patient to realize the meaning of the results and provide psychological support;
- Evaluate the level of the patient's understanding of the results (Make sure that the patient understands the meaning of the produced results correctly);
- Realizing the problems in relation to the acceptance of initial positive results and providing the necessary support. Discussing the patient's lifestyle while living with HIV, possible consequences for private life, family and social relationship;
- Answering incomprehensible questions. Referring the patient to experts possessing the required qualifications, if need be.
- Making referrals where the person can receive follow up support and psychological help.

It is necessary to help PLHIV define the sources of support, access to them, explain how important the procedures for further medical examinations are, discuss the opportunity of notification the patient's doctors and partner/partners about his or her HIV status. Pursuant to Article 15 of the Law of Ukraine "On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Social Security of the Population", PLHIV and people living with AIDS should notify the people who had sexual contacts with them prior to defining HIV, about the risk of their being infected with HIV. Notification of the partner/s about undergoing testing for HIV and its positive result is an important issue for the patient. However, the task of the doctor, who conducts post-test counseling, is to help the patient not become isolated in solving such personal situation, define at least one person who the patient could be able to tell about his or her positive results of testing for HIV and receive help from such person.

Notification of social protection, rights and duties of PLHIV according to the Law of Ukraine "On Prevention of Acquired Immune Deficiency Syndrome (AIDS) and Social Security of the Population" and the current Ukrainian legislation, is also the duty of the doctor conducting post-test counseling.

Initial post-test counseling when the result is considered undefined starts with the notification of the results of testing and their explanation. An undefined result or questionable result means that for the moment of testing it was not possible to define for sure the patient's HIV status due to a number of reasons. For example, the patient has another disease (rheumatic arthritis,



multiple sclerosis, constitutional TB, insulin-dependent diabetes, Addison’s disease, ankylosing spondulitis, chronic hepatitis, lympho-prolypherative malignant invasions, severe kidney diseases, etc.), which results in a synthesis of non-specific antibodies. It is also possible that 30 days prior to testing the patient had prevention immunization against viral influenza or participated in blood or its components transfusion manipulations or received gamma-globulin. It is important to discuss and explain to the patient the opportunity to be at the stage of the “serological window”, explain to him or her the clinical presentations of an acute stage of HIV. Tell him or her that according to literature, with a total 30-40% of PLHIV at this stage, the disease manifests as an acute antiviral syndrome and reminds that of acute respiratory infection including fever, weakness, headaches and sore throat, enlarged lymphatic nodes, sometimes rash, diarrhea. The duration of such state of health is not long and may take less than two weeks and ends up without any treatment.

Offer the patient a repeated examination in 2 weeks or 2-3 months. Explain to him or her the necessity to adhere to a safe behavior (refuse from donorship, postpone planned pregnancy, reduce the number of sexual partners, use only quality latex condoms during sexual contacts, etc.) prior to the receipt of the results of his or her repeated test. Provide the patient with informational materials and addresses of the state, communal medical care organizations and institutions that are authorized to provide VCT services, fix the date of next appointment. A list of medical care organizations and establishments providing VCT services is given in Table 4.4.

Table 4.4 List of Organizations and Institutions That Can Provide VCT Services

Organization	VCT Services	Other Services
Centers for social services to families, children and youth	HIV counseling; VCT popularization; Motivation of patients to undergo VCT; Pre-test counseling; Information for patients about the opportunity of testing for HIV at state and communal medical care institutions (MCI); Providing information on establishments, organizations, institutions and PA where medical, psychological, social assistance can be received depending on the needs of patients; In response to patient’s active referral – supportive post-test counseling (after initial post-test counseling at state and communal MCIs.	Conducting of counseling with the participation of a psychologist, lawyer, social worker, doctors of different areas of practice. Distribution of news materials. Exchange of syringes. Distribution of condoms. Enrollment into prevention programs on reducing harm, which operate in the region. Training courses.
Workers of educational	HIV counseling;	Distribution of news materials

institutions	<p>VCT popularization;  Motivation of patients to undergo VCT;  Pre-test counseling;  Providing patients with information about the opportunity of testing for HIV at state and communal medical care institutions (MCIs);  Providing information on establishments, organizations, institutions and PA where medical, psychological, social assistance can be received depending on the needs of patients;  In response to patient's active referral – supportive post-test counseling (after initial post-test counseling at state and communal MCIs).</p>	
Public associations working with IDUs, SWs, support groups for PLHIV, religious associations, etc.	<p>HIV counseling;  VCT popularization;  Motivation of patients to undergo VCT;  Pre-test counseling;  Information for patients about the opportunity of testing for HIV at state and communal medical care institutions (MCIs);  Providing information on establishments, organizations, institutions and PA where medical, psychological, social assistance can be received depending on the needs of patients;  In response to patient's active referral – supportive post-test counseling (after initial post-test counseling at state and communal MCIs).</p>	<p>Conducting of counseling with the participation of a psychologist, lawyer, and social worker.  Distribution of news materials.  Exchange of syringes.  Distribution of condoms.  Distribution of disinfectants and condoms.  Providing psychological support following the principle 'Peer to Peer', assistance in the development and implementation of individual plans to reduce the risk of infection if a person belongs to a group most vulnerable to HIV infection.  Training courses.</p>
Medical care institutions of other than state and communal forms of ownership	<p>HIV counseling;  VCT popularization;  Motivation of patients to undergo VCT;  Pre-testing counseling;  Providing patients with information about the opportunity of testing for HIV at state and communal medical</p>	<p>Conducting of counseling by doctors and a psychologist, lawyer, etc. if they are on the staff.  Distribution of news materials.</p>

	<p>care institutions (MCIs);          Providing information on establishments, organizations, institutions and PA where medical, psychological, social assistance can be received depending on the needs of patients;          In response to patient's active referral – supportive post-test counseling (after initial post-test counseling at state and communal MCI).</p>	
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**Supportive post-test counseling**

Supportive post-testing counseling is provided after the crisis counseling when a patient already realizes that he/she is infected with HIV and is ready to accept the new information about the medical, social, legal and psychological support and access to it.

The counselor's role is to help the patient understand where and how he/she can access the support services, plan the future, start a new life with HIV.

It is necessary to explain to the patient how important it is to be regularly checked up at the AIDS Center, prevent opportunistic infections, give birth to a healthy baby, prevent the transmission of HIV to his/her sexual partner, adhere to treatment if it is needed, as all these measures impact the PLHIV life expectancy, health of his/her baby, family planning or safeguarding, ability to work and professional development.

The counselor and the patient have to discuss the intention and desire of the patient to disclose the information about his/her HIV status to some other doctors and the possibility to access services depending on the awareness of these doctors of the patients' status. To explain the procedure of further medical surveillance.

Supportive post-testing counseling should follow the below procedure.

First, it is necessary to identify the family members or social environment peers, who could be of any help and support to the patient while he or she is getting adapted to living with HIV. The patient should be asked about the people who could support and help him/her get adapted to life with HIV, besides, the counselor should emphasize that emotional and physical well-being is very important for life with HIV.

Another important objective is to make sure that the patient is ready to ask for help and identify available quality services for him/her. So, the patient should be asked if he/she has ever been seeking help from a medical setting or peer-support group, if this help was available to him/her, if he/she was satisfied with it. If no, then ask why (transport, resources, discrimination etc.).

During the counseling it is relevant to discuss the confidentiality issue with the patient; to explain to him/her that it is better to disclose the HIV test result only to the most trusted people; to tell him/her about the peer support groups, social services; to ask if he/she would like to discuss his personal situation with other people, the most complicated elements of support from his/her point of view, if he/she has ever thought about coping with substance use or if there is any kind of support or services he/she would particularly like to access.

While establishing the risk behavior it is necessary to talk about the personal risk and harm reduction plan, to motivate the patient to implement this plan, to inform his/her about the harm reduction programs, to advise on safe sex practicing and condom use. After the counseling it is recommended to provide the patient with the hard copy of the list of service providers with their addresses and phone numbers. Refer the patient to some of them if needed.

4.4. Peculiarities of Counseling of Some Certain Populations

***Peculiarities of counseling of pregnant women.*** For a pregnant woman, HIV testing is part of the standard set of antenatal medical surveillance tests. In accordance with the current normative acts, testing for HIV is conducted twice upon a pregnant woman’s consent with the goal to detect HIV and, if any, to help women timely make their informative decision on delivery, to prevent HIV transmission to a newly born child or her partner, and timely receive quality medical and social assistance. Testing for HIV of pregnant women has another side, i.e. confirming HIV-negative (not infected with HIV) and timely inform them about a risky behavior, how to avoid possible viral infection under the circumstances of the existing HIV epidemic situation in the country, ensure quality care for pregnant women and young mothers.

During pre-test and post-test counseling it should be taken into consideration that in addition to the counseling aspects set forth in Article 4 of the “Procedure”, it is necessary to discuss with a pregnant woman specific issues in relation to her pregnancy, as well. The content of an individual pre-test session for a pregnant woman is given in Table 4.5.

Table 4.5. Content of Individual Pre-test Counseling for a Pregnant Woman

Stages of Counseling	Content
Inform about the ways of HIV transmission, procedure for testing and possible results	Provide information on: <ul style="list-style-type: none"> <li>• HIV disease and ways of HIV transmission;</li> <li>• Principles of HIV diagnostics;</li> <li>• Voluntariness, confidentiality, and that testing for HIV is free of charge;</li> </ul>

	<ul style="list-style-type: none"> <li>• Rights of a pregnant woman to undergo testing for HIV;</li> <li>• Meaning of positive, negative and unidentified results;</li> <li>• Procedure for testing.</li> </ul>
<p>Evaluation of an individual risk of HIV infection of a pregnant woman</p>	<p>Find out the availability of :</p> <p>Risky forms of behavior (features of sexual contacts, possible use of injective drugs, etc.);</p> <p>Instances of blood and its components transfusion, transplantation of organs, tissue, invasive procedures;</p> <p>STI;</p> <p>Contacts with blood at work</p>
<p>Explanation of the advantages of being aware of her HIV status</p>	<p>Provide a pregnant woman with information about:</p> <ul style="list-style-type: none"> <li>• Ways of HIV transmission from mother to child;</li> <li>• Prevention of perinatal HIV transmission, including chemoprevention of perinatal HIV transmission with the use of antiretroviral medications;</li> <li>• Modern principles of pregnancy excluding breast feeding if a woman is infected with HIV for timely, integrated and step-by-step prevention of HIV transmission from mother to child;</li> <li>• Chemoprevention of perinatal HIV transmission from mother to child and chemoprevention of HIV for a newly born child using antiretroviral medications, which are provided free of charge.</li> </ul>

<p>Motivation of a safe behavior during pregnancy</p>	<p>Provide a pregnant woman with information about:</p> <ul style="list-style-type: none"> <li>• Importance and meaning of a safe sexual behavior in relation to the risk of infection during pregnancy with further HIV transmission to a fetus. Risk of <u>intrauterine infection</u> during the whole period of pregnancy;</li> <li>• Necessity to change the current pattern of behavior for a safer one if the current pattern of behavior is of high risk of HIV infection.</li> </ul>
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Initial post-test counseling of a pregnant women with a negative result is based on the fact that there is a need to calm her, explain to her the meaning of a negative result for her, but discuss with her the ways of HIV transmission, rules of a safe behavior, possible ways of prevention of HIV infection, maintenance of reproductive health, and fix up the date for a repeated examination.

Initial post-test counseling of a pregnant woman with a positive result, according to the VCT algorithm, is crisis counseling. A pregnant woman should be directly notified about her positive result of testing for HIV. Such counseling is aimed at not only the opportunity to inform a pregnant woman that she is infected with HIV, but also help her accept her HIV positive status, adapt to the circumstances, inform her about prevention of HIV transmission to other family members and close people, motivate her to take a good care of her health, inform her about the opportunities of modern antiretroviral therapy and chemoprevention of perinatal HIV transmission using antiretroviral medications. It is important to lay special emphasis on factors that may produce an impact on the decision of a pregnant woman concerning her reproductive choice. Factors that dispose the woman to terminate pregnancy include: unplanned pregnancy, having a healthy child or healthy children, low socioeconomic status, fear of giving birth to a child infected with HIV or a child with abnormality, early pregnancy term and manifestations of symptoms of opportunistic infections and invasions. In the course of analyzing factors that dispose the woman to make a decision to give birth to a child, one can come to a conclusion that the most important of them are the following: desire to have a child, religious and cultural views, asymptomatic course of HIV, high living standard of the family and its readiness and opportunity to take care of a child infected with HIV, access to substitution therapy to prevent harm to the unborn child.

An example of an individual post-test counseling session for a pregnant woman with a positive result of testing is shown in Table 4.6.

Table 4.6 Content of Individual Post-test Counseling for a Pregnant Woman at a Positive Result of Testing VCT 2005 Ukraine Protocol

<b>Stage of Counseling</b>	<b>Content</b>
Notification about the results of testing	Notify about the result of testing and discuss its meaning for a pregnant woman and her child
Specify the anamnesis	Specify the possible source of infection and ways of virus transmission
Providing information about the ways of HIV infection transmission from mother to her child	Inform a pregnant woman about the ways of HIV transmission from mother to her child
Inform about the accessible methods of prevention of HIV transmission from mother to her child	Inform a pregnant woman about: <ul style="list-style-type: none"> <li>Methods of prevention of perinatal HIV transmission;</li> <li>Necessity to adhere to a healthy lifestyle , measures of prevention and responsibility for HIV transmission to other people;</li> <li>Necessity of a regular examination at clinics for women, appointments with a doctor-infectionist at a local clinic or at a territorial AIDS Center;</li> <li>Necessity to strictly adhere to the recommendations of doctors;</li> <li>Necessity of taking iron and folic acid preparations as prescribed;</li> <li>Necessity of prevention using antiretroviral medications;</li> <li>Necessity to adhere to the requirements of the procedure for hospitalization;</li> <li>Possible ways of delivery, prevention of misguided obstetric interference during pregnancy;</li> <li>Exclusion of breast feeding;</li> <li>Providing milk formula for a child;</li> <li>Reduced harm to the child when measures of prevention are taken.</li> </ul>
Explanation of peculiarities of the pregnancy of women infected with HIV	Explain: <ul style="list-style-type: none"> <li>• Importance of a timely medical examination and surveillance and a woman's adherence to the measures of prevention of complications during pregnancy (abortion, small-for-date fetus, stillbirth, premature delivery, untimely effect of amniotic fluid, bacterial pneumonia with a child, etc.)</li> </ul>
Interpretation of the opportunity of a reproductive choice	Explain to a woman that it is she who makes a decision to have her pregnancy or delivery

	terminated
Explanation of peculiarities of family planning for women infected with HIV	Provide information on the issues of family planning and raising the standards of life of women infected with HIV after delivery or opportunity of any other reproductive choice. Inform her about all existing techniques of prevention of unwanted pregnancies considering efficiency, risks, and disadvantages with an emphasis on the use of condoms, give a chance to make her choice.
Information about the necessity of a medical inspection to define the stage of HIV disease and a work-up	Inform about: <ul style="list-style-type: none"> <li>• Necessity of surveillance at the antenatal clinic, local clinic or AIDS center and the number of referrals according to the term of pregnancy at the given stage of HIV disease;</li> <li>• Conducting an additional examination for defining the stage of HIV disease;</li> <li>• Features of HIV disease among pregnant women;</li> <li>• Choice of antiretroviral preparations;</li> <li>• Entire monitoring and supply of news information materials</li> </ul>

Counseling of a woman with an unidentified HIV status before delivery. A special feature of pre-test counseling of pregnant women before delivery with an unidentified HIV-status, except highlighting general questions in relation to general information about HIV disease and ways of HIV transmission, is that an emphasis is made on the necessity and importance of carrying out instant diagnosis of HIV by way of simple/rapid testing to define antibodies to HIV and the interpretation of the results of testing. According to the Order of the Ministry of Health of Ukraine No. 255 “On Approval of Methodological Recommendations on the Use of Rapid Tests for Examination of Blood for Defining Antibodies to HIV, Registration Form No. 498/o, and Instructions on Its Filling Out” of June 9, 2003, rapid tests should be conducted by voluntary consent of pregnant women, whose HIV status was not identified before, directly at maternity hospitals. The doctor should explain that if there is a positive or an unidentified result with a view of prevention of HIV transmission from mother to her child in the course of delivery, there is a need to use antiretroviral medications, refuse from breast feeding, discuss the issue on a patient’s rights to undergo testing for HIV, procedure of examination using simple/rapid assays, meaning of results, defining of the overall result of an examination for HIV only after being examined with the use of the EIA method (sample of whole blood, regardless of the received result of testing, within 3 days shall be forwarded to a laboratory of diagnostics of HIV at the AIDS center to carry out an examination using test-systems for EIA).



Initial post-test counseling with a negative result of simple/rapid assay mainly comes to the identification of individual risks and explanation of such notions as “serological window”, “immune response”, etc.

If there is a positive result of a rapid assay for HIV, initial post-test counseling comprises the following stages: notification about the results of testing, notification about methods of prevention of HIV transmission to a newborn, explanation of the necessity of further medical surveillance after delivery.

***Peculiarities of counseling of blood donors.*** Counseling a blood donor has the same objectives upon the same issues as discussed in relation to counseling other categories of the population. At the same time, counseling donors, and mainly, a pre-testing counseling session has its own peculiarities. Such peculiarities are connected, first of all, with the fact that blood and its components, cells, tissues and organs are tested for defining HIV on a mandatory basis and this does not contradict the current Ukrainian legislation concerning voluntariness of testing for HIV, since a donor, after pre-test counseling, has the right to refuse from donorship and in such a case from a mandatory medical examination prior to the examination. Anonymity of testing, if required, may be excluded, if a person is examined as a donor.

Pre-test counseling of blood (its components) donors is conducted at a Blood Transfusion Service at MCIs or at departments of transfusiology of oblast, city or regional hospitals. Counseling cell, organs and tissue donors is conducted at state and communal MCIs.

Pre-test counseling of donors may be conducted both individually and in group. Bearing in mind the fact that pre-test counseling of donors may be a single occasion and that it is not necessarily that the same donor will come back to receive his or her results of testing for HIV, a doctor should provide him or her with as much information as possible regarding HIV, ways of its transmission, prevention measures, meaning of a risky behavior of a potential donor for possible infection of a blood and its products recipient. The content of pre-test counseling of this group of people should also comprise legal aspects and issues of moral and criminal liability of a donor for willful putting future recipients at risk of HIV infection, knowledge and awareness of such notions as „serological window”, „informed consent”, etc. During pre-test counseling, it is necessary to provide a donor (or a potential donor) with sufficient information so that he or her would be able to decide whether he or she is going to be a donor and undergo testing for HIV or not.

During individual pre-test counseling, a doctor has an opportunity to evaluate what risk group a donor belongs to, his level of understanding of the responsibility for his own risky behavior and provide him with relevant recommendations and a piece of advice. What does counseling mean to a donor? First of all, important information for him or her, awareness of his or her moral and

criminal liability for willful putting his or her future recipients at risk of HIV infection or being infected, a chance to refuse from donorship, provide his or her informed consent to undergo testing and define the procedure for notification of his or her results of testing for HIV.

A specific feature of post-test counseling of donors, regardless of the received results of testing, is the fact that a donor, as a rule, does not attend a clinic for his or her results of testing, since defining of his or her HIV status is not the main objective of his or her donorship. On those occasions when he or she does attend a Blood Transfusion Service for the results of testing, initial post-test counseling is conducted by an expert of such Service as stipulated by Section 4.3 of the „Procedure”. If a donor does not attend Blood Transfusion Service for his or her results of testing, then the notification of the results of blood tests for HIV is made by a doctor of a territorial clinic or a regional AIDS center during post-test counseling.

***Peculiarities of counseling of people with TB.*** According to researches of the Ukrainian AIDS Center, TB is the main cause of death among PLHIV with 30-50% people living with HIV die due to TB. According to the scientists, an increase of TB in the developed countries may be caused by PLHIV’s immune system being weaker and new incidences among PLHIV. Multi-drug resistance (MDR) and extreme drug resistance (XDR) where there is no treatment available is increasing in many countries among people living with HIV, including in Ukraine. In Ukraine, at present, the most burning issue is timely detection of TB and MDR-TB among PLHIV and vice versa, HIV among people with TB. Therefore, counseling and testing for HIV should be accessible for each person with TB.

The goal of initial HIV and TB pre-test counseling of this group of people is to provide information about HIV and TB, realize the importance of being aware of his or her HIV status, which the procedure for defining of treatment and obtaining informed consent to undergo testing for HIV depends on.

The goal of post-test counseling of a person with TB is to notify the person of his or her HIV status, and, if required, provide the person with psychological support and work out a plan of treatment and behavior of the patient for a period of treatment.

Pre- and post-test counseling of people who with TB may be conducted at TB clinics, hospitals, sanatoria as well as other MCIs.

The doctor conducting pre-test and post-test counseling of people with TB should take into consideration the social status of such patients, among whom there is a considerable number of those who are discharged prisoners, do not have permanent places of residence, families, who are unemployed, with a low level of social behavior and education and those given to a risky behavior. A spread of chronic forms of TB, the presence of chemioresistant TB, substantially aggravates the situation in relation to PLHIV, creates additional ethical and psychological problems, which should

be considered by the doctor who conducts post-test counseling if a positive result of testing for HIV is produced. For example, when discussing an active lifestyle of the patient with an HIV-positive status, we may encounter with an aggressive behavior of the patient when delivering him or her such information (the patient feels extremely unwell, he has incurable disease and the doctor dares to tell something about active way of life). In such a case, it is worth while refusing from discussing such issues, providing the patient with news materials, and later, considering improvements in his or her health in the course of treatment for TB, come back to the realization of this item during further sessions of supportive counseling.

An example of the content and peculiarities of post-test counseling of PLHIV with TB is given in Table 4.7.

Table 4.7. Content and Peculiarities of Post-test Counseling of PLHIV with TB

<b>Stages of Counseling</b>	<b>Content</b>
Providing information about the results of testing	Provide information about the results of testing. Upon request, issue the patient a reference containing the results of his or her testing for HIV (Form No. 503-2/o)
Explanation of the meaning of the results of testing	Explain the meaning of a positive result of HIV test, what a combination of TB and HIV means, opportunities of TB treatment for PLHIV, peculiarities of ART, the impact of the use of alcohol or drugs on efficiency of treatment
Providing a person with an opportunity to be aware of the meaning of the results of testing	Evaluate the capability of a patient to accept results of testing, give him or her a chance to realize the result
Providing necessary assistance	Calm a patient, define the people who can provide necessary assistance
Discussion of peculiarities of TB treatment for PLHIV	Explain that after treatment for TB, if required, ART may be prescribed
Defining of the opportunities of TB treatment	Explain the optimal mode and a scheme of TB treatment, and define the level of access to medical care
Evaluation of the level of access to medical services for a patient	Discuss the opportunity of receiving other medical services after discharge from the

	hospital
Defining of a patient's plans after recovery from TB	Discuss the patient's plans after recovery from TB, the importance of adhering to treatment with an emphasis on positive aspects of such treatment and health improvement
Discussion of PLHIV future life	Tell about the opportunity for PLHIV to continue active life. Discuss this topic with the patient
Defining of the short-range plans of actions of a patient	Explain in detail what the patient should do within next 24 hours, who he should turn to, what medications to take and when. Define incomprehensive questions and answer them. Fix up the date of next appointment

***Peculiarities of counseling of medical care workers.*** VCT services for employees of medical care institutions (MCIs) is one of the most important components of the system of measures aimed at prevention of HIV at a work place for the purpose of decreasing the risk of HIV transmission from a patient to a medical care worker through contacts with blood and other biological fluids that may contain HIV in the course of providing medical aid. An employee of a medical care institution, who, in the course of providing medical aid to PLHIV had a contact with the patient's biological fluids, should undergo a course of post-contact chemoprevention using antiretroviral medications, according to the Order No.120 (by his or her consent). To prescribe such a course, it is preferable to define an HIV status of the affected person at the moment of emergency at a work place.

Pre-test counseling is conducted according to the following procedure:

- Determination of the circumstances of the emergency (date and time of the contact, detailed description of the manipulations carried out, quantity of the biological fluid or material that had a contact with the skin, mucosal tunics or the wound, depth of the injury and frequency of contacts, use of individual means of protection, manner of urgent actions taken immediately after the contact, making records of the established set of fact of the incident in the register for keeping records of incidents, etc.);
- Explaining to the affected medical care worker the procedure for an examination of the person, with whose biological fluids the contact occurred (testing for HIV of the person, with whose biological fluids the contact occurred, should be carried out only

after receiving the patient's informed consent to such examination. If it is impossible to define an HIV status of such person as a possible source of infection, he or she is considered to be infected with HIV, which results in the need of taking all measures in case of a contact with blood or other biological fluids of such person);

- Explaining the procedure for examination, meaning of possible results of testing for HIV to the affected person (to justify the need to undergo an urgent examination immediately, best during first hours, but no later than 72 hours after the incident, define tactics of preventive treatment, i.e. post-contact chemoprevention of HIV);
- Receiving his or her informed consent to undergo testing for HIV at a state or communal medical care institution (Form No. 503-1/o to be filled out);
- Inform about a preventive course of treatment aimed at prevention of occupational HIV (scheme, side effects and the necessity of being under constant supervision of an expert in the field of HIV);
- Receiving informed consent to undergo post-contact prevention of HIV (informed consent form to be filled out);
- Explanation of prevention measures of the spread of HIV for a period of a regular medical check-up of the affected (refusal from donorship, reduction of the number of sexual contacts, use of condoms, termination of breast feeding , if any, postponing of planned pregnancy for some time);
- Emphasis on the need of adherence to general prevention measures of HIV at a work place;
- Motivation to continue professional activity (risk of HIV infection after a contact of a wound with blood or other biological fluids of PLHIV that contain the virus is approximately at 0.3%, an uninjured area of mucosal tunics is approximately at 0.09%, after a contact with an uninjured area of skin HIV infection has not been registered);
- Clarification and discussion of incomprehensible questions (provide additional information, direct him or her to experts possessing relative qualifications).

Again, it is important to stress that in this case we do not deal with a patient but an affected medical care worker. As a result of testing conducted within the first days after an incident, it may appear that before the moment of the incident, an affected medical care worker had not been infected with HIV and he or she does not have antibodies to HIV and, there may also be a situation in which a positive result of testing for HIV may be produced. In such a case, it shows that a medical care worker was infected earlier, prior to the incident, and thus, during initial post-test counseling we may not deal with

post-contact prevention, but an in-depth examination, defining the diagnosis and a stage of his or her disease, defining the need of prescribing EIA.

If the result of testing of an affected medical care worker is negative, initial post-test counseling shall include:

- Familiarization with the results of testing for HIV infection;
- If a positive HIV status of a patient, with whose blood or biological fluids a medical care worker had contacts, is defined, or if information about the patient's HIV status is missing, the affected person should be informed about further prevention measures tactics (explanation of the need to undergo a complete course of chemoprevention, procedure for an examination and a regular medical check-up in case of a refusal from post-contact prevention, symptoms of the disease, providing information on social protection of medical care workers in case of infection at a work place);
- If a negative HIV status of a patient, with whose blood or biological fluids a medical care worker had contacts, is defined, an affected person should be informed about termination of a course of preventive treatment and test for HIV;
- Together with the patient, work out his or her individual plan on decreasing the risk of infection at a work place; appoint officials who will be assisting him or her in the implementation of the plan, in other words, have a repeated discussion with an affected person about HIV general preventive measures at a work place.
- If a positive result of testing for HIV of an affected person is produced in the course of his or her examination 3, 6 or 9 months after the incident, post-test counseling is conducted according to the "Procedure".

#### **4.5. Peculiarities of Counseling of Most-At-Risk Populations**

Individuals can practice all kinds of behaviors. Most at risk populations are not homogenous and can practice various high risk behavior related to HIV and Hepatitis C transmission, including drug users having sex with women or men, men who have sex with men also having relationships with women or might also sell sex or inject drugs, and female sex workers that also have a fixed partner/husband and/or children and/or inject drug use. It is critical to focus on helping individuals to identify their own risk behaviors and support them to change behavior to reduce transmission. It is essential that the doctor or the counselor not demonstrate any judgmental, shaming or

stigmatizing attitudes or behaviors to the individual. Counseling needs to focus on providing a supportive, non-judgmental environment to change behavior.

***Peculiarities of counseling and testing of injection drug users (IDUs)***

The lifestyle of injection drug users (IDUs) is often related to violation of the law, conflicts with the law, and raises disapproval on the part of the society. Because of that, IDUs may have cautious and distrustful approach to all health and other services, including HIV counseling and testing that is provided either by the government facilities or by the services that work at the health care facilities. Though IDUs are the most at risk individuals for HIV, VCT services, being a part of this system, may encounter with difficulties reaching IDU patients. Programs where VCT was organized in cooperation with NGOs that implement HIV prevention programs “in the field,” when specialists walk or drive to the places where IDUs usually can be found, may serve as an example of successful solution of the problem.

Very often, former drug users are engaged in work under such programs; they know social norms and values of drug culture. Also, they are trusted by drug users, and preventive activities they carry out are often credited more by the target group. If such a person goes through a special training to be an HIV pre or post-test counselor, he/she would be able to explain testing issues and the necessity to be informed about one’s own HIV-status in a format that is more understandable and acceptable for drug users.

The former drug users’ participation in counseling on HIV disease and the process of IDUs engagement in VCT improves IDUs’ trust to government facilities that provide VCT and to other medical and social services.

The VCT 2005 Ukraine Protocol states the counseling should be carried out in the following order:

Assessing the patient’s general condition.	Make a subjective assessment of the patient’s condition (drug or alcohol intoxication or withdrawal symptoms). If the patient can’t perceive information, reschedule appointment for a later date.
Motivating a patient to pass the complete procedure of counseling and testing	Tell the patient where and when he/she can pick up the test result. Find out whether it is convenient for the patient to pick up the test results at that time. If not, explain that he/she may pick it up and get post-test counseling a bit later. Explain that: It is very important for the patient to come back for the test result; after the patient has received the test result, he/she may discuss questions that might arise with the

	counselor; if the patient needs to discuss something, he/she may feel free to come and receive additional counseling.
Talking about advantages of knowing one's HIV status. Together with the patient, analyzing all pros and cons of knowing one's HIV status.	Explain that he/she has already made a very important step having come for the counseling because knowledge the patient acquires here will help him/her to control his/her life. Discuss the advantages of knowing one's HIV status and what difficulties such knowledge might be related to. Together with the patient, make a list of pros and cons of knowing one's own HIV status.
Informing the patient about the possibility for IDUs to receive the psychological, social and other kinds of support.	Explain that if the patient needs psychological support, he/she may address organizations that provide services to IDUs. Give contact information. Indicate time and terms on which the counselor sees the patients.
Providing information about support groups	Provide the patient with information on support groups that unite people with problems similar to his/her own, give contact information. If possible, help the patient to make first contact with representatives of these groups.
Discussing possibilities of emergency prevention in case of sexual violence.	Explain that sexual violence is related to higher risk of HIV infection due to problems with integrity of mucus membranes. Tell about the possibility of emergency HIV prevention in case of sexual violence.
Jointly with the patient, assessing individual risks of being infected with HIV and STI if the patient is engaged in commercial sex.  Discussing the possibility to reduce risks.	Find out: - whether the patient uses prevention methods so that not to become infected with STI - whether there are situations when condom isn't used and what are the reasons for that. Jointly with the patient discuss how to reduce risk of infection.
Finding out about patient's wrong views on safe/unsafe sex practices.	Find out: - how the patient identifies the persons who pose greater threat to him/her regarding HIV/STI; - whether the patient has some categories of people with whom he/she doesn't associate risk of HIV infection. Why?; - in what way do these perceptions influence his/her behavior pattern?
Discussing risks of HIV infection for SW and IDU.	Find out about patient's awareness regarding prevalence of HIV among IDU and SW; Explain high risk factors of HIV infection for SW; Remind of the fact that some SW are IDU, i.e. their risk of getting infection doubles.
Discussing ways and means of infection risk reduction.	Together with the patient, draft a plan to prevent his/her partner and himself/herself from getting HIV infection. Explain that: - drug use dramatically deteriorates his/her health;



	<ul style="list-style-type: none"> <li>- to reduce risk of being infected with HIV, HBV, and HCV, he/she should stop using intravenous drugs;</li> <li>- if he/she can't stop using drugs now, at least he/she should not use somebody else's or used syringes, not share syringes, not give other people his/her own syringes, not rinse used syringe in water container that is used by others, every time use sterile syringe for injection, etc;</li> <li>- need to use a high quality condom during every sexual intercourse.</li> </ul> <p>Find out regarding his/her intentions to do a first step.</p>
Posttest counseling in case of a negative or uncertain (controversial) test result.	Provide counseling taking into account requirements of the respective activities of section 4.3 of the Protocol.
Posttest counseling in case of a positive result. Planning the future with a detailed coverage of behavior change for less risky one to improve quality of life.	<p>Assess the patient condition and his/her capability of perceiving information. If necessary, reschedule the meeting.</p> <p>Further counseling should be carried out in line with activities of section 4.3 of the Protocol.</p> <p>Find out whether patient's positive status would affect his/her decision regarding reduction of drug use. If yes:</p> <ul style="list-style-type: none"> <li>- in what way and what results does he/she expect from such changes?;</li> <li>- who can support him/her on the way to the positive changes?</li> </ul>

International research documents that injection drug users who are given substitution therapy and behavior change support can change their behavior to reduce their risk of receiving or transmitting HIV, including not injecting drugs or sharing syringes. It is critical that pregnant women who are IDUs have access to substitution therapy, so the unborn child is not traumatized or harmed since sudden withdrawal from drugs is harmful to both the mother and the unborn child. Lastly, injection drug users who live with HIV and who need HAART, also need access to substitution therapy. Substitution therapy helps to stabilize lifestyles and helps to support healthier behavior of IDUs, including increasing preparedness and adherence to ARVs, TB and other medication which many IDUs need.

***Testing- drawing blood – from injection drug users***

Many injection drug users inject drugs into their veins in their arms and hands. Often they have injected so many times that scar tissue makes it very difficult to draw blood from their arms and/or hands and/or feet. This can be especially true for female injection drug users. Often the syringe used to draw blood must have a very small gage and must be inserted in atypical vein in order to draw blood for HIV-related testing. Injection drug users (IDUs) are experts on their own

veins and which vein can be used to draw blood. It can be emotionally traumatic for IDUs to have their blood drawn especially if they believe they will be punctured many times. If one must draw blood with a syringe, it is important to ask the injection drug user if they can recommend the best vein to try to draw blood.

### *Peculiarities of counseling of sex workers (SW)*

Sexual services are usually the main source of income for a sex worker (SW). SW understand that warning the clients of STI infection risk or suggesting sexual intercourse that is less pleasant for their clients would reduce their possibility to earn money. That is why giving up on some/all forms of risky behavior may reduce ability of SW to earn money. Usually, SW avoid talking about condoms when they negotiate with their clients price, place, etc. Besides, SW, especially those who's services are inexpensive, might experience serious pressure either because of financial incentives or because of coercion of their pimp or client who makes them venture on a very risky behavior (for example, penetrating sex without a condom). These SW, who usually seek clients on a street, are informed least and have a low social and economical status, most vulnerable to aggression and cruel treatment on the part of clients, pimps, and the police. Infection with HIV and other STI as a result of their vulnerability to violence is a serious problem for SW.

Worldwide, sex workers are much more likely to use a condom with a client and very rarely use a condom with their significant other, since psychologically it is common to differentiate between a client and a partner through demonstrating intimacy, which can be unprotected sexual behavior. Many sex workers are at great risk of being HIV infected through unprotected sex with their intimate partner

A counselor should help SW in finding ways to overcome obstacles they encounter with while trying to reduce risk of HIV/STI infection. If they are already infected, tell them of the necessity to adhere to prevention methods so that not to spread HIV and other STI, warn them of the criminal responsibility for infecting their partners.

Special effort should be made to create an atmosphere of trust. Several studies demonstrate that sex workers often experience stigma and judgmental attitudes at health and other services. It is important to focus on the behavior and not judge the person. It is important to discuss ways to reduce risk of HIV and issues SWs are concerned with, discuss possibilities to provide necessary assistance, inform of institutions, organizations, and NGOs where they can get this assistance.

During the counseling, it is necessary to highlight behavior change and issues that are stipulated in sections 4.2 and 4.3 of the Protocol; particularities of the persons being counseled should be taken into account.

The 2005 Ukraine VCT Protocol states the counseling should be carried out in the following order:

<p>Informing about ways and means to prevent HIV infection through sexual intercourse.</p>	<p>Find out about STI prevention methods that are used by the patient, including condoms for oral and anal sex, etc.</p> <p>Discuss additional measures to prevent infection. Review rules of condom use using, if available, demonstration materials (diagrams, pictures, condoms, manikins). Discuss actions in case when integrity of a condom was broken.</p> <p>Ask whether client ever has sex without a condom and his/her reasons for that; ask about his/her personal assessment of risk of infection under such circumstances.</p> <p>Together with the patient, find ways to avoid such situations. Consider possibility of an alternative, non-penetrating sex.</p>
<p>Assessing the risk of sexual violence. Discussing behavior that would reduce the risk.</p>	<p>Find out about:</p> <ul style="list-style-type: none"> <li>- SW's own assessment of probability to get infected;</li> <li>- Incidence of sexual violence in the SW's environment, what it might be related to;</li> <li>- Who is the most frequent rapist (clients or somebody else)?</li> </ul> <p>Jointly with the patient, discuss his/her behavior that would help avoid or reduce risk of violence and prevent possible conflicts.</p>
<p>Informing the patient about emergency infection prevention in case of sexual violence.</p>	<p>Explain:</p> <ul style="list-style-type: none"> <li>- Reasons of high risk of HIV infection in case of sexual violence (substantial damage to the integrity of mucus membranes, etc.);</li> <li>- possibility of the emergency infection prevention in case of sexual violence.</li> </ul>
<p>Assessing the risk related to use of psychoactive substances.</p>	<p>Find out about:</p> <ul style="list-style-type: none"> <li>- sexual contacts under drug (what kind?) or alcohol intoxication;</li> <li>- sex with intoxicated clients.</li> </ul> <p>Explain to the patient that drug use, especially injection drugs use, is closely related to high risk of HIV infection.</p> <p>Develop an individual plan of HIV infection risk reduction and find out the patient's plans regarding personal protection.</p>
<p>Identifying the risks related to sexual contacts and finding the ways to do prevention.</p>	<p>Find out:</p> <ul style="list-style-type: none"> <li>- whether SW has a permanent sexual partner/partners (apart from clients);</li> <li>- whether the partner uses methods of STI prevention;</li> <li>- patient's personal assessment of safety of sex</li> </ul>

	with her/his permanent partner Discuss additional measures to prevent infection.
Identifying high risk factors for SW	Explain that: <ul style="list-style-type: none"> <li>- during sexual contacts accompanied by damaged mucus membranes, the risk of HIV infection increases;</li> <li>- persons with inflammatory diseases of genital organs are more vulnerable to HIV.</li> </ul> Together with SW draft a plan of his/her infection risk reduction.
Providing information and identifying optimal methods of infection prevention.	Find out about acceptability, conditions, advantages, disadvantages and obstacles for use of preventive methods.

***Peculiarities of counseling men who have sex with men (MSM)***

Men who have sex with men (MSM) can also be in relationships with women and also can be married and have children. MSM's rejection on the part of the society creates additional barriers for discussion of individual risks related to sexual behavior. Evidence suggests that MSM, when suspected or identified, are stigmatized by many including those in health and social services. Most often it is difficult for MSM to acknowledge that they practice unprotected sex with other men. The PLH Network of Ukraine did a study which showed men are more likely to report they inject drugs instead of admitting that they had sex with another man, even when they had never injected drugs in their life. It is necessary to find a non-judgmental and tactful approach to the patient in order to realistically assess his individual risks and give him necessary support.

It is necessary to pay enough attention to destroying the myths related to sexual behavior that exist within this social group, provide reliable information about safe and unsafe behavioral models. Unprotected anal sex is at the greatest risk due to blood and then semen having the highest concentration of HIV. It is important that a few negative test results wouldn't result in loss of MSM's proper attention to the safe sex issues. One of the counseling tasks is to improve patient's motivation to practice safe sex.

While counseling, it is necessary to highlight behaviors that put him at risk and issues that are stipulated in sections 4.2 and 4.3 of the Protocol; it is necessary to take into account particularities of persons being counseled.

2005 VCT Protocol Ukraine states the counseling should be carried out in the following order:

Discussing sexual behavior patterns.	Find out about sexual behavior patterns: <ul style="list-style-type: none"> <li>- level of bisexuality: whether the patient has sexual intercourse with the same or with the opposite sex;</li> <li>- whether the patient has a permanent partner, a</li> </ul>
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	<p>partner who has casual sex with others, or the patient has casual partners;</p> <ul style="list-style-type: none"> <li>- whether the patient uses relatively safe sex practices (mutual masturbation, sexual intercourse between the thighs, etc.)</li> </ul>
Discussing activities and methods of STI prevention.	<p>Find out about behavior patterns in cases:</p> <ul style="list-style-type: none"> <li>- when the patient and his partner use methods of STI prevention; discuss additional methods;</li> <li>- when the patient uses high quality condoms, including special condoms for anal sex, lubricants; review how to use them.</li> </ul>
Giving specific recommendations on their use.	<p>Using demonstration materials, explain the advantages and necessity to use lubricants. Explain that plain creams can't replace lubricants that can be purchased in a pharmacy.</p>
Discussing the risks of infection for "active" and "passive" partners.	<p>Find out about patient's awareness regarding relative infection risk for "active" and "passive" partners and review in detail factors that increase infection risk for both of them.</p>
Discussing the risks of infection in case of unprotected oral sex.	<p>Explain the probability of infection of "active" and "passive" partners in case of unprotected oral sex, need to use high quality condoms, etc.</p>
Discussing the risks related to frequent change of partners.	<p>Find out about patient's understanding of a correlation between risk of infection and the number of sex partners and their sexual contacts. Identify and address possibility of reduction of risk related to frequent change of sex partners.</p>
Finding out about previous HIV tests and reasons for repeated tests.	<p>Discuss the situations that raise concerns regarding possibility of HIV infection.</p>
Finding out about effect the negative test result has on patient's further behavior and assessment of his personal risk.	<p>Find out about:</p> <ul style="list-style-type: none"> <li>- safe sex practice and how long it lasts after getting negative test result;</li> </ul> <p>reasons for resuming unprotected sex practice.</p>
Identifying other kinds of risky behavior.	<p>Find out whether the patient has an experience of drug use.</p>
Discussing harm reduction principles (if the patient is an IDU)	<p>Discuss the possibility to reduce HIV infection risk in case of intravenous use of drugs; it should be done in line with section 5 of Annex 1 to the Protocol.</p>
Informing about effect of psychoactive substances on sexual behavior.	<p>Find out about the patient and his partner's experience of sex with a partner who was intoxicated by drugs (specify: what drugs) or alcohol. Explain how drugs affect sexual behavior and decrease person's critical attitude towards risk of HIV infection.</p>
Assessing the risk of sexual violence.	<p>Find out about:</p> <ul style="list-style-type: none"> <li>- patient's own assessment of the reasons and</li> </ul>

	<p>risks to become a victim of sexual violence;</p> <ul style="list-style-type: none"> <li>- prevalence of sexual violence in patient's environment.</li> </ul>
Discussing the possibility of emergency prevention in case of sexual violence.	<p>Explain why infection risk is high in case of sexual violence.</p> <p>Provide the patient with information about possibility of emergency HIV prevention in case of sexual violence.</p>
Assessing individual risks of HIV and STI infection for SW.	<p>Find out about:</p> <ul style="list-style-type: none"> <li>- whether the patient and his partners use methods of STI prevention (which ones);</li> <li>- whether there are situations when condom isn't used and why;</li> </ul> <p>In line with Section 6 of Annex 1 to the Protocol, discuss ways of infection risk reduction</p>
Finding out about patient's wrong views on safe/unsafe sex practices.	<p>Find out about criteria the patient uses to decide which contacts are safe and which are not and how that affects his behavior pattern.</p>
Discussing the risks of HIV infection for SW and IDU.	<p>Find out about the patient's awareness of prevalence of HIV among IDU and SW.</p> <p>Tell that SW, certain share of whom are IDU, have higher risk of HIV infection.</p>
Summarizing the ways and means of infection risk reduction.	<p>Discuss the following:</p> <ul style="list-style-type: none"> <li>- possibility to protect the patient and his permanent partner against HIV;</li> <li>- plan of infection risk reduction and its first step</li> </ul>

### ***Peculiarities of counseling of prisoners and convicts***

Pre and post test counseling of prisoners and ex-prisoners should be done in accordance with Section 4.2 and 4.3 of the Protocol; it should also take into account mentioned below particularities and specificity of a prisoner/convict's behavior depending on which the counseling can be carried out in accordance with sections 5 - 7 of the Annex to the Protocol.

Before these people went to prison, many of them had a risky lifestyle; it was risky both for themselves and for others. Among imprisoned people, it is important to focus on the behavior that can put one at risk for HIV and Hepatitis C: men having unprotected sex with other men, sharing unsterilized syringes (for injecting drugs, tattooing and other behaviors), and unprotected sex with a person who might be infected with HIV. Women also practice unprotected sex with other women. Drug use can be practiced in male and female prisons. The main obstacle for VCT of these groups of patients is a fear of condemnation by other members of the group. That is why the counselor's role is to create an atmosphere of trust, ensure strict confidentiality both of the fact that the patient had an HIV test done and his/her test result. It is necessary to explain to the patient that the test result is a medical secret and disclosure of information about the test result may be done only in cases stipulated

by Ukrainian laws. At the same time, it is necessary to explain the importance for the patient to know his HIV status and motivate him to be tested.

Many ex-prisoners, especially those who have multiple convictions, have lost all their family relations. When counseling such persons, it is necessary, jointly with the convict, to find out what organizations or communities he would like to get assistance from after he is released from prison. In penitentiary institutions, keeping disposable syringes is prohibited by law; supply of disposable shaving accessories and condoms is limited due to the fact that prisoners don't have enough funds to buy them. That is why, the counselor should mention that it is possible to disinfect shaving accessories, tools for tattoo making, and syringes in prison environment and explain where the convict can get disinfectants; explain where the convict may buy a condom in the facility. If the convict doesn't have funds, suggest him to ask relatives or people he knows to include condoms in the packages they might mail to him.

#### 4.6. Counseling Mistakes

Before analyzing possible mistakes in the course of providing counseling services, let us recall what aspects the notion "counseling" comprises. Let us agree right now that under "counseling" different people understand different things, since there is medical and psychological counseling, organizational and management, pedagogical and vocationally oriented, personnel and marketing counseling. In general, counseling as one of the types of work is used in those fields of human activity where, alongside with special knowledge and skills, the use of knowledge of psychology is required, because counseling is a process of communication or, as we have already said, an interview and it comprises some aspects of impact. Knowledge of human psychology, his or her qualities (motivation, needs, and his or her emotional reaction) is the most important in the course of counseling on the issues related to health, including providing VCT services. This is the reason why the counselors often make mistakes of psychological nature.

While providing HIV-related counseling one should remember that HIV is a behavioral problem and not related to morality. So, it is recommended that the counseling should be provided by specially trained professional psychologists; however, for better VCT services coordination other doctors should also be able to provide psychological counseling since, according to the laws, it is the doctors who are in charge of HIV diagnostics.

While reviewing the counseling mistakes one should pay attention to the definition of counseling in the entire VCT procedure. Counseling is a confidential dialogue between the counselor and the patient. In fact, the counselor helps the patient make a well-informed decision to have the HIV test done and cope with the stress.

Among common pre-test counseling mistakes at the initial stage are the following: the

counselor doesn't mention the confidentiality principle; the counselor's office is in fact a connecting room or he/she shares this office with some other medical officers; the counselor mentions judgmental statements if the client admits high risk behavior; the counselor assumes based on profession, appearance or age that the client does not practice risk behavior; uncomfortable situation for the patient, when the counselor is filling out some medical forms and talking to a patient without looking at him/her or sitting with his arms or legs crossed, when the counselor is sitting at the table while the patient is sitting in the middle of the room etc. In this case there can be no trust relationship between the counselor and the client so the whole procedure could fail.

Most doctors focus on medical history, examination and treatment results rather than on psychological and behavioral components of the counseling. The counselor has to collect information on the way of life, risk behavior, awareness of HIV and its prevention, and, if possible, not to waste time discussing other issues. Yet, the attitude of the counselor will affect how much information the client is willing to disclose.

Being keen on the patient's history, the counselor provides him/her with medical information only and never focuses on HIV transmission, prevention, testing and importance of being aware of one's HIV status.

Sometimes, vice versa, little time for counseling ruins the whole procedure and the doctor-counselor doesn't discuss the problem with the patient but only provides some information so the patient is not assisted in making the right choice and decision.

No feedback from the patient results in no testing and personal risk-behavior-reduction plan development.

Among common post-test counseling mistakes are the emotional extremes of the counselor, when he/she either indifferently informs the patient about the test result, doesn't let the patient have some time to realize the meaning of this test result, doesn't apply the elements of crisis counseling and refers the patient immediately to the AIDS Center, or, vice versa, assures the patient that everything is ok, and tries to pacify him/her. The important components of informing the patient about his/her HIV status, especially if it concerns HIV-positive one, are the even and non-judgmental attitude towards the patient, crisis counseling and psychological support. Most patients are in shock when they find out their status, so absorbing the information is limited. It is important that in a week or so, after some time passes for people to get used to the idea that they are infected with HIV, that all the information is repeated to the patient to ensure the information is retained. If the doctor can't provide crisis counseling, the patient should be given some time to calm down, then asked if he/she would like to see some other counselor and referred to the psychologist after the related phone call. So, servicing should be based on partnership between public, community and private organizations. No algorithm of such partnership and cooperation doesn't promote the access



of the population to VCT quality services.

**Table 4.8 Common mistakes and the ways to avoid them**

<b>COMMON MISTAKES</b>	<b>WAYS TO AVOID MISTAKES</b>
Restrictions on the client's expression of his/her feelings and needs	Encourage the client to express spontaneously his/her feelings and needs
Condemnation, moralizing, and lecturing to the patient (especially about risk behavior such as injection drug use, men having sex with men or sex work)	Take the patient as he/she is
Labeling the patient	Finding out about patient's motivation, fears and anxiety
Assuming that the patient is not at risk based on profession, physical appearance and age	Ask clearly and non-judgmentally about all potential risk behavior to all patients no matter their age (even over 50 and/or married) or their profession or appearance; do not assume you can tell who has injected drugs or which men have had sex with other men
Groundless consolation and optimism, underestimation of the patient's understanding of the problem complexity	Proper examination of the patient's problem, identifying the cause of his/her fears and anxiety, helping to control them.
Failure to perceive the patient's feelings, giving hasty advices	Motivate the patient to make independent decisions
Accusative tone of counseling, use of the question «Why? »	Finding out about life circumstances, problems and fears of the patient
Making the patient more dependent on the counselor; strengthening the patient's need for the counselor's presence and guidance	Strengthen the client's own potential
Encouraging the patient to accept a new type of behavior using flattery, compliments, or delusion	Encouraging and motivating the patient regarding the identification of the first steps needed to realize a plan for HIV infection risk reduction

## **Section 5. VCT Supervision, Monitoring and Evaluation**

### 5.1. Supervision: Goal and Objectives

### 5.2. VCT Monitoring and Evaluation System

#### **5.1. Supervision: Goal and Objectives**

A doctor providing VCT services must be familiar with the terms of VCT supervision, monitoring and evaluation and at the same time be ready to act in the capacity of a supervisor when he or she is vested with such duties by the chief doctor of a medical care institution or when he or she is attracted to supervision by the Ministry of Health of Ukraine, the Ukrainian AIDS Center etc.

Supervision literally means “to see from above” and is to enable a counseling doctor to improve his or her expertise by way of guidance, provision of methodological assistance and support with the goal of rendering high quality counseling services and bettering VCT services management. In other words, supervision is an official form of mutual assistance that makes it possible for a VCT counseling doctor to discuss the work he or she does with a more experienced and competent colleague (supervisor) and receive advice as to improving the efficiency of counseling practice on a regular basis.

The goal of supervision is cooperation aimed at improving the efficiency of pre- and post-test counseling! Supervision does not involve gaining any profits. It is built on responsibility and respect for both a doctor and a patient. Ethics, confidentiality, safety, efficiency and competency are the prerequisites of supervision.

Supervision can be conducted at various levels. For example, at the governmental level supervision is conducted by specialists of the Ministry of Health of Ukraine, the Ukrainian AIDS Center, research and development institutes and centers with the participation of representatives of public associations, including international ones. At the regional level the duty of supervision is vested by the relevant order of a regional department of health in the most experienced specialists of AIDS centers as well as obstetric-and-gynecologic, pediatric, infectious diseases, drug rehabilitation, STI, transfusiological, TB and other agencies.

At every medical care institution a doctor, who is the most trained one in terms of VCT and who has passed post-graduate area-specific improvement courses on VCT and has obtained a certificate to that effect, is vested with the duty of supervision upon the chief doctor’s order.

A supervisor plays the key role in the provision of VCT services, determines and analyzes problems, and gives advice on their solution!

The functions a supervisor has are divided according to two aspects: ensuring that counseling is of high quality and performing day-to-day control over the provision of counseling services.

A supervisor's task can be set forth according to the "Procedure" as follows:

1. Day-to-day analysis.
2. Conduct of conferences and briefings on VCT matters, including problems.
3. Overview of plans of action to change a patient's risky behavior.
4. Monitoring of counseling services.
5. Organization of the training.
6. Evaluation of patients' satisfaction.

Day-to-day analysis is divided into two types: one concerns the quality of patient counseling and observation, and the other one – administrative and organizational matters (broadening of the range of services, gathering of data, drawing of work schedules, etc.).

Quarterly conferences may be dedicated to discussing theoretical and practical matters relevant to the activity of VCT service providers and discussing and studying specific cases without personifying them, because a supervisor shall guarantee confidentiality. One of the topics for regular briefings and conferences may also be an overview of plans of action to change patients' risky behavior.

Supervision of counseling gives the one who conducts such supervision complete information and a clear vision of the problems a doctor encounters in his or her daily practice, and makes it possible for the supervisor to evaluate such doctor's expertise. Undoubtedly, the supervisor shall receive the doctor and his or her patient's consent in order to be able to be present during counseling and shall explain the purpose of his or her presence and reassure that all requirements relevant to counseling confidentiality will be met. The supervisor may not talk in the course of counseling. The only oral statement he or she may permit himself or herself is a statement of gratitude to the patient for his or her understanding the need for supervision. The supervisor shall be present from the beginning through the end of counseling. However, whenever it is impossible, it makes sense to use tape or video recording, the "false patient" technique or role games. The supervisor shall ensure that on the day of supervision the counselor is delivered a constructive response, one aimed at building up his or her counseling capacity. The following kinds of counseling supervision exist: "tête-à-tête" (a supervisor and a doctor being supervised), group supervision performed by one supervisor (several supervisors), "tête-à-tête" supervision with an equal colleague, group supervision with equal colleagues.

As far as VCT doctors' training and upgrading is concerned, it makes sense to determine a list of people who need training and compile a schedule of their training as part of doctors' post-graduate area-specific improvement courses. In the attachments one can find the existing training schedules and programs for Voluntary HIV Counseling and Testing doctors, which were developed by the P. L. Shchupryk National Postgraduate Academy of Medicine, Ministry of Health of Ukraine

(the academy chancellor is Yu. V. Voronenko, professor and corresponding member of the Academy of Medical Sciences of Ukraine). Other training schedules and programs as well as the schedule of conducting courses on HIV disease, HIV laboratory diagnostics, modern laboratory diagnostics of HIV, parenteral acute viral hepatitis and herpes virus infections are available at the website of the P. L. Shchupyk National Postgraduate Academy of Medicine.

Various mechanisms and techniques can be applied to evaluate the extent of VCT patients' satisfaction. This can be done through asking patients to check out a separate survey form, receiving prompt feedback with the use of "suggestion boxes", conducting individual interviews among parturient women at maternity hospitals and patients at drug rehabilitation hospitals, etc.

In order to ensure that the quality of VCT services is managed on a day-to-day basis, a supervisor needs to monitor how doctors perform certain activities in the course of counseling, such as ensuring that counseling services comply with the "Procedure" and data confidentiality is guaranteed, and analyzing interaction with other institutions and its efficiency through the analysis of VCT services accessibility as well as patient flows and coverage.

A supervisor must obtain a statement from all counseling doctors of a center or VCT unit confirming their awareness of the effective legislation of Ukraine as regards VCT organization and conduct, confidentiality terms and access to them.

Evaluation of the quality of VCT services requires analyzing the services provided, the working schedule of counseling doctors, the flow and coverage of patients (number of visits), and the system of interaction and accountability.

## **5.2. VCT Monitoring and Evaluation System**

The system for monitoring and evaluation (M&E) of VCT services is part of the national system for monitoring and evaluation of the HIV epidemic counteraction. The goal of M&E of VCT services is to evaluate the efficiency of such services in terms of reducing the risk of infection, changing sexual behavior, and assisting PLHIV in perceiving their HIV-positive status and receiving necessary services. Such evaluation involves casual studying of changes that are attributable to the effect caused by VCT services and that characterize their qualitative results.

At the regional level M&E is performed by oblast AIDS centers (in the Autonomous Republic of Crimea – by the republican AIDS center), and at the national level it is performed by the Ukrainian AIDS Center, which is subordinate to the Ministry of Health of Ukraine. Generalized M&E data is posted and can be familiarized with at the website of the Ministry of Health of Ukraine.

While evaluating the content of counseling of various groups of population, a supervisor must above all determine if a doctor's counseling dedicated to matters specific to the peculiarities of

a group and adjusted to them is complete. As an example, please find below the evaluation of the content of counseling of pregnant women as well as prevention of HIV MTCT, and the evaluation of the content of counseling aimed at preventive treatment for tuberculosis. In the forms below, the supervisor shall check out appropriate answers by placing “+” in relevant squares.

**Example 1. Evaluation of the Content of Counseling of Pregnant Women as well as Prevention of HIV MTCT. Which of the circumstances listed below took place during the counseling session? In the course of early pregnancy. Were those matters sufficiently discussed:**

Patient’s knowledge of pregnancy specified	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Information about HIV during pregnancy and the risk of HIV MTCT	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Advantages of awareness of one’s HIV status and available preventive measures in case of receiving a positive status (including explanations that ARV medications cannot be prescribed for pregnant women with an unidentified status)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Consequences of an HIV positive status for her child	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Consequences of an HIV positive status for her future children	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Consequences of an HIV positive status in terms of breastfeeding	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Consequences of an HIV positive status for her relations with the child’s father	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Discussion of the advantages of testing together with the child’s father	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Significance and advantages of informing the child’s father of her HIV status	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Clarification of the fact that testing is not compulsory and the woman will not be denied access to gynecological and prenatal care as well as other services if she decides not to undergo testing	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Miscarriage options	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Post-test counseling of pregnant women infected with HIV at gynecological and prenatal care facilities. Were the following matters included into the supplements to the general information that must be discussed in the course of post-test counseling:

Information about ART	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Information about baby feeding options and breast-feeding risks	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Information about family planning	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Information about treatment, care and support services that are available and can be referred to	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Discussion of the potential advantages and risks of informing the partner and family about the HIV status	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Information about safe sex and use of condoms for preventing the transmission of HIV and STIs	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Information about child care (including advice on feeding and making a timely request for medical aid in case of illness)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Planning of the future (including emotional, spiritual and legal support)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Options for referral to specialists, if necessary	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Were specific matters relevant to the prevention of HIV transmission and ART discussed?

Previous experience of taking ARV medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ART does not cure HIV	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Need for visiting gynecological and prenatal care facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Need for taking ARV medications according to the schedule prescribed by the doctor	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Verification of whether the patient understands the information provided or not	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Discussion of contraindications and precautions during taking of ARV medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Reaction to the medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Taking of other medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Information clarifying the course of preventive treatment using ARV medications was provided in a due manner, and this process involved:

Specification of the schedule of taking the medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Stating of the need to take the medications on a regular basis according to the schedule of treatment and to adhere to the mode of treatment, and explanation of the risks associated with irregular taking of medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Explanation of possible side-effects that require medical aid	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Verification of whether the patients understands everything or not	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Post-test counseling of pregnant women not infected with HIV at gynecological and prenatal care facilities involved:

Provision of information about safe sex and the necessity of using condoms (especially during pregnancy and breast-feeding)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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Explanation to couples how they should behave if one of the partners is infected	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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**Example 2. Evaluation of the Content of Counseling Aimed at Preventive Treatment for TB. Which of the circumstances listed below took place during the counseling session? Discussion of matters relevant to early TB detection and treatment. Matters relevant to TB screening (indicating symptoms):**

Cough	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Expectoration	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Fever	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Loss of weight	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Family contacts with a person with TB	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Discussion of contraindications to preventive treatment for TB and precautions: Reaction to the medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Taking of other medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Pregnancy	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Case history (TB)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does the patient take TB medications?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Sufficient information clarifying preventive treatment for TB was provided, in particular in respect of the following: the schedule of treatment	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Need to take the medications according to the schedule of treatment and possible aftereffects of not adhering to the schedule of preventive treatment for TB	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Possible side-effects that require medical aid	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Extent of understanding was verified		

The evaluation methods are described and explained in more detail in the Protocol, they are also included into the training programs for trainers and supervisors.

## Test Questions

1. Which family does the HIV virus belong to?
  1. Herpesviridae
  2. Hepadnaviridae
  3. Retroviridae
  4. Rhabdoviridae
2. HIV taxonomic characteristics:
  1. Family Herpesviridae, subfamily Pneumovirus
  2. Family Retroviridae, subfamily Spumavirus
  3. Family Retroviridae, subfamily Lentivirus
  4. Family Rhabdoviridae, subfamily Lyssavirus
3. What is the structure of HIV?
  1. The virion of a spherical form containing a centrally located nucleocapsid and supercapsid envelope, the size of which is 100-120 nm.
  2. The virion of a spherical form containing an ex-centrally located nucleocapsid in a cylindrical form and the supercapsid envelope, the size of which is 100-120 nm.
  3. The virion of a bullet-like form containing the nucleocapsid and supercapsid envelope, the size of which is 80 x 120 nm.
4. What genome does HIV have?
  1. Two similar linear RNA chains (diploid human genome)
  2. Linear double-stranded DNA
  3. Annular double-stranded DNA
  4. Fragments of single-stranded linear RNA
5. What unique enzyme does HIV have in its structure?
  1. Reverse transcriptase
  2. Neuraminidase
  3. Restrictase
  4. Thymidinekinaze
6. Where in the structure of HIV is enzyme reverse transcriptase located?
  1. In the core
  2. Forms the matrix membrane beyond the core
  3. In the structure of the supercapsid envelope
7. What is the function of HIV reverse transcriptase?
  1. Ensures synthesis of a DNA copy of the HIV virus
  2. Ensures the invasion of HIV into a target cell
  3. Ensures quality gathering of virions, their mature and leaving the cell
8. How long does it take HIV to synthesize DNA provirus?
  1. About three days
  2. 4-5 hours
  3. About 10 days



**9. Which of these medications are inhibitors of the process of reverse transcription at HIV reproduction?**

1. Azidothymidine (AZT), zalcitabine, stavudine, lamivudine
2. Acyclovir, famcyclovir, pencyclovir, epervudine
3. Sacvinaur, ritonavir, indinavir, nelfinavir, amprenavir
4. Ribavirin, peg interferon, laferon, albuferon

**10. What is the function of HIV protease?**

1. Ensures post-translation processing of inner HIV proteins
2. Ensures post-translation processing of HIV glycoproteins
3. Ensures integration of DNA provirus with the host cell genome
4. Ensures destruction of the viral RNA after the synthesis of a DNA copy of the viral genome

**11. Which of these medications are inhibitors of HIV protease?**

1. Sacvinaur, ritonavir, indinavir, nelfinavir, amprenavir
2. Azidothymidine (AZT), zalcitabine, stavudine, lamivudine
3. Amantadine, rimantadine, zanamivir, ozeltamivir

**12. Which protein performs binding of HIV-1 to the surface of antigen-sensitive cell?**

1. gp120
2. gp41
3. p24
4. p18

**13. Which HIV-1 protein ensures virus invasion into the antigen-sensitive cell?**

1. gp41
2. gp120
3. p24
4. p18

**14. On which receptors of the antigen-sensitive cell is HIV adsorbed?**

- CD4-receptors
- Residue of sialic acid available on glycoproteins and ra gangiosides
- CD21-receptors
- CD 8 -receptors

**15. Which type of interaction of HIV genomes and an antigen-sensitive cell takes place at HIV infection?**

1. Integrative
2. Autonomous
3. Both

**16. Which of these preparations deactivate HIV?**

1. 6% hydrogen peroxide for 30 minutes, a 70% ethyl alcohol solution during 10-20 minutes
2. 4% hydrogen peroxide for 30 minutes, a 20% ethyl alcohol solution during 10-20 minutes

**17. Define the strategy of the HIV genome:**

1. RNA-DNA-iRNA-protein
2. RNA-protein
3. RNA-iRNA-protein
4. DNA-iRNA-protein

**18. Define genes encoding structural HIV proteins:**

1. gag, pro, pol, env
2. tat, rev, vif, nef, LTR
3. gag, tat, env, nef

**19. Define genes encoding non-structural (transregulation) HIV proteins:**

1. tat, rev, vif, nef, vpu, vpr, vpx
2. gag, pro, pol, env
3. gag, tat, env, nef, rev

**20. How many HIV-1 genetic different **env** subtypes are there?**

1. Nine, which are symbolized by the capital Latin letters **A, B, C, D, E, F, H, J, I**
2. Three, which are symbolized by the capital Latin letters **A, B, C**
3. Only one

**21. Which human cells are highly sensitive to HIV?**

T4-lymphocytes/helpers, macrophages, neuroglia cells, astrocytes, neurons  
Muscle cells, T8-lymphocytes, EK cells  
Epithelial cells of the mucous coat of the upper air passages

**22. What are the main features of HIV pathogenesis?**

1. Formation of irreversible pervasive changes in the human immune system followed by the development of opportunistic infections and neoplasms.
2. Destruction of lung tissue cells and, as a result, the development of pneumocytic pneumonia.
3. Capacity of HIV to directly cause malignant transformation of the cell followed by Kaposi's sarcoma.

**23. What is the standard number of T4-lymphocytes/helpers in 1 mm<sup>3</sup> of blood of an adult in health?**

1. About 800-1,200
2. About 2,000
3. About 400-500
4. About 100-50

24 What is the standard number of T4-lymphocytes/helpers in 1 mm<sup>3</sup> of blood of a child in health?

1. About 500
2. About 2,000
3. About 100

**25. What is the standard ratio between T4-lymphocytes/helpers and T8-lymphocytes – suppressors in the body of a healthy adult?**

1. 1.8 – 2.2
2. 1.0
3. 0.5
4. 10.0

**26. What changes in the humoral immune response occur at HIV in an adult?**

1. Definitive non-specific hyperimmunoglobulinemia, humoral immune response to initial immunization and synthesis of antibodies to a new antigen is decreased or absent, the number of immune complexes in serum is increased.
2. Definitive hypimmunoglobulinemia, humoral immune response remains unchanged, synthesis of specific antibodies for a new antigen, etc. is observed, and the level of acid-labile interferon is decreased.
3. The humoral immune response to initial immunization and synthesis of specific antibodies for a new antigen is decreased or absent, the number of immune complexes in serum is increased, the level of acid-labile interferon is decreased.
4. The number of immune complexes in serum is decreased; the level of acid-labile interferon is decreased.

27. What number of T4-lymphocytes/helpers in 1 mm<sup>3</sup> of blood is considered critical and it is strongly required that specific antiretroviral therapy should be initiated and constantly applied for the rest of the patient's life?

1. 200
2. 400
3. 500

**28. What laboratory monitoring of PLHIV is considered optimal for adequate initiation of antiretroviral therapy?**

1. Monitoring the number of T4-lymphocytes in 1 mm<sup>3</sup> of blood, defining p24-antigen and copies of HIV RNA-genome (viral load).
2. Monitoring the number of T8-lymphocytes in 1 mm<sup>3</sup> of blood, defining specific antibodies to HIV.
3. Monitoring the number of T4-lymphocytes in 1 mm<sup>3</sup> of blood , defining the number of specific anti-p24-bodies

**29. How does the ratio between T4-lymphocytes and T8- lymphocytes change at the stage of early manifestation of HIV?**

1. Remains almost unchanged
2. Decreases to 1.0
3. Increases to 3.0 for a short period of time

**30. How does the ratio between T4-lymphocytes and T8- lymphocytes change at AIDS?**

1. Sharply decreases to the indications below 0.5

2. Remains almost unchanged
3. Decreases to the indications approaching 1.2-1.5

**31. How does the ratio between T4-lymphocytes and T8- lymphocytes change at the stage of early manifestation of HIV?**

1. in 10-20 days on average
2. one year after infection
3. 2-3 days after infection
4. 5-6 months after infection

**32. What is the dynamics of the HIV virus uptake in the blood of PLHIV?**

1. HIV virus occurs in blood as early as 10-20 days after infection, the level of which is decreased, on average, in 2 years, recurrent viremia occurs as early as 3-5 years after infection and a considerable number of the HIV virus remains in the human body for the rest of the person's life.
2. Initial viremia manifests as early as 2-3 days postinfection, lasts 3-5 months, after which the virus is completely eliminated from the body for good.
3. HIV virus occurs in the biological fluids of the human body as early as 3-5 months after infection and its high concentration remains in the body of the patient for the rest of his or her life.

**33. When is it possible and what method is used to define provirus HIV DNA in PLHIV?**

1. DNA provirus first occurs as early as 3-5 days after infection and is defined for the rest of the PLHIV life with the use of the polymerase chain reaction (PCR) method
2. DNA provirus first occurs as early as 6 months postinfection, is defined within 20-30 days, eliminates and is not defined at all in EIA.
3. DNA provirus first occurs as early 6 months after infection, is defined within 20-30 days, eliminates and is not defined at all by the PCR method.

**34. How long does the incubation period of HIV last?**

1. 2-4 weeks
2. 3-5 years
3. 2-6 months

**35. At what stage does PLHIV become a source of infection for other people?**

1. At the stage of acute HIV
2. At a symptom-free stage of HIV
3. At the stage of persistent generalized lymphadenopatia
4. At the terminal stage of HIV
5. At any stage of HIV

**36. In which of the biological fluids given below can the antibodies to HIV be defined during testing?**

1. Blood (whole blood, serum, plasma)
2. Male semen
3. Vaginal discharge

4. Saliva
5. Cerebrospinal fluid
6. Breast milk

**37. What is defined during the initial test for HIV in EIA?**

1. Antibodies to HIV
2. HIV antigens
3. HIV DNA-provirus
4. Antibodies to HIV1/2 and p24
5. Antibodies/p24 antigen to HIV1/2

**38. When do antibodies to HIV in PLHIV, which are defined in EIA, occur?**

1. in 1.5 - 6 months
2. in 2-6 days
3. in 1-2 years

**39. Which HIV markers can be defined using laboratory methods during the first month of HIV infection?**

1. All HIV1/2 antigens, DNA-provirus, RNA (viral load)
2. Antigen p24
3. Antigens to HIV (overall, separate classes)

**40. When is it most appropriate to use the PCR method to diagnose HIV?**

1. At the stage of acute HIV
2. At the stage of generalized swollen lymph nodes (lymphadenopatia)
3. At clinical stage 3
4. At clinical stage 4
5. At all stages of HIV

**41. What is the aim of verification assays in the diagnostics of HIV?**

1. Defining false positive results during initial testing using the EIA method.
2. Defining false negative results during initial testing using the EIA method.
3. Defining false negative results during initial testing using simple/rapid assays.
4. Verification of the presence of specific antiviral antibodies to HIV1/2 in plasma/serum.

**42. Which laboratory diagnostic method for HIV is the “golden standard” among assays for verification?**

1. Immunoblot (Western blot)
2. EIA
3. Simple/rapid assays
4. Isolation of the virus in the cell culture
5. Electronic microscopy

**43. Choose a set representing an absolutely positive result in the immunoblot method, which verifies the presence of HIV:**

1. p24, p55, p34, gp120, gp41
2. p18, p55, p51/66, gp41
3. p18, p55, p34, p11

**44. Which biological fluids of those listed below are most dangerous in relation to the epidemiological spread of HIV?**

1. Saliva, semen, blood
2. Vaginal discharge, breast milk
3. Tear, sweat, urine
4. Cerebral-spinal fluid (CSF)
5. Any fluids that may contain blood residue

**45. How are the results of EIA for HIV evaluated?**

1. When two positive results are produced by two or three tests, the sample of blood is forwarded to the assay that should verify the EIA positive result.
2. When two positive results are produced by two or three blood tests in EIA, the patient is considered infected with HIV.
3. When one positive or doubtful result is received in EIA, the sample of blood is forwarded to the verification assays

**46. Give the correct definition of HIV:**

1. HIV is a disease that develops as a result of a long-term persistence of human immunodeficiency virus in lymphocytes, macrophages, and cells of the nervous system and is characterized by gradual involvement of the immune and the nervous systems of the body, which is manifested by recurrent infections, growths, sub-acute encephalitis, and other pathological manifestations.
2. HIV is a chronic incurable progressing infection process with a wide spectrum of clinical presentations of the disease and complications.
3. HIV is an incurable blood disease.

**47. Why PLHIV are prescribed two and more antiretroviral medications during complex therapy?**

1. To fight against the formation of HIV strains resistant to medications, which is a consequence of a unique variability of the virus?
2. To reinforce antiviral action of medications according to the defined mechanism of antiretroviral action.
3. To decrease the impact of toxic action of medications on the patient's body.

**48. Highly active antiretroviral therapy (HAART) makes it possible to:**

1. Decrease viral load
2. Restore the number of T-cells and improve the functionality of the immune system
3. Reduce risks of HIV MTCT
4. Prolong the life of PLHIV and improve their living conditions
5. Make a full recovery of HIV
6. Eradicate the HIV virus for good.

49. Which factors from the list below can be considered ART risks?

1. Non-adherence to a regime of taking medications and their dosage
2. High cost of medications as a reason for interruption of a course of treatment
3. Side effects of medications
4. Necessity to receive ART constantly and continuously for the rest of a patient's life
5. Formation of HIV-resistant strains of the virus
6. Low level of readiness to undergo treatment and compliance

50. Reasons for a false positive result in EIA may be:

1. presence of some interfering leukocytic antigens in the patient's body
2. presence of autoreactive antibodies
3. presence of antibodies to a rheumatoid factor
4. antibodies to Epstein-Barr
5. immunoglobulin medications injections
6. vaccination against any viral disease
7. presence of new neoplasms
8. immunodeficiency of other origin

51. What aspects should be taken into account while deciding on simple/rapid assays?

1. capability of defining antibodies to HIV-1, HIV-2, group O HIV-1, generalized antibodies separately
2. diagnostic characteristics of an assay
3. simplest algorithm to perform testing
4. date of testing and date of expiry
5. cost
6. level of qualifications of experts who are going to perform an examination
7. opportunity of further verification of the results of initial testing at a HIV-infection diagnostic laboratory

52. To which group of assays does a simple/rapid immunochromatographic assay belong?

1. Continuous assays
2. Agglutinative assays
3. Immunochromatographic assays

53. Ways of HIV penetration in the human body:

1. Sexual, perinatal, from mother to child
2. Alimentary, transmissible, respiratory
3. Transplacental, fecal-oral, social contacts

54. HIV is not transmitted through:

1. Respiratory route
2. Fecal-oral route
3. Transmissible route (through blood-sucking insects and ectoparasites)
4. Social contacts
5. Sexual way through homo- and bi- and hetero-sexual contacts
6. From mother to child during delivery
7. Blood and blood products transfusion
8. Injections and injection of narcotics

55. HIV may occur:

1. through using a cup, fork, clothes, telephone, restroom, drinking water fountains
2. through kisses
3. through unprotected sexual contacts
4. through transfusion of untested blood and blood products
5. through injection drug use and sharing syringes and needles
6. through vaccination against influenza

56. HIV may be transmitted by:

1. mosquitoes and other insects
2. domestic animals
3. birds of passage during their migrations
4. wild animals bites and salivation
5. only from person to person

57. Which subpopulation can belong to groups at risk or subpopulation vulnerable to HIV infection?

1. Injection drug users
2. People who live a disorderly life and have a risky sexual behavior
3. Men who have sex with men
4. Military



5. Medical care workers
6. Blood and its products recipients
7. Blood and plasma donors
8. Elderly people
9. People with hemophilia
10. Sex workers
11. Service workers (shop assistants, public transport drivers, bath attendants, flight attendants, waiters, etc)
12. Youth

58. In which biological materials of PLHIV HIV can be present?

1. fecal matter
2. urine
3. saliva
4. blood
5. male semen
6. vaginal secretion
7. breast (human) milk

59. The highest level of virus at HIV, at any stages whatsoever, is present in:

1. Saliva, tear fluid, perspiratory glands secretion
2. Blood, breast milk, vaginal secretion, male semen
3. Fecal masses, vomit mass, oil glands secretion
4. Cerebrospinal fluid, pleural fluid, any biological fluid

60. If I know that among my patient's family members there are PLHIV, I will recommend him:

1. immediately break with them and never communicate with them in the future
2. not to refuse from social contacts, make a referral for VCT services
3. undergo testing for HIV

61. Can isolation of PLWA be justified?

1. Yes, since it decreases the risk of HIV.
2. No, since it does not make any impact on risks of HIV infection.
3. No, since it violates the human rights and does not have any medical or scientific grounds for recognition.

62. What is the tendency of the development of HIV epidemiologic process in Ukraine (as of 2007)?

1. No signs of stabilization
2. Tendency towards a stabilization of the epidemiologic process
3. Progress in the development of the HIV epidemic
4. Indefatigable regression of HIV
5. Spread of HIV in the country is suspended

63. What is the way of HIV transmission from mother to child?

1. In utero, when the virus penetrates through the placenta
2. During child delivery at contacts of the affected areas of skin or the mucous coats of an child with the blood or other biological fluids of an infected mother as a result of penetration of the biological fluids of the infected mother into the mouth cavity of her child.
3. During breastfeeding
4. During artificial feeding through kitchen utensils or milk formula
5. During caring for toddlers and social contacts

64. Which of the factors given below impact the risks of perinatal HIV transmission?

1. Level of viral load in mother's plasma
2. Number of T4-lymphocytes in mother's blood
3. Duration of child delivery
4. Presence of the dry period in child delivery
5. Invasive methods of interference or testing
6. Caesarean operation or other methods of child delivery
7. Factors associated with the fetus
8. Pathology of placenta

65. What measures of HIV prevention are taken at therapeutic institutions and establishments in Ukraine?

1. Only a propaganda campaign against drugs and prostitution
2. Only adherence to sanitary and hygiene norms and procedures for prevention of viral hepatitis B.
3. Use of disposable and sterile medical instruments

4. Active propaganda of a healthy way of life together with adherence to sanitary and hygiene norms and habits, industrial normative standards.
5. Introduction of harm mitigation programs
6. Support of medical care workers, providing them with means of protection and conducting regular examinations for HIV

66. What human biological fluids are tested for antibodies to HIV1/2?

1. Urine
2. Saliva
3. Whole blood (vein or capillary lake)
4. Serum
5. Plasma
6. Cerebrospinal fluid
7. Any biological fluids

67. What up-to-date methods of HIV testing are used in medical practice?

1. Simple/Rapid assays
2. EIA
3. Immunoblot (IB)
4. PCR
5. Electronic microscopy
6. Isolation of the virus in the cell culture

68. Which of the up-to-date methods of HIV testing are screening ones?

1. Simple/rapid assays
2. EIA
3. IB
4. PCR
5. Electronic microscopy

69. Which of the up-to-date methods of HIV testing are verification ones?

1. Simple/rapid assays
2. EIA
3. IB
4. PCR

5. Electronic microscopy

70. What antigens to HIV-1 are defined using verification assays?

1. P24
2. P53
3. P7,9
4. Gp120
5. Gp41
6. Gp160

71. What does the notion “HIV testing” include?

1. Undergoing laboratory examinations for the presence of antibodies/antigens to HIV with the use of simple/rapid assays or EIA at specialized HIV diagnostic laboratories at state and communal medical care institutions accredited according to established procedure.
2. Undergoing laboratory examinations for defining of the viral load in plasma at specialized HIV diagnostic laboratories at state and communal medical care institutions accredited according to established procedure.
3. Undergoing laboratory examinations for the presence antibodies to agents of opportunistic infection and invasions with the use of simple/rapid assays or EIA at specialized HIV diagnostic laboratories at state and communal medical care institutions accredited according to established procedure.
4. Any type of laboratory examinations aimed at defining the number of T4-lymphocytes in 1 mm<sup>3</sup> of blood (CD4/mm<sup>3</sup>) with the use of EIA or flow cytometry at specialized HIV diagnostic laboratories at state and communal medical care institutions accredited according to established procedure.

72. Define mandatory minimal requirements to the procedure of HIV counseling and testing:

1. Voluntariness
2. Confidentiality
3. Anonymity
4. Accessibility
5. Non-discrimination
6. Information integrity
7. Completeness of information
8. Professional and technical perfection
9. Mobilization of resources
10. All listed above

73. What should the affected medical care worker do, if a contact with the blood or any other biological fluid of PLHIV is followed by solution of continuity of the skin (puncture mark, cut)?

1. Take off the gloves rolling them inside-out, force blood out of the injury, use one of the disinfectants (a solution of 70% ethyl alcohol, a tincture of 5% iodine for cuts, 3% hydrogen dioxide), carefully wash your hands with soap in stream water, use a solution of 70% ethyl alcohol, apply a plaster on the injury, put on a finger stall, immediately notify the management of the medical care institution of the emergency
2. Disregard and continue working
3. Immediately stop working and make a referral for post-contact chemoprevention using antiretroviral preparations
4. Make an attempt to use specific prevention treatment for HIV

74. What should the affected medical care worker do, if a contact with the blood or any other biological fluid of PLHIV is not followed by solution of continuity of the skin?

1. Ignore and continue working.
2. Immediately stop working and make a referral for post-contact chemoprevention using antiretroviral preparations.
3. Make an attempt to use specific prevention treatment for HIV.
4. Work out the affected area using one of the disinfectants (a 70% ethyl alcohol solution, 3% hydrogen dioxide, a 3% chloramines solution), wash with water and soap and work out the injury using a 70% ethyl alcohol solution once again.

75. What should the affected medical care worker do, if there is a contact of the blood or biological fluids of PLHIV with the mucous membrane of the mouth cavity?

1. Ignore and continue working.
2. Immediately stop working and make a referral for post-contact chemoprevention using antiretroviral preparations.
3. Make an attempt to use specific prevention treatment for HIV
4. Irrigate with a 70% ethyl alcohol solution
5. Rinse out your mouth with vodka or a 40% ethyl alcohol solution three times.

76. What should the affected medical care worker do, if there is a contact of the blood or biological fluids of PLHIV with the mucous membrane of the nasal cavity?

1. Inject drops using a 30% sulfacetamide solution into the nose.
2. Rinse out your nose using a 70% ethyl alcohol solution.
3. Rinse with vodka or a 40% ethyl alcohol solution three times.
4. Disregard and continue working.

77. What should the affected medical care worker do, if there is a contact of the blood or biological fluids of PLHIV with eyes?

1. Irrigate with water (clean hands), inject drops of a 30% sulfacetamide solution.
2. Rinse out using a 70% ethyl alcohol solution.
3. Rinse out using vodka or a 40% ethyl alcohol solution three times.
4. Disregard and continue working
5. Irrigate with a 0.05% sodium permanganate solution, inject drops of a 30% sulfacetamide solution into the eyes.

78. What should be done to reduce the risk of HIV infection at work place?

Nothing

Make sure that first aid kits are well-stocked, carry out manipulations in the presence of other expert, do not rub mucous coats with hands, if there is a contact of blood or any other biological fluids with clothing, put it off and presoak it in a disinfectant solution, if the skin of hands and other areas of the body are stained through your clothing, they first should be cleaned with a 70% ethyl alcohol solution and then washed out with water and soap and

cleaned with alcohol again, stained shoes should be cleaned with a duster moistened with a disinfectant.

Have annual vaccination against influenza

Provide medical assistance to PLHIV only at specialized medical care institutions.

79. What is the goal of HIV pre-test counseling?

1. Provide information about prevention of HIV transmission, emotional and psychological support to those who hesitate to undergo testing for HIV and make an informed decision on such testing.
2. Discuss the results of testing for HIV; provide necessary information and psychological support.
3. Define effective treatment for HIV.
4. Only provide information about the consequences of a risk behavior of the patient.

80. What is the goal of HIV post-test counseling?

1. Provide information about prevention of HIV transmission, emotional and psychological support to those who hesitate to undergo testing for HIV and make an informed decision on such testing.
2. Discuss the results of testing for HIV; provide necessary information and psychological support.
3. Prescribe effective treatment for HIV
4. Only provide information about the consequences of a risk behavior of the patient.

81. What is the difference between group pre-test counseling and an individual counseling session?

1. Does not evaluate an individual risk of HIV infection
2. Provides information about the ways of HIV transmission
3. Provides information about behavioral risks of infection
4. Does not develop the ways to decrease individual risks of infection
5. Does not provide details of an impact on an individual, if there is a positive result of testing
6. Is conducted for groups of people

82. Who may conduct pre-test counseling?

1. Doctors
2. Nurses
3. Psychologists
4. Social workers
5. Representatives of PA who are involved in the activity in the field of HIV services
6. PLHIV after special training

83. Who has the right to conduct a medical examination for defining HIV and issue official conclusions in Ukraine?

1. Only state medical care institutions that possess adequately equipped laboratories and are accredited according to the procedure established by the Cabinet of Ministers of Ukraine
2. Only communal medical care institutions that possess adequately equipped laboratories and are accredited according to the procedure established by the Cabinet of Ministers of Ukraine
3. State and communal medical care institutions that possess adequately equipped laboratories and are accredited according to the procedure established by the Cabinet of Ministers of Ukraine

4. Any medical care institutions of different forms of ownership with adequately equipped modern laboratories.
5. Public associations, non-governmental organizations, family, children and youth social services centers
6. Religious societies and employees of educational institutions.

84. What is stigma?

1. Conviction of people that some features of a person or his/her way of life are disgraceful or indecent and shall be discriminated.
2. Preconceived and hostile attitude to people
3. "Brand" or "label"
4. Obsessive inadequate feeling of horror, groundless anxiety of a specific content

85. What is supervision?

1. System of improvement of a VCT counselor's competence and skills
2. System of control over quality of counseling and training of counselors
3. Mechanism of evaluation of plans to reduce the risk of patients and the evaluation of the level of satisfaction of patients.
4. Tool of ongoing analysis of a spectrum of providing VCT services and quality of VCT services' activity.
5. System of improvement of skills and raising of the level of competence of a VCT counselor by way of guidance, providing him or her methodological assistance and support, improvement of management of VCT services.
6. Guidance, supervision and control over a counselor's work and support to ensure quality counseling.

86. What is monitoring and evaluation of VCT?

1. Regular monitoring of key elements of VCT services' current activity
2. Carrying out of episodic study of changes that can be explained by the involvement of VCT services and quality results of performance of the service.
3. Mechanism of evaluation of plans to decrease the patients' risk and evaluation of the level of the patients' satisfaction.
4. Tool of ongoing analysis of a spectrum of VCT services and quality performance of VCT services.

87. What organizations and institutions are authorized to provide VCT services?

1. Centers for social services to family, children, and youth
2. Employees of educational institutions
3. PA that work with IDU, SW, PLHIV support groups
4. Religious associations
5. Medical care institutions of different forms of ownership
6. Only state and communal medical care institutions that possess adequately equipped laboratories and are accredited according to the procedure established by the Cabinet of Ministers of Ukraine.

88. What is anonymous counseling?

1. Counseling conducted without providing personal data that may identify a person (passport details: family name, first name, patronymic; date of birth, place of birth, place of residence, place of work, study, etc.)
2. Counseling conducted for a group of people who have common testing objectives (people who undergo testing to be issued a certificate, pregnant women, etc.) with a view of

providing them with information about the ways of HIV transmission, risks of infection, procedure for testing and preventive measures teaching.

3. Counseling during which information about a person, his or her private life, contacts is provided, but a counselor is obliged to keep this information confidential, including medical secrecy, except otherwise stipulated by legislation.

89. What factors should a doctor take into account while making decision on simple/rapid assays or classical diagnostic EIA-test-systems for HIV testing?

1. Cost of test-systems, reagents, equipment, simple/rapid assays, their availability
2. Availability of medical personnel possessing high level qualifications
3. Availability of a specialized laboratory
4. Number of samples for testing
5. Opportunities for collecting samples and their delivery
6. Local conditions for carrying out testing
7. Convenience and opportunity for patients to return for test results



Correct answers to the test questions

Question	Answer	Question	Answer	Question	Answer
1		22		43	
2		23		44	
3		24		45	
4		25		46	
5		26		47	
6		27		48	
7		28		49	
8		29		50	
9		30		51	
10		31		52	
11		32		53	
12		33		54	
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## Case Exercises Related to the Topic: “Laboratory Diagnostics of HIV/AIDS”

1. Antibodies to HIV are found at EIA in the blood of a 10-month-old child. HIV is diagnosed in the child’s mother during her pregnancy.

- a) Is such examination sufficient to diagnose HIV in the child?
- b) Which methods of examination are most adequate to diagnose HIV in a child of this age?
- c) If HIV in the child is defined, what was the way of HIV transmission?

2. Antibodies are found in a pregnant woman (12 weeks of pregnancy) during a repeated examination for HIV. The results of the verification assay (immunoblot) are negative.

- a) How can such result be interpreted?
- b) What factors may cause such results?

3. Antibodies to HIV1/2 are defined in a 3-month-old child and this is verified by immunoblot assay. The child’s mother is examined for HIV on her admission to a maternity hospital and her result in EIA is negative. The child is being fed with breast milk.

- a) Can we draw a conclusion that the child is infected with HIV?
- b) What method can be offered to verify that the child is HIV-infected?
- c) If HIV infection is verified, how HIV infection was transmitted to the child?
- d) Is it necessary to conduct a repeated examination for HIV infection of the child’s mother?

4. The results received in two EIA for HIV1/2 of a 4-month-old child are positive. The result of the verification test is negative (using EIA, a test-system of another manufacturer with some differences in the antigen structure of proteins immobilized on the dish). The presence of HIV in the child’s mother is excluded.

- a) Is the child infected with HIV?
- b) Is there a need of supplementary laboratory examinations for HIV?

5. Antibodies to HIV1/2 are defined in a 2-year-old child, which is verified by immunoblot assay and the polymerase chain reaction method (PCR). The child’s mother is infected with HIV.

- a) Can we draw a conclusion that the child is infected with HIV?
- b) Is there a need of supplementary laboratory examinations for HIV?

6. During the blood test of Patient P’s sample, the ICT method for defining antibodies to HIV1/2 was used, in 15 minutes the following was visualized: in the area T -- a strip of red color, in the area C – a distinct strip of red color.

- a) Interpret the results of testing.
- b) Define a doctor's tactics.

7. With the aim of initial screening for defining antibodies to HIV1/2, Patient P attends an HIV diagnostic laboratory, from whom it is almost impossible to take a sample of blood (atrophied tonicity of veins is observed).

- a) Define a virologist's tactics.

8. During EIA, you encounter with a problem of unfounded intensive ground-color (coloring) in the basin of the whole dish.

- a) What is the reason for that?

9. Patient C, aged 29, attends a therapist complaining about weaknesses, running nose, temperature rise up to 37.6°C, pain in the joints of his upper limbs. His anamnesis reveals that a month ago, he completed a treatment course for urinogenital clamidiosis.

Define a doctor's tactics concerning the patient's HIV status.

## **Right Solutions to Case Exercises Related to the Topic: “Laboratory Diagnostics of HIV/AIDS”**

### **№1.**

- a) Using EIA, antibodies of the child’s mother, infected with HIV, can be defined in the blood of a 10-month-old child (most likely transmitted through placenta), in other words, EIA is not sufficient to draw a conclusion that the child is infected with HIV.
- b) The most adequate method of laboratory diagnostics of HIV in the child is the PCR method.
- c) It is the likelihood that the child was infected during delivery, when the child is in close contact with the mother’s infected biological fluids. There is also an opportunity that infection occurred through placenta or during breastfeeding.

*Reference: Zaporozhan V. M., Ariayev M. L. HIV and AIDS / K.: Zdorovya, 2004. - p. 635.*

### **№2.**

- a) The result of the examination for HIV is pseudo-positive with the use of EIA, in other words, according to the results of the examination, HIV infection in the pregnant woman is not defined.
- b) The reason for a pseudo-positive result could be the presence of auto-antibodies to human leukocyte antigen (HLA), the presence of a rheumatoid factor in the serum of the patient, or serum cholesterol, or bacteria contaminated serum, or hemolyzed serum.

*Reference: Zaporozhan V. M., Ariayev M. L. HIV and AIDS / K.: Zdorovya, 2004. - p. 636.*

### **№3.**

- a) Yes. The presence of antibodies to HIV1/2 in the child when they are not present in the child’s mother will reveal that the child is infected with HIV.
- b) The best method to verify that the child is infected with HIV is the PCR method.
- c) It is reputed that the child’s mother at the moment of her admission to the maternity hospital had already been infected with HIV, and was in the period of serological window (at the stage of initial viremia, antibodies are absent). The child’s mother could have transmitted HIV infection to her child during child delivery (most likely) or during breastfeeding.

*Reference: Zaporozhan V. M., Ariayev M. L. HIV and AIDS / K.: Zdorovya, 2004. - p. 635.*

### **№4.**

- a) According to the results of the examination, the child is not infected with HIV.
- b) The examination for HIV1/2 can be repeated in one month and should a positive result of EIA be produced again, conduct testing for a HIV status of the child and find out what is the reason for pseudo-positive EIA results.

*Reference: Zaporozhan V. M., Ariayev M. L. HIV and AIDS / K.: Zdorovya, 2004. - p. 635.*

**№ 5.**

a) Yes. The presence of antibodies to HIV1/2 in the 2-year-old child considering verified HIV in the child's mother will reveal that the child is infected with HIV.

b) There is no need to conduct a supplemental specific etiological examination of the child for HIV. However, there is a need to define a HIV status of the child, the level of viral load, and the clinical stage of HIV.

*Reference: Zaporozhan V. M., Ariayev M. L. HIV and AIDS / K.: Zdorovya, 2004. - p. 635.*

**№6.**

The presence of the red strip in the area (T) will reveal that the sample contains a small number of antibodies to HIV1/2. The presence of the strip in the area (T) of less intensive coloring is fully explained by the dynamics of the formation of antibodies in PLHIV. If there is HIV, the immune system is drastically suppressed and the number of antibodies that are present in the serum of such patient is decreased. The presence of the red strip in the area (C) reveals that a sufficient amount of serum was used and that all necessary conditions of the test were observed. Thus, the result of the test is positive, i.e. the sample contains antibodies to HIV1/2. A positive result with the use of the immunochromatographic test (ICT) should be verified by EIA using the diagnostic test-systems registered in Ukraine at specialized HIV diagnostics laboratories.

*Reference: "Recommended Practice for Use of Rapid Assays in Laboratory Diagnostics of Viral Diseases". Shyrobokov V. P., Dziublyk I. V., Voronenko S. G. and co-authors, Kyiv-2004, - p. 32*  
*Order of the Ministry of Health of Ukraine No. 467 dated September 23, 2004, "On Approval of Recommended Practice for Rapid Assays of Blood for Defining Viral Diseases, Record Form and Instructions For Filling It"*

**№ 7.**

Samples of serum in the volume of not less than 2.0 ml are supplied for screening to an HIV diagnostics laboratory. On some occasions, we may take 3-4 drops of blood on blotting paper (when using special blotting paper intended for this purpose). Such sample may be kept in a fridge within 7-10 days at a temperature of +2°C - +4°C in a tightly closed polyethylene bag. Prior to testing, carry out elution using the "dry drop" method, as appropriate, and investigate the solution as a sample of serum. .

*Reference: Instructions on Organizing Work of an HIV Diagnostics Laboratory (Order of the Ministry of Health of Ukraine dated February 22, 2002, No. 71).*

**№8.**

Intensive ground-color (coloring) in the basins of the whole dish may be the result of the following: low quality distilled water; water contaminated with bacteria; contaminated washer; use of the same medical utensils for different reagents or contaminated utensils; presence and use of disinfectants containing chlorine at a work place; reduction of the number of cycles of the dish washing; expiration of the test-system age; rise of temperature or extension of the term of incubation of the dish.

*Reference: Textbook for Medical Virology /under the editorship of V. M. Hyrin, Kyiv, Zdorovya, pp. 99-105.*

*Practical Course in Enzyme-Immune Assay /under the editorship of A. L. Hyral and M. Y. Spivak, Kyiv, 2003, - p. 51.*

**№9.**

During the appointment, at a patient's request, conduct a blood test for defining of antibodies to HIV1/2 using rapid immunochromatographic tests (ICT) following the requirements of the instructions for use. Such investigation shall be carried out provided that mandatory pre- and post-test counseling were conducted. A positive result produced using the ICT method should be verified by EIA with the use of the test-systems registered in Ukraine at specialized HIV diagnostic laboratories.

If a negative result was produced using the ICT method, it is worth offering the patient to undergo a repeated examination for defining antibodies to HIV1/2 in 1-1.5 month (with the aim to exclude the period of serological window).

*Reference: Recommended Practice for Use of Rapid Assays in Laboratory Diagnostics of Viral Diseases". Shyrobokov V. P., Dziublyk I. V., Voronenko S. G. and co-authors, Kyiv-2004, - p. 32*

*Order of the Ministry of Health of Ukraine No. 467 dated September 23, 2004, "On Approval of Recommended Practice for Rapid Assays of Blood for Defining Viral Diseases, Record Form and Instructions for Filling It"*

*Order of the Ministry of Health of Ukraine No.415 dated August 19, 2005, "On Improvement of Voluntary HIV Counseling and Testing".*

## **Case Exercises Related to the Topic “VCT as an Effective Tool for HIV Prevention, Diagnostics and Treatment”**

1. Male Patient N, aged 27, was brought by his parents to an urgent hospital in a very serious condition: the patient is unconscious, pupils-dilated, on the internal surface of his forearm there are traces of multiple injections. According to his parents, during the last month their son's behavior was a bit strange to them, he avoided communication, sometimes, he seemed to be under the influence of alcohol, though he did not have a scent of alcohol on him.

Define a doctor's tactics.

2. Female Patient S made an appointment with a gynecologist for a medical examination, since two weeks earlier she had had an unprotected sexual contact with a casual acquaintance of her. The doctor carried out an examination, took a swab, and let her go home and drew a conclusion that she was not pregnant. In reply to her question “What should be done?” the doctor said, “Keep living”.

Which aspects of an appointment procedure related to women and legislation were violated by the doctor?

What measures, including prevention measures, the doctor should advise the patient of?

3. During the examination of pregnant Woman D in his office, the doctor prescribed her to undergo testing for HIV. He proposed that she come up to the manipulation unit and said that a nurse would bring her appointment card.

What ethic principles did the doctor violate?

4. A group of young people attended a regional hospital according to the doctor's appeal to donate blood for transfusion for Patient V, who was injured in a car crash; the patient had brain confusion, open fracture of his hip, and lost approximately 300-400 ml of blood. Samples of blood from all 10 students were taken, testing for HIV was conducted using rapid assays methods and, after the operation on the patient, direct blood transfusion of a relevant blood group to the injured patient was performed.

Define which approaches of the doctor's were adequate and correct the mistakes made in the exercise?

5. A 10-year-old student turned to the “Trust” office for anonymous testing for HIV. The result of testing is positive.

Define legal aspects of counseling of adolescents?

6. An HIV-service organization that has been providing HIV pre-test counseling services for a long time purchased rapid assays using charity funds and is prepared to use them.

Under what circumstances it is possible to start providing VCT services considering such circumstances?

## **Right Solutions to Case Exercises Relevant to the Topic “VCT as an Effective Tool for HIV Prevention, Diagnostics and Treatment.”**

1. To institute detoxication therapy, conduct, if possible, testing for injection drug use, call a narcologist for counseling. After reviving the patient, offer him VCT services. If the result of testing for HIV is negative, offer him a plan to decrease the risk of infection.

*Reference: Order of the Ministry of Health of Ukraine date August 19, 2005, No. 415 “On Improvement of Voluntary HIV Counseling and Testing”.*

2. The doctor failed to provide information on the opportunity of testing for HIV and measures of individual HIV and STI prevention, violating Article 39 of the Law of Ukraine on “The Fundamentals of the Ukrainian Legislation on Health Promotion”, Article 9 of the Law “On Prevention of AIDS and Social Security of the Population”.

The doctor’s recommendations should be: undergo VCT, use condoms as a mean of HIV and STI prevention.

*Reference: Law of Ukraine “The Fundamentals of Ukrainian Legislation on Health Promotion” dated November 19, 1992, No. 2801-XII and Law of Ukraine “On Prevention of AIDS and Social Security of the Population” dated November 12, 1991, No. 1972-XII.*

3. The principle of confidentiality, trustworthiness, completeness of information and occupational perfection shall be considered.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 “On Improvement of Voluntary HIV Counseling and Testing”.*

*Law of Ukraine “On Prevention of AIDS and Social Security of the Population” dated November 12, 1991, No. 1972-XII (Article 48, 9. Criminal Code of Ukraine No.2341 dated April 5, 2001 (Article 132)*

4. The group of young people who attended the regional hospital was not provided with HIV counseling and testing, and thus, people who are at risk of HIV infection were not defined, including the period of “serological window”. Direct blood transfusion was not required, since loss of 300-400 ml. of blood does not pose a real threat to human life. There is a high risk of HIV infection in this case.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005 No. 415 “On Improvement of Voluntary HIV Counseling and Testing”.*

*Law of Ukraine “On Prevention of AIDS and Social Protection of the Population” dated November 12, 1999, No. 1972-XII (Article 48, 9, 10.)*

5. During counseling at the “Trust” office, a counselor should ask the patient about his or her age and warn him or her that a medical examination of people who are under 18 and individuals, who are considered incapable, according to established procedure, is conducted only at request or consent of their legal representatives who are entitled to be present during such examination.

*Law of Ukraine “On Prevention of AIDS and Social Security of the Population ”.*

6. The realization of the project of a public HIV-service organization providing VCT services in this case is possible provided that experts of this organization conducting pre-test counseling took relevant training courses, and testing with the use of rapid assays and post-test counseling should take place only at a communal or state medical care institution.

*Reference: Article 7 of the Law of Ukraine “On Prevention of AIDS and Social Security of the Population ”.*



## Case Exercises Related to the Topic “HIV Pre- and Post-test Counseling”

1. A woman, aged 19, attends a confidential consulting room for HIV testing. Evaluate the risk-taking behaviors.
2. You are conducting HIV pre-test counseling. Ask questions relevant to the evaluation of the level of awareness of the patient of such testing and his capability to manage crisis.
3. You are conducting HIV pre-test counseling. Name the criteria of efficiency of HIV pre-test counseling.
4. You are conducting HIV pre-test counseling. Name the criteria of efficiency of HIV post-test counseling at a negative result.
5. Name the criteria of efficiency of HIV pre-test counseling. Name the criteria of efficiency of HIV post-test counseling at a positive result.
6. You are conducting HIV pre-test counseling. Name the criteria of efficiency of HIV post-test counseling at an identified result.
7. Patient H refused from counseling and filling out the form of informed consent for HIV testing. What is the way you would act?
8. Patient P, after pre-test counseling, refused from testing. What is the way you would act?
9. Patient K, aged 21, was released from prison half a year ago, he has been under treatment for disseminated pulmonary tuberculosis at a TB clinic. Although, he has been taking TB preparations for 4 months, there has been no positive dynamics of treatment; peripheral lymph node enlargement and loss of weight are observed.  
What are the key questions you would ask the patient during HIV pre-test counseling?
10. A pregnant woman with the term of pregnancy of 38 weeks is admitted to a maternity hospital. She refuses from HIV testing. Name one of the benefits for her to be aware of her HIV status you are going to use during pre-test counseling.

## Right Solutions to Case Exercises Relevant to the Topic “HIV Pre- and Post-test Counseling”

### 1. Risks evaluation:

- present and previous sexual behavior (constant partner or frequent change of partners);
- High-risk sexual behavior (relevant to the category of sex workers, frequent unprotected vaginal, oral, or anal sex);
- use of condoms;
- injective drug use;
- sexual contacts with an injection drug user;
- experience in blood transfusion or transplantation of organs;
- other injection manipulations; (tattoo, manicure, multiple use of non-sterile instruments, etc.).

*Reference: Manual for training “HIV/AIDS Counseling Sessions”, worked out in the framework of the project PATH, Georgia, 2005*

### 2. Questions to evaluate the patient’s level of knowledge about testing and his/her capability to manage a crisis:

- what is the advantage of being aware of own HIV-status?
- what are the ways of HIV transmission?
- what risky patterns of behavior facilitate HIV transmission?
- has the patient ever thought of possible results of testing, what would be his/her reaction to a negative or positive result?
- if the result of testing is positive, who of his family members can provide emotional support to the patient?

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 “On Improvement of Voluntary HIV Counseling and Testing”.*

### 3. The efficiency of pre-test counseling is based on the following:

- increase of the level of awareness about HIV prevention, formation of a tolerant attitude of the population towards PLHIV;
- assistance to the patient to evaluate his/her individual risks of HIV infection and work out a plan to decrease them;
- familiarization with the procedure for testing and obtaining his consent to undergo testing;
- assistance in understanding of the meaning of testing results (motivation of a patient); *Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No 415 “On Improvement of Voluntary HIV Counseling and Testing”.*

### 4. The efficiency of post-test counseling at a negative result comprises the following:

- providing the patient with information about the opportunity of “serological window”;
- working out a plan of safe behavior in terms of HIV;
- strengthening of knowledge about skills of safe sex;
- formation of a tolerant attitude of the population to PLHIV;
- providing the patient with information about other forms of assistance and institutions where he/she can receive medical, psychological, and legal assistance

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 “On Improvement of Voluntary HIV Counseling and Testing”.*

### 5. The efficiency of post-test counseling at a positive result comprises the following:

- be certain that the patient understands the result of testing;
- providing the patient with information about the fact that HIV does not mean AIDS at all, and if AIDS is defined, explain to him or her that it is a disease with a chronic course, and its treatment insures improvement of quality of living conditions and prolongs the patient’s life;

- providing information about the necessity to initiate prevention measures against opportunistic diseases;
- working out a plan of prevention measures to prevent HIV transmission to a partner;
- formation of the patient's disposition to ART, treatment for opportunistic diseases;
- providing the patient with information about institutions where he/she can receive psychological support and medical, social, and legal assistance;
- setting a date of next appointment.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 "On Improvement of Voluntary HIV Counseling and Testing".*

6. The efficiency of post-test counseling at an unidentified result comprises the following:

- providing the patient with information about possible reasons for an unidentified result;
- providing the patient with information about the necessity of repeat testing in 2 weeks or 2-3 months and examinations during this period for other diseases that might have caused such result;
- providing the patient with information about institutions where he/she can receive medical, psychological, legal assistance;
- setting a date of next appointment.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 "On Improvement of Voluntary HIV Counseling and Testing".*

7. A patient's refusal from pre-test counseling or filling out the form of informed consent for HIV testing (No. 503-1/o) should not influence the patient's desire to undergo voluntary testing. In this case, as an exception, a doctor should make a note about the patient's consent to undergo HIV testing and the patient puts his signature in his/her medical card.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 "On Improvement of Voluntary HIV Counseling and Testing".*

8. If a patient, after pre-test counseling, refuses to undergo testing, offer him or her a repeat counseling session and remind the patient about the decrease of risks of HIV infection.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 "On Improvement of Voluntary HIV Counseling and Testing".*

9. During counseling of Patient K concerning his or her HIV testing, it is advisable to focus on the following issues:

- define risks of HIV infection;
- explain to him or her the advantages of being aware of his or her HIV-status and keep patient informed that TB/HIV co-infection impacts on the course and efficiency of treatment for each of them;
- if the result is positive, explain to the patient that timely prescribed chemoprevention and treatment will improve his/her life and living conditions (encourage him or her to undergo treatment).

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 "On Improvement of Voluntary HIV Counseling and Testing".*

10. One of the most important motives to undergo HIV testing for a pregnant woman is timely initiation of preventive measures and, as a result, for her giving birth to a healthy baby.

*Reference: Order of the Ministry of Health of Ukraine dated August 19, 2005, No. 415 "On Improvement of Voluntary HIV Counseling and Testing".*

### **Case Exercises Relevant to the Topic “VCT Supervision, Monitoring and Evaluation System”**

1. You are appointed a supervisor. What sections of ongoing analysis would you focus on?
2. Draw up a supervisor’s work plan (key sections).
3. Evaluate the level of organization of VCT services.
4. Offer your own methods of monitoring you would practice to evaluate the level of organizing VCT services.

## **Right Solutions to Case Exercises Related to the Topic: “VCT Supervision, Monitoring and Evaluation System”**

1. A supervisor should focus on improvement of the management system and quality of VCT services.

2. The work plan of a supervisor comprises the following items:

- carrying out an ongoing analysis;
- holding VCT conferences, meetings;
- review of the risk reduction plan;
- monitoring the quality of VCT counseling;
- organizing training courses;
- evaluating the level of satisfaction of patients.

3. To evaluate the level of VCT Service organization and management systems, it is required to:

- carry out an analysis of VCT services;
- analyze the schedule of VCT services;
- study the functionality of the system of cooperation between organizations-partners;
- carry out monitoring and evaluation of the level of VCT services

4. To evaluate the level of VCT Service organization and management systems, the following methods of monitoring can be used:

- level of proficiency of institutions to provide quality VCT services;
- page 46 of the “Protocol”.

## GLOSSARY

**The following terms and concepts are widely used in the manual:**

- **Adsorption (Viral adsorption)** – the first stage of virus reproduction, an initial contact of a virus with a cell, during which the binding of virus particles to a specific receptor on the surface of a host cell takes place. There are two ways of adsorption - non-specific and specific. During non-specific adsorption, a virus particle is retained on the surface of a cell due to electrostatic and Van-der-Vaals forces of intermolecular attraction. During specific adsorption, protein-surface interactions (glycoproteins) between virus-specific cell receptors take place. For example, for HIV-1 gp120 interacts with CD4-receptor on the surface of T4-lymphocytes.
- **Anonymous counseling and testing** – counseling and testing without providing the data that would facilitate identification of an individual (passport details: last name, first name, middle name; date of birth, place of residence, work, study, etc.).
- **Antigens** – foreign protein substances or macromolecular compounds that induce an immune response to the formation of specific antibodies in the human or animal body.
- **Antibodies** – substances of protein origin (immunoglobulins), which are formed in the human and animal body under the influence of various antigens, neutralizing their negative effects, ensuring specific protection of the body against human and animal pathogenic agents, including viruses.
- **Active prevention of HIV** – prevention of the spread of HIV by the introduction of the “harm reduction” strategy against illicit drug use, promoting protected sex (use of condoms, etc.).
- **Antiretroviral therapy** – a combination of preparations.
- **Safe behavior** – behavior that reflects an individual’s responsible behavior in relation to his or her life, conducts and actions. It comprises a healthy way of life, understanding of the risk and harm for his or her health, which may be caused by unhealthy nutrition, drugs, alcohol, tobacco and refusal from their use and protected sex, accordingly.
- **Virion** – the extracellular virus form, a complete virus particle (single virus particle)
- **HIV** – an infection of human immune virus (HIV) and as of August 2006, WHO has classified 4 stages of HIV disease with various stages of development: from carrying to clinical presentations
- **HIV status** – the presence or absence of HIV according to the results of laboratory findings (testing)
- **HIV screening test** – is intended for defining HIV in people who made a referral to medical and preventive treatment facilities or other medical care institutions of state or communal form of ownership to have their HIV status defined, since such awareness opens access for them to specific prevention programs and specific treatment. What is meant here are the patients who do not have any specific complaints about their health status and do not possess any clinical presentations of HIV. Such group of people, who may receive adequate help with the use of HIV screening tests, including, for instance, pregnant women, MARPs, and, under generalized stage of the HIV epidemic, all those who make referrals for medical assistance to preventive treatment facilities. When HIV screening is performed, testing and counseling constitute a separate element of a set of services when medical assistance is provided.
- **Viremia** – penetration of the virus into the blood stream (from the lymphatic system, vessel endothelial cells or by way of transmission by leucocytes)
- **Verification** – findings to verify the presence of antiviral antibodies in human plasma/serum

- **Secondary prevention** – kind of activity aimed at taking preventive measures among high-risk groups in order to prevent the disease from breaking out, and mainly, among injection drug users (those who cannot or are not ready to refuse from drugs), with a view to initiate preventive measures against negative effects of drug use and to prevent HIV transmission and infection in healthy people, including the “harm reduction” strategy.
- **Gene** – a unit of heredity. A viral gene is a fragment of DNA or RNA molecules consisting of a combination of nucleosides carrying information about the amino acid structure of a certain protein. The number of genes with viruses differs, i.e. from 3-4 in simple viruses, up to 150 and more in viruses of a complex structure.
- **Viral genome** – a rich concentration of genes (genome) in the structure of viral nucleic acids (DNA or RNA)
- **Most at risk population** – people of common social, economical, biological, ecological, and other backgrounds that facilitate the highest level of behavior that puts them at risk for HIV or other illnesses, traumas and negative health conditions. At present, the term MARP is widely used.
- **Voluntary consent** – a patient’s decision to undergo laboratory examinations for HIV, provided that he or she made such a decision under no pressure whatsoever.
- **Voluntary HIV counseling and testing (VCT)** – rests on the assumption that an individual himself or herself actively looks for organizations and institutions providing pre-test counseling, testing for HIV and post-test counseling services. The goal of VCT is to provide counseling assistance to the population concerning the ways of HIV transmission and prevention, assistance in making a voluntary informed decision on testing for HIV, defining an HIV status of an individual, support in maintaining a safe behavior in relation to the risk of HIV infection, timely referral or receipt of medical assistance: examinations for TB, sexually transmitted infections (STI), opportunistic infections and treatment for them, timely start of ART, PMTCT, services for family planning and overall support (including the principle “Equal to Equal”). VCT is the key entry point for preventive programs for treatment and care for PLHIV. Recommendations of a counselor to undergo testing for HIV are of a voluntary nature, and the final decision is with a patient at that. VCT services are provided by state and communal medical care institutions, medical care institutions of other forms of ownership, public associations (PA) working with IDUs, SWs, support groups of PLHIV, religious communities, officers of educational institutions, centers for social services to family, children and youth
- **Discordant pair** – when one of the partners is infected with HIV and the other partner is not infected
- **Discrimination** – prepossession of an individual, violation of human rights or acts of hostility towards an individual caused by stigma.
- **Diagnostic HIV testing** – is performed during examinations or treatment of certain patients who made a referral for assistance to a preventive treatment facility having certain complaints, clinical presentations of a disease, which might be potentially caused by HIV. Diagnostic HIV testing of those with TB or those who might be with TB is also performed. A doctor bears the responsibility for prescribing diagnostic testing for HIV as a standard element of providing appropriate medical assistance to any individual.
- **External stigma** – is in the layer of social stereotypes, prejudice, philosophy, myths of society. It drastically impacts an individual’s self-comprehension and may gradually flow from externality into internality, something personal – internal stigma.
- **Informed consent** – the consent of a patient who is capable of making an informed decision to undergo laboratory examinations (testing) for HIV. Informed consent may be obtained from a patient only after pre-test counseling.
- **Immunodeficiency** – incapability of certain areas of the immune system to function properly, which results in clinical manifestations of decreased immune response of the

human body to infection agents and an increased risk of the development of illnesses. As far as HIV is concerned, first of all, T-cell immunity is considered here.

- **Capsid** – the protein coat of a virus. The capsid is built up of morphological protein subunits such as capsomeres that self assemble in a geometrical pattern typical of a particular virus. There are two models of symmetry – spiral and icosahedral.
- **Counselor** – an officer of a state, communal medical care institution, other state or communal institutions, organizations or an institution, medical care institution of other forms of ownership, representative of a public association, who after having taken corresponding training courses is authorized to perform HIV pre- and post-test counseling.
- **Confidentiality**– an undertaking to keep a secret including the one in respect to a health status, medical secrecy. Pursuant to Ukrainian legislation and normative acts of Ukraine established by the Cabinet of Ministers of Ukraine, Ministry of Health of Ukraine, etc., not a single person is liable to disclose his or her HIV status except as otherwise stipulated by law.
- **Commercial sex partners** – are those who provide commercial sex services to others for any type of material incentives, or those who such commercial services were provided to for any material incentives.
- **Compliance – the practice of following medical direction fully and correctly**, it is the capability of a person to take medications as prescribed according to a schedule of treatment, adhere to recommendations in terms of dietary and other special recommendations.
- **Client** – a person (irrespective of sex), who receives services at non-medical institutions, establishments, organizations and public associations.
- **Nucleocapsid** – a structure consisting of nucleic acid molecules (DNA and RNA) surrounded by the capsid.
- **People living with HIV (PLHIV)** – a term used to denote that HIV is present in the human body. It is perceived more positively in terms of emotions than the term “HIV-infected” (negative perception is associated with the emphasis on the word “infection”) or the term “HIV-positive” (emphasis is on a positive result of HIV testing).
- **Monitoring of institutions providing VCT services** – monitoring of key elements of ongoing operations of institutions providing VCT services.
- **Public associations** – associations of people, including international ones, registered according to the procedure established by the Law of Ukraine “On Charity and Charitable Organizations”, “On Public Associations” involved in the sphere of HIV prevention, caring for and support to people living with HIV.
- **Patient** – a person (irrespective of sex) who receives services (including VCT services) at medical care institutions.
- **Pre-test counseling** – counseling prior to testing (laboratory examinations) for HIV.
- **Initial positive result** – a positive result received during a preliminary blood/serum test using a screening test.
- **Primary prevention** – preventive measures taken against drug addiction among those who do not use drugs. It includes awareness-raising educational programs, implementation of projects with a view of a good rest, formation of a healthy lifestyle, employment programs, etc.
- **Post-test counseling** – counseling after receiving the result of testing (laboratory findings) for HIV.
- **Positive result after repeated testing** – a positive result received after repeated plasma/serum tests using the same screening test.
- **VCT services** – voluntary counseling including counseling on medical, psychological, legal issues services, etc. Providing medical, social and other types of assistance at state and communal institutions and organizations, medical care institutions and organizations



of other forms of ownership and public associations. Testing for HIV at state and communal medical care institutions equipped with specialized laboratories accredited according to the procedure established by the Cabinet of Ministers of Ukraine.

- **“Harm reduction” programs** – work with IDUs following the “harm reduction” strategy. This strategy in preventive measures and social assistance is targeted at solving burning issues and the decrease of risks of injective drug use among those who cannot or are not ready to refuse from drugs.
- **Spread of HIV** - the number of PLHIV in a certain subpopulation.
- **Replication of viral nucleic acids (NA)** – one of the biosynthetic stages of reproduction of viruses related to synthesis of the daughter nucleic acids, totally homological to the matrix nucleic acid.
- **CD4-receptor** – the main receptor for HIV1/2. It is a glycoprotein having a molecular weight of 58 kDa, which is on the surface of T-lymphocytes (almost 60%), T-lymphocytes precursors, eosinophil cells, dendritic cells, and cells of CNS microglia.
- **Virus uncoating** – one of the earliest stages of virus reproduction. It occurs almost simultaneously or immediately after the penetration of the virus into the cell. It is based on setting free the capsid. The final result is freeing nucleic acid.
- **Screening** – (screening-selecting) – human serum tests in certain subpopulations (donors, pregnant women, IDUs, etc) to define human plasma/serum, which most likely contain antiviral antibodies, and to exclude human plasma/serum, which do not contain specific antiviral antibodies.
- **Structural proteins** – are proteins encoded by the viral nucleic acid and which are included into the structure of viral particles.
- **Supervision** – management, supervision and control over a counselor’s activity and providing him or her support to ensure quality counseling
- **Sexual identification** – a concept closely associated with sexual orientation of an individual, which is evidenced by a sexual behavior. Identification is considered as operation of the mind by way of which an individual gives himself or herself a label of other individual or group; as a process of establishing an emotional connection between himself or herself and other individual or group. Sexual identification may or may not reflect sexual orientation. According to sexual orientation and sexual identification, human nature comprises bisexuality, heterosexuality, and homosexuality.
- **Serological window** – a period between contamination and the appearance of antibodies, which may last from 1 up to 6 months, when the number of antibodies is still not high enough to receive a positive result for HIV.
- **Serological status** – the presence or absence of antibodies in blood serum. The serological status during HIV may be “HIV-positive” (HIV+, seropositive) or “HIV-negative” (HIV-, seronegative). It is quite often that instead of the term “HIV serological status”, the term “HIV status” is used.
- **Sexual orientation** - erotic and love desire of a person, his or her fancy, feelings
- **AIDS phobia** – it is often the ungrounded horror caused by risk of exposure to infection and development of HIV/AIDS, conviction that HIV is a sentence and AIDS is inevitable death
- **Stigma** is the conviction of the society that some features or way of life of an individual are disgraceful or indecent and should be discriminated. An HIV-positive status can be a stigma in a society, where PLHIV are treated with prejudice or hostility. Literally, stigma means “brand” or “label”
- **Testing** - undergoing a laboratory examination for defining antibodies to HIV (HIV testing) using the screening and verification methods of examinations for HIV
- **Testing and counseling on medical care workers initiative** -- it is an approach based on the performance of HIV counseling and testing at medical care institutions where a patient

made a referral. It can be twofold: HIV diagnostic testing and HIV-screening. It should be noted that such approach is voluntary and in both of them, HIV counseling and testing on medical care workers' initiative, three main principles should be adhered to – informed consent, voluntariness, and confidentiality

- **Tertiary prevention** – it is treatment, rehabilitation, re-socialization of those IDUs, who want and strive to refuse from injection drug use
- **Phobia** – it is obsessive inadequate fear, groundless anxiety of a certain sense that causes persistent obsessive neuroses. The term derives from the Greek word “phobos” (horror)
- **Excretion** - egestion of a medical agent and/or products of its metabolism from the body without further changes in their chemical structure. This term can also be used for viruses and their components, as well as the immune and infection complexes.
- **Empathy** – it is the ability to emotionally accept anxiety of other person or people. A faculty to feel a patient's/patients' state but not to allow them to impact the quality of counseling
- **Quality of life** – level of satisfaction of material and non-material needs of individuals, families and communities. It is defined by unbiased indicators (quantitative and qualitative, material and qualitative), for example, life duration, rate of poverty, level of education, how high the level of income is, how high the level of satisfaction of conditions and different aspects of life is.
- **Response characteristics of a test-system** – according to the results of findings, part of positive samples of plasma/serum are defined as those containing antibodies
- **Specificity of a test-system** – part of negative results received during plasma/serum tests and where such components do not contain specific antiviral antibodies.
- **True positive result** – a positive result received during tests of plasma/serum that contain specific antiviral antibodies
- **True negative result** – a negative result received during tests of plasma/serum that do not contain specific antiviral antibodies
- **False positive result** – a positive result received during tests of plasma/serum that do not contain specific antiviral antibodies
- **False negative result** – a negative result received during tests of plasma/serum that contains specific antiviral antibodies.
- **Predictive ability of the test-positive findings** – part of positive findings, which are true positive.
- **Predictive ability of the test-negative findings** – part of negative findings, which are true negative.

## Recommended Literature and Additional Resources Providing Useful Information about HIV and VCT

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## **Additional Sources of Information about VCT Services Broadening**

### ***Policy and Legal Guidance***

- Handbook for legislators on HIV/AIDS, law and human rights, UNAIDS/IPU, 1999 ([http://whqlibdoc.who.int/unaid/1999/UNAIDS\\_99.48E.pdf](http://whqlibdoc.who.int/unaid/1999/UNAIDS_99.48E.pdf))
- Guidance on provider-initiated HIV testing and counselling in health facilities, WHO, 2007 (<http://www.who.int/mediacentre/news/releases/2007/pr24/en/index.html>)
- International guidelines on HIV/AIDS and human rights, 2006 consolidated version, UNAIDS/OHCHR
- Counseling and Testing for HIV, FHI, 2006 (<http://search.fhi.org/sitesearch.asp?query=VCT+models&hivpubSearch=true>)
- Service Delivery Models for HIV voluntary counseling and testing, FHI, 2005 <http://www.fhi.org/NR/rdonlyres/enjgig3dojredmsbucesa6ey2i2wbz3erszczmhjl6pz62ogzln4guycffb4kk2egibf6p5oafwg3k/ModelsofCT2pager122706.pdf>
- Statement on the UNAIDS/WHO Policy toward HIV Testing, 2004 ([http://data.unaids.org/una-docs/hivtestingpolicy\\_ru.pdf](http://data.unaids.org/una-docs/hivtestingpolicy_ru.pdf))

### ***Appropriateness of HIV Status Disclosure and Partner Counseling***

- Opening up the HIV/AIDS epidemic: Guidance on encouraging beneficial disclosure, ethical partner counselling & appropriate use of HIV case-reporting (UNAIDS Best Practice Collection, Key Material, UNAIDS/WHO, Geneva, November 2000). <http://www.who.int/hiv/pub/vct/en/IncreasingReportE.pdf>
- Scaling up HIV testing and counselling services – a toolkit for programme managers, WHO, 2005, (Online version: <http://who.arvkit.net/tc/en/index.jsp>; PDF version: <http://www.who.int/entity/hiv/pub/vct/counsellingtestingtoolkit.pdf>)

### ***HIV Testing of Women***

- Sexual and reproductive health of women living with HIV/AIDS, WHO/UNFPA, 2006, (<http://www.who.int/hiv/pub/guidelines/sexualreproductivehealth.pdf>)
- Prevention of mother-to-child transmission of HIV: generic training package, WHO and CDC, 2004, (<http://www.cdc.gov/nchstp/od/gap/PMTCT/> )
- Nutrition counselling, care and support for HIV-infected women, WHO, 2004, (<http://whqlibdoc.who.int/publications/2004/9241592125.pdf>)
- Antiretroviral drugs for treating pregnant women and preventing HIV infection in children, WHO, 2004, (<http://www.who.int/hiv/pub/mtct/en/arvdrugswomenguidelinesfinal.pdf> )

### ***At Risk Populations***

- WHO online sex work toolkit (Online version: <http://who.arvkit.net/sw/en/index.jsp>; PDF version: [http://www.who.int/entity/hiv/pub/prev\\_care/sexworktoolkit.pdf](http://www.who.int/entity/hiv/pub/prev_care/sexworktoolkit.pdf))
- Strategies for involvement of civil society in HIV testing within context of “3 by 5”: Focus on marginalized communities, UNAIDS, 2004, ([http://data.unaids.org/Topics/Human-Rights/hr\\_refgroup3\\_06\\_en.pdf](http://data.unaids.org/Topics/Human-Rights/hr_refgroup3_06_en.pdf))

### ***HIV Testing and Children***

- Convention on the rights of the child, U.N., 1989, <http://www.un.org/russian/documen/convents/childcon.htm>
- Convention on the rights of the child general comment No 3: HIV/AIDS and the rights of the child, UN, 2003, Website: <http://whqlibdoc.who.int/publications/2002/9291730254.pdf>

### ***HIV Testing Techniques. Simple/rapid assays***

- Training package for HIV rapid testing, CDC and WHO, 2006. (<http://www.phppo.cdc.gov/dls/ila/hivtraining/default.aspx>)
- WHO Guidelines on HIV rapid testing, WHO (to be published)
- Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach, CDC and WHO, 2005 ([http://www.who.int/diagnostics\\_laboratory/publications/HIVRapidsGuide.pdf](http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf) )
- Revised recommendations for the selection and use of HIV antibody tests, UNAIDS/WHO, 1997 (<http://www.who.int/docstore/wer/pdf/1997/wer7212.pdf>)
- The importance of simple/rapid assays in HIV testing, WHO/UNAIDS, 1998 (<http://www.who.int/docstore/wer/pdf/1998/wer7342.pdf>)