

Diagnosis, clinical assessment of HIV infection in a pregnant woman and legal aspects of HIV infection

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Abstract

HIV infection is diagnosed using serological tests (detection of HIV1/2-specific antibodies) and tests based on molecular biology techniques (detection of viral nucleic acids: HIV RNA, HIV DNA). Currently, infection with HIV mediated by blood-derived preparations is practically impossible. HIV-specific antibodies pass through placenta to foetal blood, where they may persist till 18th month of life and, therefore, serological tests in children below this age may be falsely positive, which makes establishing a correct diagnosis more difficult. In Poland, only 10% of pregnant women undergo tests aimed to detect infection with HIV while in some Western countries such tests are performed in as many as 98% of pregnant women. During pregnancy in a HIV(+) woman, HIV blood load and number of Th CD4+ lymphocytes should be monitored. In Poland, compulsory tests for presence of HIV infection are performed in persons suspected of HIV infection/AIDS; newborns and infants, pregnant women, carriers and individuals in contact with the infected material.

Key words: human immunodeficiency virus, serodiagnosis of AIDS, diagnosis of HIV infection/AIDS, HIV infection, law.

Diagnosis

Diagnosis of HIV infections, which is of interest for several branches of medicine, includes tests linked to screening studies (manifesting high sensitivity), used, e.g. in transfusiology and studies of a high specificity, inseparably linked to the clinic of HIV infection/AIDS and branches such as infectious diseases or venereology.

Currently, infection with blood-derived preparations is practically impossible [1]. Screening tests targeted at HIV represent a routine procedure, used to estimate suitability of a given blood donation for transfusion. They include serological tests aimed at detection of HIV-1/2-specific antibodies and tests based on molecular biology techniques, aimed to detect HIV RNA [2]. In order to diagnose HIV infection two serum samples should be isolated from a single blood drawing in a given patient. Subsequently, screening tests are conducted, including EIA (enzyme immunoassay). Negative results of EIA are not further verified. The exception involves the situation in which a test can be suspected to be performed within the

so-called serological window or during the period of recent infection, when antibodies have not been produced yet and, therefore, the serological tests give falsely negative results. In the latter case, the serological tests should be repeated after 2 weeks and tests of a higher sensitivity should be taken into account (e.g. tests for presence of viral nucleic acids, HIV DNA, HIV RNA). A positive result of EIA in a single sample requires confirmation using the other sample. In the case of contradictory results, the screening test should be repeated and when both samples yield positive results, a verification test should be performed. If both screening tests and the verification test yield positive results, HIV infection can be diagnosed (since the serum contains HIV-specific antibodies) [1].

Establishment of a correct diagnosis in cases of newborns, infants and children exposed to HIV-1 infection is difficult since HIV-specific antibodies penetrate through placenta to foetal blood, in which they may persist for a long time [3]. Therefore, serological tests in children below 18 months of life may be falsely positive and cannot be considered the final, definitive and confirming test.

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Thus, diagnosis of HIV infection in children below 18 months of life should be based on tests directly detecting presence of the virus or its components (e.g. HIV RNA, HIV DNA or a very sensitive test for presence of p24 antigen) confirmed by another virological test on a sample obtained from independent blood sampling at the time more than 4 weeks after birth [4].

Every woman who is pregnant or plans pregnancy should be tested for HIV. In countries such as Great Britain, France or the Netherlands, the tests are performed in around 98% of pregnant women, in Poland, they cover slightly less than 10% of pregnant women only [5].

Medical personnel's knowledge of biology of mother-to-child HIV transmission is also an important factor [6] HIV infection is frequently accompanied by other STI (sexual transmitted infections) such as *C. trachomatis* infection, which may be transmitted vertically [7, 8].

An HIV-infected pregnant woman should be subjected to control of HIV viral load in blood (VL) and of the number of CD4+ cells in blood three times during pregnancy with the last tests performed in the 36th week of pregnancy. In cases when the woman became infected by a partner infected with a drug-resistant strain, the treatment proves to be insufficient or ineffective, drug resistance of the virus should be examined [5].

A very sensitive method for detection of HIV presence was found to involve PCR (polymerase chain reaction), a test capable of detecting even very low amounts of nucleic acids. If in the 48th h of newborn's life the test yields a positive result (pointing to presence of the pathogen) the infection took place inside the uterus, when the result of the test is negative in the 48th h but positive between the 7th and 90th day the infection developed most probably during delivery [9].

Cytometric measurement of lymphocytes T CD4+ and of lymphocytes T CD8+ numbers is of a key importance for the patient's prognosis and for the decision on ART implementation. In line with current recommendations, patients with a number of lymphocytes T CD4(+) < 350/μl should undergo antiretroviral treatment [10].

Recent studies demonstrated that the total number of lymphocytes CD4(+) achieved following application of HAART is markedly dependent on both lymphocytes T number determined as soon as possible following seroconversion (the so-called baseline CD4 level) and the lowest lymphocyte T level noted in the patient anytime in the past (the so-called CD4 nadir). Moreover, the baseline CD4 remains directly related to the post-HAART number of lymphocytes CD4, independently of the other prognostically significant variables (e.g. CD4 nadir). In other words, the more lymphocytes are contained in the patient's blood at the moment of seroconversion, the more favourable is his/her prognosis. The quoted reports imply that the baseline CD4 level is of a prognostically important significance for a patient's therapy [11].

Management of an HIV(+) pregnant woman depends mainly on her blood lymphocyte CD4+ number and on the

degree of clinical advancement. The management was specified by WHO recommendations [4] (Table 1).

Legal and medical aspects of HIV infection and AIDS diagnosis

Due to their specificity, problems linked to infection with HIV and with acquired immune deficiency syndrome (AIDS) are not simple and continue to pose several difficulties of a legal and medical type for physicians. Most of the doubts are related to problems associated with the patient's rights to autonomy and to definition of secrecy limits related to results of performed studies. Problems of the patient's rights form a significant portion of medical law and within recent years were subject to several alterations, updates and modifications. Every physician who provides health care is obliged to know rights of patients while related ignorance or behaviour violating the legal rules exposes the physician to penal, civil or professional liability [17-20].

Isolation of a blood sample from a patient and its testing for presence of HIV infection results in encroachment into the patient's privacy area, which is legally protected by various regulations.

Under the principal act, the Constitution of the Republic of Poland of 2 April 1997 (Journal of Laws No. 78, item 483, as amended) every citizen has right to have his health protected (Art. 68.1), and also has a guaranteed right to self-estimation, privacy and decisions related to his/her fate (Art. 41 "Personal inviolability and security shall be ensured to everyone.") [21].

The problem is also regulated by the Penal Code in its Art. 192: "whoever performs a therapeutic procedure with no consent of the patient will be liable to a penalty of a fine, restriction of freedom or imprisonment". Also the Code of Medical Ethics in its Art. 15 indicates that "a diagnostic, therapeutic and preventive procedure requires consent of the patient" [22, 23].

Furthermore, the Act on Patients' Rights and on Advocate for Patients' Rights provides that the patient has the right to have his/her intimacy and dignity respected, to express his/her consent to provision of specified health-care services and refuse such consent following obtaining information on his/her health condition. A medical procedure performed in the absence of patient's consent or when the consent is improper, even if the procedure was performed correctly from the medical point of view, represents an illegal action. Patient's consent can be revoked at any time before the start of the medical procedure. The above legal acts belong to the patient's autonomy [24].

Analysis of legal regulations indicates that the diagnosis of HIV infection can be established only upon patient's consent. A visit to a physician's office cannot be and is not equivalent to patient's acceptance of a suggested diagnosis and treatment. The patient admitted to

a hospital upon preliminary examination in the admission office affixes his/her signature in the history of a disease, concluded with the following statement: "I agree to the treatment and operative procedure suggested to me". Such an agreement of the patient, the so-called formal consent, represents no agreement to the operative procedure or respective examination procedures of a higher than average risk. Patient's consent provided upon admission to a hospital does not cover subsequent procedures.

Blood sampling for examination of anti-HIV antibodies fails to pose a direct risk to the patient's health but, due to the specific type of the diagnosis, it should not be covered by the general consent of the patient before examination and treatment [25-30].

The principal normative rules related to management in cases of suspicion of or diagnosis of infection with HIV are provided in the Act on Prevention and Combating Infections and Infectious Diseases in Humans of 5 December 2008 (Journal of Laws No. 234, item 1570), the Act on Patients' Rights and Advocate for Patients' Rights of 6 November 2008 (Journal of Laws of 2009 No. 52, item 17), and the Council of Ministers' regulation of 15 February 2011 on the National Programme for Prevention against HIV Infections and Combating AIDS [24, 31, 32].

Diagnosis

In the diagnosis of infection with HIV, two categories of tests are distinguished: compulsory tests, voluntary tests.

Compulsory diagnostic tests

Such tests are performed regardless of the patient's consent or even against the patient's will. Such tests are conducted in cases of prevention and combating of infectious diseases. Infections with human immunodeficiency virus (HIV) and the acquired immunodeficiency syndrome (AIDS) were classified as infections and infectious diseases within legal meaning with all its consequences. The tests are controlled by the Act of Prevention and Combating Infections and Infectious Diseases in Humans of 5 December 2008 [31].

In the discussed respect, its Art. 5.1 is of a decisive significance as it stipulates that individuals staying in the Republic of Poland are obliged to undergo sanitary/epidemiological tests, including procedures aimed at sampling or securing material for such tests.

In line with Art. 6 of that Act, individuals obliged to undergo sanitary/epidemiological tests include:

- Individuals suspected of being infected/infecting with an infectious disease (HIV or AIDS; an individual suspected of AIDS is a person manifesting clinical signs/symptoms or deviations from a normal condition in laboratory studies which may indicate AIDS; an individual suspected of being infected is a person who does not manifest signs/symptoms of HIV infection or AIDS

but who had contact with a source of infection and the type of infectious agent or circumstances of the contact justify the suspicion of the infection);

- Newborns, infants and pregnant women, suspected of infection or an infectious disease (HIV or AIDS), which might spread from mother to her foetus or a child;
- Carriers, convalescents and persons who were exposed to infection due to their contact with infected individuals, AIDS patients or the infectious material. In the above-mentioned cases, the individuals are referred for tests by a regional state sanitary inspector, appropriate for the place of stay of the individual to be tested;
- Pupils, students and PhD students trained to perform occupations with the potential for transmission of HIV infection or AIDS to other persons. They are referred for such tests by a director/vice-chancellor of the school or a person authorized by him/her;
- Persons undertaking or performing work with a potential for passing HIV infection or AIDS to other persons. Such persons are referred for tests by their employer or principal.

Art. 33 of the Act indicates that in cases of suspected HIV infection or AIDS, a state regional sanitary inspector may order, by an administrative decision, immediate performance of compulsory testing etc. of the suspected individual or person in whom the infection or the disease has been diagnosed, as specified by Art. 5.

Blood donors who voluntarily donate blood, even in the absence of their clear consent to blood sampling for purposes of diagnosis of HIV infection, are also tested for HIV infection. In order to voluntarily donate blood, a person has to be healthy, which is linked to systematic testing [26, 27].

Newborns of mothers who did not undergo HIV tests in the course of their pregnancy due to their refusal, are tested for HIV after informing the mother about it. Such a testing is treated as a routine procedure, similarly as e.g. in phenylketonuria. The procedure follows the recommendation of the Polish Gynaecological Society related to prevention of HIV perinatal transmission of 24 October 2008 [5].

Regulations of penal law provide for situations in which obligatory tests can be performed. In a penal process, a defendant, as specified in Art. 74 of the Code of Penal Proceedings, is obliged to undergo psychological and psychiatric examinations and examinations linked to performance of procedures on his/her body except for surgery. Nevertheless, if performance of such studies is indispensable, the procedures have to be conducted by a qualified health care employee with preservation of indications specified by medical knowledge and they cannot endanger health of the defendant. Specifically, upon preservation of such conditions, the defendant is obliged to submit to blood sampling. In specific cases, the procedures can be performed under duress [22].

Table 1. Criteria of evaluation of HIV infection/AIDS advancement according to WHO, modified on the basis of WHA recommendations [12]

| Degree of clinical advancement according to WHO | Clinical signs/symptoms | Remarks |
|--|---|---|
| 1. Degree of clinical advancement according to WHO | Asymptomatic patient | Absence of signs suggesting HIV infection in physical examination |
| | Persisting generalized lymphadenopathy | Painless enlarged lymph nodes (> 1 cm in diameter) in two distant sites (other than inguinal lymph nodes) with no detectable cause persisting for at least 3 months |
| 2. Degree of clinical advancement according to WHO | Moderate unexplained loss of body weight by 10% | Detected unexplained loss of body weight and inability to increase it during pregnancy |
| | Recurrent bacterial infections in upper respiratory pathways (the event manifested now plus one or more during recent 6 months) | Variable symptomatology: rhinorrhoea with unilateral facial pain (sinusitis), primary otalgia (otitis media), pharyngitis and tonsillitis with no signs of viral infection (such as cough or rhinitis) |
| | Herpes zoster (re-infection with VZV, <i>Varicella zoster virus</i>) | Painful vesicular eruption restricted to dermatome supplied by a single nerve, it does not cross midline of the body |
| | Angular stomatitis (lip sores) | Skin cracks in angles of the mouth not linked to deficiency of iron or vitamins, usually reacting to antifungal treatment [13] |
| | Regressing ulcerations in the oral cavity (2 or more episodes within recent 6 months) | Aphthous ulcerations, painful, with a typical inflamed halo and yellow-green pseudomembrane |
| | Pruritic papular eruption | Papular lesions accompanied by pruritus, frequently with postinflammatory discoloration |
| | Seborrhoeic dermatitis | Pruritic dermal eruption of uneven surface, located within hairy skin (skin of the head, in axillae, upper part of trunk, inguinal regions) [14] |
| 3. Degree of clinical advancement acc. to WHO | Fungal infection of nails | Painful, red, enlarged nail bed – paronychia. Separation of the nail plate from its bed – <i>onycholysis</i> (white discoloration, affecting in particular proximal parts of nail plates with its thickening and separation of the plate from its bed) [15] |
| | A pronounced, unexplained loss of weight (over 10% of body weight) | The above loss of weight with evident slimming of face, trunk and extremities, with cachexia or BMI below 18.5 kg/m ² . In pregnancy, loss of body weight may be hidden |
| | Diarrhoea of unexplained aetiology lasting for more than 1 month | Chronic diarrhoea (3 or more loose or watery stools per day) noted for more than 1 month [16] |
| | Continuous or relapsing unexplained fever persisting for at least 1 month | Fever, nocturnal sweats persisting for more than 1 month, relapsing or continuous, with noted lack of reaction to treatment with antibiotics and anti-malaria agents, with no evident focus of infection upon physical examination. In regions affected by malaria it should be excluded to diagnose fever of unexplained aetiology |

Table 1. cont.

| Degree of clinical advancement according to WHO | Clinical signs/symptoms | Remarks |
|---|---|--|
| | Blastomycosis of the oral cavity | Persisting or relapsing crême-coloured pseudomembranous scales (which could be scraped off upon examination) or red spots on the tongue, palate, oral mucosa, usually painful and sensitive (erythematous form) |
| | Leukoplakia in mucosa of the oral cavity | Fine, white linear lesions on lateral tongue margins, which cannot be scraped off |
| | Pulmonary tuberculosis | Chronic signs/symptoms (persisting for at least 2-3 weeks): cough, bloody sputum, dyspnoea, pain in the chest, loss of body weight, night sweats, fever + a positive result of microbiological testing of saliva for presence of tuberculous bacilli or a negative result of such test with X-ray examination confirming tuberculosis (including involvement of upper pulmonary lobes, pulmonary fibrosis and an decrease in lung volume, formation of cavities, the lesions may be more widespread). Lack of proof for involvement of extrapulmonary tissues |
| | Acute bacterial infections (e.g. pneumonia, meningitis, empyema, purulent myositis, infections of bones and joints, bacteraemia, PID – syndrome of inflammation in organs of small pelvis) | Fever accompanied by local signs, symptoms and their alleviation following introduction of an appropriate antibiotic therapy |
| | Acute, necrotic, ulcerative inflammation of the oral cavity, gingiva or periodontium (the so called Plaut-Vincent's angina) | Acute pain, ulcerations of interdental papillae, pathological movement of teeth, spontaneous bleeding, foul smell from mouth, rapid loss of osseous tissue and/or soft tissues |
| | Unexplained anaemia (HB < 8 g/dl), neutropoenia (neutrophils number < $0.5 \times 10^9/l$) and/or chronic (persisting for at least a month) thrombocytopenia (number of platelets $50 \times 10^9/l$) | Diagnosis established on the basis of laboratory tests on blood |
| 4. Degree of clinical advancement acc. to WHO | HIV wasting syndrome | Documented loss of weight (above 10% of body weight) with visible cachexia and patient's BMI not exceeding the value of 18.5 kg/m^2 or Unexplained chronic diarrhoea (loose or watery stools eliminated at least thrice a day) persisting for more than 1 month or Episodes of fever or nocturnal sweats appearing for more than 1 month with no other reason than HIV infection and not reacting to treatment with antibiotics and anti-malaria drugs. In regions with manifestation of malaria, this disease should be excluded before HIV infection-linked exhaustion syndrome can be diagnosed |

Table 1. cont.

| Degree of clinical advancement according to WHO | Clinical signs/symptoms | Remarks |
|---|---|--|
| | Pneumocystosis – pneumonia induced by <i>Pneumocystis jiroveci</i> | Exertional dyspnoea or dry cough, which appeared within the last 3 months; <i>tachypnoe</i> and fever and lung radiogram confirming a widespread, bilateral interstitial infiltration and lack of evidence pointing to bacterial pneumonia. During auscultation bilateral cracks over both lungs with/without obturation |
| | Relapsing bacterial pneumonia (current event plus one or more such infections within the recent 6 months) | Acute beginning of such a disease, lasting less than 2 weeks, in which fever, cough, dyspnoea and pain in the chest appear + Development of new adhesions seen in chest radiograms. The infection responds to treatment with antibiotics |
| | Chronic infection with <i>Herpes simplex virus</i> (oral-labial; anorectal or genital) persisting for at least 1 month or any visceral infection with <i>H. simplex</i> independently of the infection's duration | Painful, progressing anogenital ulceration, or such an ulceration of oral cavity mucosa or lips. Lesions induced by relapsing infection with <i>H. simplex virus</i> , manifested for at least 1 month. In anamnesis relapsing episodes of herpetic infections. Herpetic lesions of inner organs require further diagnostic efforts |
| | Blastomycosis of oesophagus (candidiasis) | Recent development of retrosternal pains and problems with swallowing (food and drinks) associated with blastomycosis of the oral cavity |
| | Extrapulmonary tuberculosis | Systemic disease (fever, nocturnal sweats, weakening and loss of body weight). Extrapulmonary or disseminated tuberculosis may manifest by lesions located in pleura, pericardium, peritoneum, cerebrospinal meninges, mediastinum; it may be accompanied by lymphadenopathy of mediastinal and abdominal lymph nodes, osteitis. Miliary tuberculosis: it is uniformly disseminated in the form of small miliary shadows noted on radiograms Infection with tuberculous bacilli of cervical lymph nodes may be treated as a milder form of extrapulmonary tuberculosis |
| | Kaposi's sarcoma | Typical localization involves skin or oral portion of pharynx (oropharynx). Persisting at the beginning flat spots of dermal lesions, with a pink or purple colour which used to form scales or nodules of a violet colour |
| | Toxoplasmosis of the central nervous system | Recent appearance of a focus of neurological disturbances or a lowered level of awareness and response to an appropriate treatment within 10 days |
| | Progressive multifocal leukoencephalopathy (PML) | Progressive neurological disturbances: (cognitive disturbances, disturbed gait, speech, narrowing of visual field, weak extremities, paralysis of cranial nerves) linked to demonstration of lesions of white matter in neuroimaging studies or a positive result of PCR test on JC polyomavirus, the etiological agent of PML presence, in the cerebrospinal fluid |

Table 1. cont.

| Degree of clinical advancement according to WHO | Clinical signs/symptoms | Remarks |
|---|---|--|
| | Infection with a cytomegaly virus or CMV infection in other organs, except liver, spleen and lymph nodes) | The diagnosis established on the basis of isolated retinitis can be concluded only by experienced clinicians. The typical lesions noted upon examination of fundus of the eye involve clearly outline white spots in retina spreading centripetally, frequently along blood vessels, linked to reticular vasculitis, haemorrhage and necrosis |
| | Extrapulmonary cryptococcosis (including cerebrospinal meningitis of this aetiology) | <i>Meningitis</i> : usually of a subacute character, fever with increasingly pronounced headache, meningeal reaction, patient's disorientation, altered behaviour; the disease responds to anticytococtal treatment. Definitive diagnosis results from isolation of <i>Cryptococcus neoformans</i> from a sample of extrapulmonary tissues or a positive result of tests for presence of CRAG infection linked antigen in blood or cerebrospinal fluid |
| | Disseminated mycobacteriosis | The diagnosis is based on detection of atypical bacilli in microscope examination of faeces, blood, body fluid samples or samples of other tissues other than samples isolated from lungs |
| | Encephalopathy in the course of HIV infection/AIDS | Diagnosis of cognitive disturbances and/or motor disturbances linked to basic functions, progressing within weeks or months upon absence of diseases/events other than HIV infection which might explain the above mentioned signs/symptoms. The diagnosis can be established following exclusion of other potential causes; if possible, neuroimaging should be performed (computer-assisted tomography or magnetic resonance tomography) |
| | Cryptosporidiosis (with a diarrhoea persisting for at least 1 month) | In cases of manifestation of the disease cysts of <i>Cryptosporidium</i> can be identified in preparations of unformed faeces isolated from the patient and stained according to Ziehl-Neelsen |
| | Chronic isosporiasis | <i>Isospora belli</i> should be identified in a sample isolated from the patient to confirm infestation with the parasite |
| | Wide spread fungal infections (coccidiomycosis, histoplasmosis) | Histological examination, detection of antigens or preparation of appropriate cultures of respective samples or blood |
| | Recurrent episodes of sepsis (including sepsis induced by non-typhoid salmonellosis) | Final diagnosis can be established by culture of blood samples |
| | Primary cerebral lymphoma or non-Hodgkin B-cell lymphoma or other solid tumours linked to HIV infection | Diagnosis is established by histopathological examination of an appropriate sample and, in cases of tumours in the central nervous system on the basis of neuroimaging |
| | Invasive uterine cervix carcinoma | Definite diagnosis is obtained on the basis of histopathological or cytological examination |
| | Atypical wide spread leishmaniasis | Histological examination demonstrating <i>Leishmania amastigotes</i> and/or culture of samples obtained from the patient |
| | Nephropathy in the course of HIV infection/AIDS | Final diagnosis can be obtained by performing renal biopsy |
| | Cardiomyopathy in the course of HIV infection/AIDS | The diagnosis requires demonstration of cardiomegaly and proving of restricted left ventricular ejection fraction, confirmed by echocardiography |

Persons sentenced basing on the Executive Penal Code can be subjected to compulsory testing. Art. 116 of the Code contains the order for a defendant to submit to the tests, treatment, medical and sanitary procedures and rehabilitation specified by regulations, regardless of obligations defined by norms related to combating infectious, venereal diseases, tuberculosis, alcoholism and drug abuse.

The obligation to submit to such studies is also specified in the Code of Petty Offences. In the light of law, an offence includes also refusal to provide explanation related to an (infectious) disease, failure to submit to protective vaccination or obligatory examination (Art. 115.1 of the Executive Penal Code: "...those who fail to undergo compulsory examination of his/her health condition...") [33].

Voluntary diagnostic tests

Blood tests for the purposes of diagnosis of HIV infection can be conducted on request of the patient. Such tests are performed and data on HIV infection are protected by professional secrecy. The patient is entitled also to have blood tested anonymously. According to the law, the voluntary diagnosis of HIV infection takes place when the following conditions are fulfilled:

- blood sampling and the test were performed upon consent of the authorized person,
- the consent was given in an evident manner,
- the patient agreed to the test after being informed about the purpose and character of the test or when a presumptive consent can be assumed.

If the above mentioned conditions are not fulfilled and the patient has requested that a doctor establish cause(s) of his/her complaints, particularly clinical signs/symptoms typical of an infectious disease, protozoan infection, viral infection including HIV, the diagnosis is legal and consent can be surmised as implied consent.

Basing on the same principles, blood can be sampled for needs of HIV infection diagnosis in the case when a patient reported to a doctor for full check-up examinations of his/her health condition of a preventive character. In either situation, the patient did not refuse but also did not agree to blood sampling for purposes of HIV infection diagnosis.

Apart from the cases of voluntary and obligatory studies, HIV infection diagnosis can be performed when such an action is secret to the examined person (without permission) or even when the examined person is wilfully misinformed (erroneous consent). Such situations have no legal basis and, thus, they should be treated as wilful blood sampling by a doctor for the purpose of testing the blood for presence of anti-HIV antibodies without patient's awareness of this secrecy or following misinforming the patient or fully openly when the patient cannot object to it because the blood has already been drawn.

In cases of tests directed to HIV infection diagnosis involving blood samples taken legally earlier for other purposes and stored in the lab, rules of penal law do not apply since the blood has already been legally drawn earlier upon consent of the patient.

In some cases, performance of secret diagnostic tests for HIV will not result in legal responsibility of the physician if such tests are conducted in order to protect third parties in a state of necessity (Art. 26 of the Penal Code), specifying that endangered values can be saved at the cost of sacrificing another value. Art. 26.1 of the Penal Code can be applied when health and life of other persons present a higher value than rights to self-determination, freedom and immunity of the tested individual. In a state of necessity we are posed with a conflict of values since blood sampling and performance of HIV diagnostic tests against the patient's will in the well based medical interest, e.g. protection of third parties (medical staff) against infection from the patient violates personal rights of the patient [22].

This takes place in a situation when a direct risk endangers health of a person in whose interest the test was supposed to be performed but the risk could not have been omitted in any other way, e.g. to protect medical staff from becoming infected.

The direct nature of HIV infection risk to third parties is fulfilled when specific situations arise. In such situations, the requirement of undertaking immediate rescue measures is of a principal significance. The physician is confronted with an alternative: to take actions or to tolerate the imminent danger. The direct risk to health and life of third parties, despite ignorance as to seropositivity of the individual who might represent the source of risk, can be concluded when:

1. Implications exist pointing to a potential HIV infection in a patient who is supposed to be subjected to involuntary and not obligatory tests (e.g. manifesting signs/symptoms typical of AIDS-linked opportunistic infections);
2. A real potential exists for getting infected from the examined individual by third parties, e.g. during operation with violation of skin continuity the medical staff is exposed to such a risk.

The state of necessity may also develop when activities have been undertaken to eliminate risks for health and life of the tested individual. In such situations, e.g. the following circumstances argue for performing diagnosis of HIV infection:

- the fact that upon earlier detection of HIV infection, therapeutic measures can be applied which slow down development of the disease and the earlier the infection is diagnosed, the higher are chances for making the carrier's life longer;

- detection of seropositivity allows to apply other security measures, e.g. isolation;
- in the infected individual, surgery and therapeutic methods not indicated in the carriers may be given up.

According to some authors, referring to the state of necessity upon compulsory drawing patient's blood is intolerable and violates the law. This view can be approved from the point of view of sensibility and, on the other hand, it would violate the patient's right to self-determination [25-29].

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