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# ETHICAL CHALLENGES IN THE MANAGEMENT OF THE HUMAN IMMUNODEFICIENCY VIRUS INFECTION

Andrei VĂȚĂ<sup>1</sup>, Luminița Gina VĂȚĂ<sup>2</sup>, Mihaela Cătălina LUCA<sup>3</sup>

## Abstract

The detection of the first HIV infections at the end of the 20<sup>th</sup> century and the subsequent worldwide spreading of this still incurable disease were initially accompanied by the stigmatization and the discrimination of infected individuals. The unprecedented rallying of resources used to understand and control the mechanisms of this infection, as well as the development of a wide range of therapeutic methods, which have currently led to the significant increase of the quality and length of the life of infected individuals, have brought about a change of attitude and view on this condition. There is probably no other disease involving so many ethical principles and raising so many moral dilemmas as HIV infection/AIDS. They even precede the moment of infection diagnosis setting, starting with the time of HIV testing and patient consent obtaining, followed by disease disclosure to the patient or to third parties and by provision of support and counseling, with fair therapy resources distribution and setting of the best customized treatment plan, palliative care and support during the final stages of the disease. Medical ethics principles play an essential role in the fundamental research in the field, as well as in the therapeutic trials conducted, in the ongoing vaccine development process, mother-to-infant transmission or pre-exposure prophylaxis.

*Keywords:* AIDS, vaccine, prophylaxis, communication, diagnosis, research

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## Introduction

More than 30 years elapsed from the description of the first cases of acquired immune deficiency syndrome (AIDS) and from the discovery of the agent that causes it. Despite the considerable efforts of the medical and scientific world, a curative solution has yet to be found for this disease, which has become in time one of the most serious current medical challenges, with many social, economic and ethical implications at both the individual and public health levels.

According to current estimations, there are over 34 million people infected with HIV in the world, most of whom (97%) live in underdeveloped or developing countries, especially in Sub-Saharan Africa. Since the beginning of this pandemic, AIDS has already killed about 30 million people (WHO/UNAIDS/UNICEF, 2013). Almost half of the new infection cases occur in patients under 25, and have serious consequences on their family life, work productivity and social relations.

In Romania, the first case was detected in 1985. 20646 HIV-positive persons were diagnosed ever since, 13277 of whom are still alive (Compartimentul pentru Monitorizarea si Evaluarea Infectiei HIV/SIDA în România, 2015). Our country has been a unique example of epidemic spreading through the infection of a high number of infants during their first year of life within a short span of time (around 1989), by a mechanism that is still unknown (or unadmitted).

The detection and rapid spreading of this disease worldwide has been accompanied by an unparalleled gathering of forces at the political, medical and research levels, which has contributed to the clarifications of numerous aspects related to its etiology, pathogenesis and clinical assessment, as well as to the spectacular development of therapeutic means. Although the antiretroviral therapy (ART) has not managed to eradicate the virus yet, it surely contributes significantly to the prolongation and improvement of the quality of life of infected individuals, whose life expectancy is currently almost similar to that of uninfected individuals.

The fear of the unknown is one of the most powerful stimuli in human society. At the beginning of the pandemic, this infection would automatically lead to the stigmatization of the infected individuals, to discrimination and social marginalization, especially considering that the first cases were detected amongst the members of a sexual minority (MSM).

There is probably no other disease involving so many ethical principles and raising more complex moral dilemmas than HIV infection/AIDS. They even precede the moment of infection diagnosis setting, starting immediately after HIV testing need setting and patient consent obtaining, followed by disease disclosure to the patient or to third parties and by provision of support and counseling. Other ethical issues are related to fair therapy resources distribution and setting of the best customized treatment plan, palliative care and support during the final stages of the disease.

## Ethical Dilemmas Related to HIV Testing

The ethical point of view regarding the required testing for infection diagnosis has known significant alterations lately. After 1985, when HIV was discovered, the people diagnosed with this infection were stigmatized by the disease, and subject to discrimination and isolation from society, due to the absence of a specific treatment and to its unclear transmission pathways and pathogenic mechanisms.

At that time, the communities of patients and the medical ethics specialists strived to ensure everybody's right to refuse to be tested (in the absence of their voluntary informed consent), to counseling before and after the tests and to the strict confidentiality of the results.

Although a curative solution has not been found yet, the development of a wide range of anti-HIV therapeutic means contributed to a spectacular increase of the life expectancy of infected individuals, especially in case of an early diagnosis. An efficient viral replication control (by ART) contributes significantly to the diminution of the sexual or percutaneous disease transmission risk.

Knowing the HIV status of every pregnant woman as early as possible in her pregnancy and applying a set of therapeutic measures to the mother and another set of prophylactic delivery-related measures to the newborn may lead to a spectacular decrease of the vertical infection transmission risk (from 15% in the 1990's to under 2% at present (Vocks-Hauck, 2012).

Therefore, considering all the individual and group advantages, which result from knowing the HIV positive status, the need to know whether a person is infected or not seems to have currently outweighed the importance of that person's right of refusing to be tested.

According to the specialists' current estimations, a large number of HIV infected people (namely 18% in the USA (Lansky, Prejean, Hall, 2013) and 30% in the European Union (Hamers & Phillips, 2008) are undiagnosed. This contributes significantly to infection spreading. 49% of the new HIV infections in the USA were traced back to people who were unaware of their HIV positive status (Hall, Holtgrave, Maulsby, 2012).

The need of a different approach to testing patients suspected of HIV infection arose in the early 21<sup>st</sup> century, especially in areas with high infection prevalence rates. Although Sub-Saharan Africa contains about 10% of the world's population, over 2/3 of the HIV infected people and 90% of the HIV infected children live here. 77% of the deaths due to AIDS also occur here (De Cock, Mbori-Ngacha, Marum, 2002). Given this wide scale epidemic with serious social and economic consequences, a need has been felt for active disease detection, for simplified preliminary testing procedures, for prevention methods promotion and for large scale specific treatment.

Lately, developed countries have also preferred a more relaxed approach to HIV testing. In the USA, the CDC changed its HIV testing recommendations

(Branson, Handsfield, Lampe et al., 2006) and removed the special consent requirement (the general consent for medical investigations was considered enough); the doctors' sole obligation is to inform the patient that he/she will be tested, after which the latter may choose to refuse the procedure (opt-out). Also, the pre- and post-testing counseling is no longer mandatory, but optional. These practices have also been adopted by the WHO and UNAID, starting with 2010 and they have been implemented in 2/3 of the Sub-Saharan Africa countries (WHO, UNAIDS, UNICEF, 2010), leading to better results in detecting infected individuals than the previous approach (opt-in) (Baisley, Doyle, Chagalucha, et al., 2012).

## **Ethical Problems related to HIV Testing Result Communication**

There are many factors influencing the disclosure of one's HIV positive status to one's sexual partners. About 79% of HIV positive people in developed countries and only 49% of HIV positive people in developing countries admit their diagnosis to their current (or stable) sexual partner. The lowest percentages were recorded among women in poor African countries who tested positive in the antenatal period: 16.7-32%.

The most common reasons justifying one's refusal to disclose the diagnosis to his sexual partner are: the fear of abandonment and of losing the latter's financial support, the fear of violence, of infidelity accusations or discrimination.

The voluntary disclosure of one's diagnosis to one's immediate family and friends may also have positive results materialized in emotional support, partner testing promotion and sexual practices changes, breastfeeding disruption and increased ART adherence.

When his/her patient refuses to admit his/her HIV positive status, any attending physician faces an ethical dilemma as he/she has to decide between the patient's right to confidentiality and his/her partner's and/or their children's right to a healthy life. In some African countries with high HIV infection endemicity the law provides the obligation of notification of the partner of a person diagnosed with HIV infection either directly by the party involved, or indirectly by the healthcare professionals (Bott, Makhoulf Obermeyer, 2013; Oprea *et al.*, 2013). According to the UNAIDS and United Nations recommendations (2006), healthcare providers have the right (and not the obligation) to disclose a patient's HIV positive status to his/her sexual partners if after thorough counseling the patient does not agree to this disclosure or if he/she refuses to change his/her risky sexual practices, and a real risk of infection transmission still exists. The patient will be informed of the decisions of the healthcare providers and he/she will be given reasonable time to react. To the extent possible, the patient's name will not be disclosed to his/her sexual partners, who will also be provided with counseling support.

## **Ethical Issues related to HIV/AIDS Research**

The occurrence of the HIV/AIDS pandemic also brought about major changes in medical research ethics involving human subjects.

The non-ethical (Nazi) experiments conducted during the Second World War or the subsequent ones (Tuskegee experiment) have led to the development and international implementation of codes of ethical conduct in this field (Nuremberg Code, Belmont Report), designed to protect the rights of human subjects in medical research.

The rapid spreading of the HIV/AIDS pandemic at the end of the 1980's and the total lack of adequate therapeutic solutions have caused radical perspective changes in applied medical research ethics, which reconsidered the role of randomized trials, of the use of control groups treated with placebo, of the researchers' paternalistic attitude towards the subjects enrolled in the trial or of the clear distinction between fundamental and therapeutic research.

An active role in this paradigm change was played by different patients' associations who demanded that they be entitled to be included in clinical trials and thus have the chance to influence the otherwise inexorable evolution of this type of infection. These associations also demanded deeper involvement of subjects in trial protocol development and decision making, in preventing the imposition "from high places" of sets of immutable rules and in using more democratic arguments and negotiations with the medical scientific authority. Thus, the individuals involved in scientific medical research projects came to be regarded as "participants" and not as "subjects".

Another challenge and change brought about by HIV infection occurrence is the universal application of these new sets of ethical regulations and not only in developed countries. A trend has been often noted, namely that some researches, the ethical implications of which would not have allowed for their carrying out in developed countries (such as the USA, Western Europe), were translated and conducted in less socially and economically developed countries, where medical research ethics laws were more permissive.

Codes of ethical conduct, according to which experimental research should satisfy the needs and priorities of the community where it is conducted, were developed in order to prevent the poor to be exploited for the sole benefit of the rich nations (Council for International Organizations of Medical Sciences, 1993).

Another matter that caused vivid debates is the ethics of using placebo in trials involving human HIV positive participants. Despite the fact that the WHO concluded in 1994 that comparative placebo-controlled trials are the best way to achieve rapid and scientifically reliable results, their use on HIV/AIDS patients is considered unacceptable in most developed countries (Bayer, 2004). Limiting the access of the participants to the best existing therapeutic solution (by administering placebo) is considered non-ethical. The supporters of this tide of opinion argue that this concept should have a universal application and even the trials conducted in underdeveloped countries should compare the new experimental

therapeutic molecules with the best available (standard) therapy worldwide. Its detractors consider the past use of these placebo-controlled trials as justifiable given the urgent need to find solutions. Even nowadays they continue to be useful, since they alone are able to provide “final”, “safe” and “reliable” information (Bayer, 2004) on the therapeutic or prophylactic procedures that are truly efficient.

Given the economic inequalities in the world, underdeveloped countries, where HIV infection has high endemicity, cannot afford the large-scale use of the best therapeutic/prophylactic methods currently available on the market, and finding other cost-effective solutions, which are locally acceptable, is not possible without resorting to derogations from the ethical codes or to placebo-controlled trials.

## Ethical Dilemmas and anti-HIV Vaccination

Since no curative solution is currently available, the development of an efficient anti-HIV vaccine might have a decisive contribution to the stopping of the epidemic, as was the case with other infectious diseases such as variola or poliomyelitis.

Many types of vaccines including peptides, proteins, nucleic acids or viral vectors have been developed in almost 30 years of research, yet the effectiveness of only 3 vaccine variants was tested on human subjects. Neither the first, based on the HIV glycoprotein 120, nor the second, which used an adenovirus carrying pieces of the *gag*, *pol* and *nef* HIV genes, offered protection to MSM subjects and intravenous drug users, on whom they were tested. The third candidate (RV-144) provided a certain amount of protection (31.2%) against infection among heterosexual subjects at risk and revived hopes for an efficient product, which led to the development of several improved variants that are currently being analyzed.

There are many vaccines in various stages of research, but in addition to the technical problems there are numerous ethical and legal controversies related to their testing on human subjects.

Vaccine research funding is suboptimal as the big pharmaceuticals companies are less interested in vaccines and more interested in the therapeutic HIV infection area.

Although there are at least 9 HIV1 (group M) subtypes, most initial research was conducted on the subtype B, which prevailed in developed countries (USA, Western Europe). There are differences between subtypes as concerns the infection transmission risk, the disease progression rate or the degree of protection offered by a possible vaccine, which have not been clearly understood yet.

The subjects enrolled in vaccine effectiveness trials should be well informed of the possible risks associated with the vaccine (adverse effects, immune tolerance development) and they should receive counseling in order to avoid exposing themselves to additional risks of HIV infection transmission by relying on the

often delusive “protection” provided by the tested product. Buchbinder, Mehrotra, Duerr et al. (2008) have noted, for reasons that have not been fully elucidated yet, higher rates of new HIV positive patients in a group of patients who had been given the MRKAd5 vaccine (gag/pol/nef HIV-1) than in the control group.

## **Ethical Dilemmas and Pre-exposure Prophylaxis**

As concerns the other infection prevention means, developed countries have witnessed a change of attitude which consists of the more relaxed imposition of behavioral changes (safe sex) and of the increase of the frequency of use of medical interventionist prevention methods such as circumcision, microbicides or ART (Nodin, Carballo-Dieguez, Ventuneac et al., 2008, Rowniak, Portillo, 2013).

The application of pre-exposure (PreEP) drug-based prophylaxis bloomed after the publication of the results of Grant, Lama, Anderson et al.’s research (2010) and after the approval by the FDA (in July 2012) of the use of emtricitabine/tenofovir disoproxil fumarate (Truvada®) in HIV negative patients. According to Frieden (2011), the early use of Truvada in the non-infected partner in the discordant couple significantly decreases the HIV infection transmission risk.

Although this may be a useful tool in the fight against HIV infection spreading, its use raises many ethical dilemmas. Despite the fact that the infection risk may drop by up to 44% (Grant et al, 2010) due to the prophylactic administration of this drug, PreEP use does not provide absolute protection against it.

The fact that a tablet per day might diminish the risk of sexual infection transmission may lead to wrong interpretations and to the patient’s giving up a series of vital behavioral changes (exclusive monogamous intercourse with an HIV negative partner) and of safe sex practices (condoms). Therefore, the end result of the implementation of this prophylactic method may be contrary to the expected one and it may even be accompanied by the increase of the prevalence of other sexually transmitted diseases (Ostrow, Silverberg, Cook et al., 2008).

Another matter is the contribution of this medication to the occurrence of resistant HIV variants in individuals whom PreEP will not be able to protect against infection. The efficient control of HIV infection usually requires an association of 3 antiviral drugs, and the emtricitabine/tenofovir combination does not fit the purpose (Youle & Wainberg, 2003). Specialists also fear that this PreEP may delay the occurrence of antibodies, allowing a delayed disease diagnosis, thus contributing to a potentially longer infection transmission interval. Initial research revealed no severe adverse effects due to Truvada® administration to HIV negative people, yet the risk of occurrence of these effects will be higher with the increase of the duration of use and the number of people using this prophylactic method. The economic consequences of the large-scale use of PreEP have ethical implications; the PreEP cost is not negligible, which may reduce the access of HIV positive patients to adequate therapy in poorer countries. Would it be better, we



wonder, to use some of the money indented for patient treatment to administer prophylactic medication to HIV negative individuals when there are other prevention methods, with higher effectiveness, available?

The ethical principle according to which specialists should have the patient's *beneficence* at heart supports the use of PreEP, since any effort designed to limit HIV/AIDS pandemic spreading is welcome. Yet it needs to be compared to the second ethical principle: the intent of *nonmaleficence* – PreEP may be accompanied by sexual disinhibition, neglect of minimal contraceptive methods, long-term adverse effects, occurrence of viral mutations and significant costs. Observing the patient's absolute autonomy may mean that any and all individuals thought to run a risk of acquiring HIV infection should be given PreEP; yet, considering the risks described above and the concept of fairness in the distribution of patient care resources, infectious diseases doctors have the difficult task of arbitrator in this matter.

## Conclusions

There is probably no other disease involving so many ethical principles and raising so many moral dilemmas as HIV infection/AIDS. Despite the existence in literature of guides and sets of rules for the management of these patients, they are far from being able to cover all the cases and situations met in practice, and the attending physician is often in a difficult situation towards the patient or the society as a whole and he/she must make decisions based on the regional and individual background and according to his/her own conscience.

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