

# MEDICÍNSKA ETIKA & BIOETIKA

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### Precautionary Principle<sup>[1]</sup>

The early stages of national and international environmental policies can be characterized by a curative model towards our natural environment. With increased environmental impacts of growing populations and industrialization, the environment was no longer able to cure itself; it had to be helped in repairing the damage inflicted upon it by human activities. For reasons of equity and feasibility, governments sought to apportion the economic costs of such intervention by requiring polluters to pay the cost of pollution. It soon became apparent, however, that this *Polluter Pays Principle* was practicable only if accompanied by a preventive policy, intended to limit damage to what could be repaired or compensated for. This 'prevention is better than cure' model marks the second stage of governmental action for environmental protection. This stage was characterized by the idea that science can reliably assess and quantify risks, and the *Prevention Principle* could be used to eliminate or diminish further damage. The emergence of increasingly unpredictable, uncertain, and unquantifiable but possibly catastrophic risks such as those associated with Genetically Modified Organisms, climate change etc., has confronted societies with the need to develop a third, anticipatory model to protect humans and the environment against uncertain risks of human action: the *Precautionary Principle* (PP). The emergence of the PP has marked a shift from *post damage* control (civil liability as a curative tool) to the level of a *pre-damage* control (anticipatory measures) of risks.

**Precautionary Principle, Working Definition.** When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. Morally unacceptable harm refers to harm to humans or the environment that is: threatening to human life or health, or serious and effectively irreversible, or inequitable to present or future generations, or imposed without adequate consideration of the human rights of those affected. The judgement of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review. Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm. Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

**What the PP is not.** To avoid misunderstandings and confusions, it is useful to elaborate on what the PP is not. The PP is not based on 'zero risks' but aims to achieve lower or more acceptable risks or hazards. It is not based on anxiety or emotion, but is a rational decision rule, based in ethics, that aims to use the best of the 'systems sciences' of complex processes to make wiser decisions. Finally, like any other principle, the PP in itself is not a decision algorithm and thus cannot guarantee consistency between cases. Just as in legal court cases, each case will be somewhat different, having its own facts, uncertainties, circumstances, and decision-makers, and the element of judgement cannot be eliminated.

[1] World Commission on the Ethics of Scientific Knowledge and Technology (COMEST): The Precautionary Principle. UNESCO, Paris, 2005, 52 pp., Box 2, p. 7, 14.

## CONFIDENTIALITY AND DUTY TO WARN THE THIRD PARTIES IN HIV/AIDS CONTEXT

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### Introduction

Since the first cases of AIDS were reported in 1981, the epidemic has posed a great challenge to public health officials, policymakers and the public at large. Current figures estimate that in 2004, about 40 million people were living with HIV. The AIDS epidemic claimed more than 3 million lives and close to 5 million people acquired the human immunodeficiency virus (HIV) in 2004. On 2 June 2005, UN Secretary General Kofi Annan highlighted that despite encouraging signs that the AIDS epidemic begins to be contained in a small, but growing number of countries, it still continues to expand worldwide. [1] The rapid spread of the infection and its peculiarities stipulate discussions on such issues of medical ethics, which have already been thoroughly reviewed in the past, but now seem to acquire new meaning(s). This happened to the problem of confidentiality *vis a vis* the present 'AIDS crisis'. The most complicated ethical and legal questions arise, when the infected person deliberately avoids to inform the individuals of concern about the potential danger of contracting the infection.

The *aim of this paper* is to explore the limits of confidentiality in the situation of HIV infection/AIDS, as there is a conflict with a duty to warn the third party about the danger of HIV transmission – even when the HIV-infected individual categorically refuses doing so. The problem will be analyzed step by step. At first, we shall discuss the importance of keeping confidentiality and the specificities of HIV infection. Then we shall focus on the responsibilities of the physician concerning the third party, in particular his duty to warn him/her. Then, we shall consider cases, when HIV-infection has to be reported after patient's death, or when the disclosure of the confidential information is related to the post-exposure prophylaxis.

### The specificities of confidentiality during the HIV epidemics

Generally speaking, physicians have a legal and ethical obligation of keeping confidentiality regarding their communications with patients. For example, the American Medical Association has announced that "[t]he physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law". [2] The Article 10 of amended Lithuanian Law on patients rights and compensation for the health damage [3] states that all information about the patient's health status and applied treatment is confidential and should be kept confidential even after the patient's death, unless the patient has decided to the contrary. Any such information could be reported with-

out expressed patient's consent to the directly related third party only on the grounds of patient's interests.

It may be observed that the principle of confidentiality comes into play when a person seeking medical help and his/her physician establish a particular relationship. This requires mutual respect, trust, honesty and a certain degree of confidence, to say nothing about other aspects. Then, the physician's professional skills could be used effectively for the good of the patient. [4] This underlines the most important motive for keeping the confidentiality: both the physician and the patient want to hear the truth from each other. The physician's efforts to learn as much as possible about his patient is not at all a matter of petty curiosity. **Knowledge of the person's health and his/her private life is necessary for the physician for making the best possible decisions concerning the diagnostic and treatment procedures.** Thus, acquiring certain private information from the patient (*anamnesis*) does not disturb the person's privacy. Moreover, it is an obligatory procedure for the physician.

Besides, it is a well-known fact that the principle of confidentiality shows how much the society trusts medicine altogether. A human being is a social being. He/she lives in a community. So, the right to protect one's private life – and the obligation to respect it, become a social duty in order to have sincere and trustworthy human relationships in the given society. This mutual trust should enable a sick person to look for medical help. [5] This relational code has become a basis for mutual relationships of generations of patients and physicians. Then, a question arises, why confidentiality in healthcare has become a problem in view of the 'AIDS crisis'? Why is it so important for the relationships between the physician and the HIV patient?

An important factor, shaping the discussion about confidentiality in HIV cases, is the character and mode of HIV transmission. There are some specific features that make keeping the confidentiality of utmost importance:

– **The danger of fatal disease.** At present, as there is no possibility to cure a person with HIV infection, a direct connection exists between AIDS and death. Moreover, in contrast to other fatal diseases (e.g. cancer) the AIDS patients are being despised, avoided and otherwise discriminated against. [6]

– **The ways of transmission.** Often, alongside with the fact of HIV infection, the physician learns more details about his/her patient's private life: his/her homosexual (lesbian) orientation, frequent change of partners, adultery, etc. The society sometimes mocks such cases of infection. They serve to condemn and discriminate against such person. Even people that have contracted HIV infection differently are in danger to be attributed to a certain 'risk group', and eventually being discriminated against too. For this reason, it is vital for the patient to build around him/her the confidentiality barrier, which protects him/her from an excessive social anxiety. [7]

– **Prevention and surveillance.** In absence of an effective HIV vaccine, the prevention of transmission becomes the main means of fighting the infection. However, the successful management of prevention from the public health perspective is possible only, when the real epidemiological situation in the given society is known in a sufficient detail. The necessary epidemiological information can only be obtained by carrying out HIV tests. When confidentiality is not guaranteed, the people from the 'risk groups' may be afraid to let to carry the tests out for them. [8] With, or without the information on their HIV status, they do not change their risky behavior, thus making the infection spread even quicker. Consequently, the prevalence and dynamics of HIV infection in the population remain unknown. This does not allow to predict HIV infection's behaviour in the community, to choose

the best prevention measures, and to distribute the resources effectively. [9]

The context of confidentiality in HIV/AIDS shows its serious importance in view of the AIDS crisis. The 'right to privacy' becomes a guarantee of personal independence and freedom; it guards a person from discrimination dangers, enables to choose the best prevention measures, and consequently to save lives. The recognition of the 'right to privacy', which is expressed in health care setting as the 'principle of confidentiality', gives a person an opportunity to make his/her own choice on what kind of information, especially the information concerning his/her health should – or should not be disclosed.

However, there are situations, when the 'right to privacy' of an HIV-infected person comes into conflict with other people's interests. In particular, with another individual's right to protection of his/her health and life. In this case, a physician seems to be caught in an ambiguous situation. He/she is to decide, what counts more: the patient's privacy, the physician's professional loyalty to the patient – or the responsibility for the other individual's ("third party") health/life. Moreover, the principle of justice clearly demands to protect innocent human life (and health of the 'third party').

### **HIV-infected person's voluntary reporting to the third party**

A 'voluntary report' takes place, when a HIV-infected person voluntarily discloses this fact to the third party (e.g. a spouse, a partner, a person with whom he/she has shared the syringe, a physician). Such report often reflects the person's wish to protect others, and at the same time to receive some help. As stated in the UNAIDS document *Guidance on Encouraging Beneficial Disclosure, Ethical Partner Counseling & Appropriate Use of HIV Case-Reporting*, the voluntary report respects the infected person's dignity: it retains confidence, considers his/her spouse's and children's rights, gives the society an opportunity to talk more openly about HIV/AIDS, and also meets the ethical requirement to take into account the well-being both of the HIV-infected person and the third party. [10] A person, who has a chance to report about his/her disease, or infection feels safer; he/she "controls the situation" and bears the responsibility not only for his/her own health but for the health of other people too.

Accordingly, the voluntary report should be considered an ideal, which should be strived for. There is no ethical problem, when the patient does not report himself/herself, but allows his/her physician to do so. In this case, however, he/she has to know exactly to whom and how this report will be presented to. It should also be noted that a person gives his/her agreement for a particular case of disclosure, considered in advance, not for all possible disclosures that may be considered in the future. Moreover, the HIV-infected person has to be warned about the possible consequences as the third party might viciously use the information received. On the other hand, the physician has to disclose only as much as it is absolutely necessary for the third party to know at the moment. For example, to report the fact of HIV infection, while keeping silent about the indices of the way of contamination. The 'broader than required' disclosure has no good sense, and may mean an irresponsible violation of the confidentiality principle.

Legal doctrine has brought already into focus certain aspects of the relationship between the sexual partners, for example, the legal responsibility for the negligent or intentional transmission of the HIV virus. Such relationship, with explicit legal rights and obligations of the indi-

viduals, has been defined in the beginning of the 20<sup>th</sup> century in many jurisdictions in the context of syphilis and other venereal diseases, and has been adapted more recently to the context of HIV. [11]

### **Disclosure, in spite of the HIV-infected individual's refusal to inform the third party**

The problem of confidentiality becomes more apparent, when – despite the need to protect the health and well being of the third party, the HIV-infected person categorically refuses to inform him/her about the actual danger. Refusal to inform about HIV-infection may affect the most vulnerable members of the community, i.e. the women/children, who live/are born in the families of HIV-infected people, and are then themselves infected. [12] So the purpose of the disclosure in these circumstance is as follows:

- to stop HIV spread (by informing the people who have contacts with the HIV-infected person and thus are being exposed to contamination); [13]
- to improve the quality of medical care and support offered the HIV-infected persons, or patients with AIDS (having received the necessary information, the third party is able to consider and perform necessary precautions, and also have the HIV testing – and then, if necessary, also the treatment of HIV infection at a relatively early stage).

UNAIDS document *Guidance on Encouraging Beneficial Disclosure, Ethical Partner Counseling & Appropriate Use of HIV Case-Reporting* draws ethical guidelines concerning the reporting to the third party. It sets the criteria on reporting without the approval/consent from the HIV-infected person as follows:

- the HIV-infected individual has been encouraged to report to the third party himself/herself;
- it was impossible to change the irresponsible behavior of the HIV-infected individual (e.g. stopping risky sexual contacts, injecting i.v. drugs with the same syringe, etc.);
- the HIV-infected individual did not report to the third party and refused categorically to allow the physician doing so<sup>[1]</sup>;
- a real risk of HIV transmission to the identifiable partner(s) exists;
- the healthcare worker (physician) has warned the HIV-infected individual on the possibility to inform the third party even without his/her approval;
- the third party is guaranteed to receive help after he/she had been informed (e.g. medical consulting, HIV testing, psychological help). [14]

Similar requirements might be found and reflected in a number of international documents concerning human rights and HIV/AIDS [15], and in the works of several authors. [16] [17] [18] UN Human Rights Commission in its resolution 1999/49 invites "to ensure the respect, protection and fulfilment of HIV-related human rights as contained in the Guidelines on HIV/AIDS and Human Rights" and requests "the States, in consultation with the relevant national professional bodies, to ensure that codes of professional conduct, responsibility and practice respect human rights and dignity in the context of HIV/AIDS." [19]

These requirements appeal to concrete, critical and conflicting situations. They aim to balance the protection of rights of both the infected individuals and of the other people. Moreover, some studies conclude that almost all

<sup>1</sup> This denial is usually provoked by the fear of being condemned and outcast or blamed for HIV contamination. It is very rare when the denial is based on the desire to contaminate the spouse or the partner.

patients would support disclosure in most situations, in which third parties are at risk. [20]

However, more problems appear, when we examine the physician's responsibility in relation to the involuntary disclosing of sensitive health information (i.e. the positive HIV status) of his/her patient to the third party. Some authors are simply sure that it is an absolute duty, and the refusal to inform the third party on HIV infection would undermine the respect of the highest human value – the third party's health or life, and would also ignore the physician's duty not to cause harm. On the other hand, there are some authors, insisting that the duty to report to the third party is not absolute. They argue that the refusal to inform the third party could be based on the fact that the physician has not any direct obligation to it (i.e. him/her), as he does not treat directly the third party and has learned about its existence only from his/her patient. [21] Well, it could be observed that one person, in the present situation the physician, should not have the absolute control upon the behavior of the other person. Nevertheless, while choosing his/her profession, a physician takes responsibility not only for the people that directly approach him/her. He/she is to serve the health interests of all people in his/her care. In the relationship physician – patient – community, especially in the case of a potential danger to the third party, there is no completely independent part. All individuals in the community have a general moral obligation to avoid harm or wrongdoing to others, if possible. [22] So, the physician's obligation to be loyal to his patient goes together with the moral responsibility to be honest and careful.

The duty to warn a foreseeable victim of a known danger has been in focus while examining the case *Tarasoff vs. Regents of the University of California*. [23] In the trial, a physician has been accused of not taking any action to prevent the damage to the third party. A psychotherapist, in the course of the treatment of a patient, learned the patient harbored violent feelings toward Ms. T. Tarasoff. Although Ms. Tarasoff was not identified by name by the patient, her family alleged in the complaint that her identity could have easily been determined because of the obsessiveness of the patient's feelings toward her, and the common knowledge of that fact on the university campus they both attended. The therapist failed to take any action toward warning Ms. Tarasoff or the campus police of the patient's violent threats expressed during his therapy. The patient ultimately stabbed Ms. Tarasoff to death on campus. Her estate brought an action against the therapist and the university, his employer, for breach of his duty to warn a foreseeable victim of the apparent danger posed by the threatening patient. [24] In spite of the fact that the case was dealing with the psychiatrist's negligence, which caused death of a young woman, the attention was drawn to the other potential cases of carelessness. The court called the special attention to the precedent, when in similar situations the physician sees clearly the danger to the health and life of the third party and still does not care to warn the endangered person(s). Examining the case, it was acknowledged that the record of the fact of death or serious health damage caused by contamination would be sufficient to charge such physician not morally only, but judicially, as well. [25] Tarasoff case became a classical precedent in the US litigation practice, and no wonder that Tarasoff's "duty to warn doctrine" had been more recently refined in the context of HIV/AIDS both in the case law and legislation. [26]

On the other hand, to inform the third party doesn't mean to inform everyone, who might be interested. If the HIV-infected individual behaves irresponsibly, the primary moral duty is to inform his/her spouse. [27] [28] A report to the spouse has a long history. It used to be

practiced long before HIV discovery. [29] Only afterwards it would be appropriate to inform the other member(s) of the family. The latter are being informed, if they are taking care of the sick person and exposed to contamination through the contact with the body liquids. It also means that the confidential information should not be passed to the people non-involved. Yet, it would be somewhat difficult to recognize as the 'third party' the employed health personnel taking care of the patient: they must always follow the safety requirement.

A lot of ethical discussions and disagreement arises in the case, when the third party is not a factual spouse, but a lover, a homosexual partner, another drug user with whom they have shared the syringe, and similar. [30] The above-mentioned individuals have no obligations before the patient, so they hardly have any 'right' to the confidential information. The disclosure to such "partners", or drug-mates may not be ethical. Moreover, it would actually make any confidentiality impossible, as the number of people 'allowed to know' might grow unlimited.

Another problems may pop up, when the third interested party is the physician himself, while the patient with HIV/AIDS is being treated for a different disease. At present, the workplace safety rules demand to treat every person in health care settings as potentially infected, and to observe preventive measures. While treating a HIV/AIDS patient, the first question would be, whether the disclosure of the HIV status would change the patient's course of treatment. If "yes", then the HIV-status should be disclosed. The physician has the right to know the truth not so much for his own sake, as for the sake of the patient, to be able to institute an appropriate treatment and prevention measures (e.g. to temporarily isolate the HIV/AIDS patient to prevent him/her from contracting other contagious diseases from other people in the ward, etc.) [31] Consequently, the patient should inform the health professional(s) about his/her HIV status for his/her own sake. It would be ideal, if the patient had that understanding, and could openly communicate with his physicians.

Another problem of confidence arises, when the infected individual is not a patient, but the physician himself/herself. The question is, whether the patient has the right to know about his physician's HIV infection? Mostly, the physician's infection does not affect the patient. In such case, there is no need to inform the patient. Besides, even the courts argue that naming such professionals would cause "public panic and alarm, perhaps on an unprecedented scale". [32] Yet, when the danger appears higher (e.g. punctured or cut wound), the HIV-infected physician should inform his/her patient and give him/her a chance to make up his/her mind: whether to continue his/her treatment with him/her, or to choose another health care professional. There is an alternative decision – the physician might change his job into less dangerous to his patient's discipline. [33] This may sometimes be very difficult. However, such step would protect not only the patient; it would give more guarantees to the physician himself/herself. There would also be no need to disclose his/her HIV status to everyone asking for his/her help.

### **Disclosure to the third party upon death of the infected**

A different ethical problem arises, when the information about HIV infection is being disclosed after the patient has died. It is even more complex, because the obligation to keep confidentiality seems to become less important and noticeable after the patient's death. Usually, confidentiality is associated with the patient's ability to control his/her private information. Upon his/her death,

this ability disappears. For this reason, some authors are inclined to talk about "a crime without a victim", insisting that it is impossible to harm physical, emotional or psychological interests of a person who has died. Sometimes they argue that the deceased cannot be interested, whether the physician keeps the confidentiality or not. [34]

However, the importance of confidentiality and the need to keep it do remain after the person's death. Moreover, keeping confidentiality after death is the expression of respect towards the deceased and it also protects his/her interests in relation to the people (especially his/her relatives) that outlive him/her. [35] In certain sense, keeping confidentiality after death expresses the wishes of the deceased. After all, if he/she did not reveal details of his/her private life while being alive, it is quite evident that he/she did not want any disclosure afterwards. If a dying person did not arrange otherwise, it means he had the wish to continue keeping this information confidential.

Keeping confidentiality after death has also a practical sense. Knowing that the information would remain confidential even after death, a sick person would trust his/her physician and would be more willing to cooperate. Confidentiality keeping also protects the interests of his/her relatives. HIV infection/AIDS, as no other disease, provokes certain social and psychological consequences (stigmatization, discrimination). Sometimes the society is inclined to associate AIDS with a certain group of people (e.g. homosexuals, drug addicts). So after death of the affected person his/her relatives are exposed to the danger of discrimination. For the rest of their lives they may remain 'in the eyes of other people' only as a 'sister of the drug addict', or the 'father of the prostitute', etc. Thus, upon the patient's death, the confidentiality keeping holds for the same reasons, which motivated it while the person was alive.

However, there is some difference in the level of confidentiality, when a person is alive and when he/she dies. This difference appears analogous to the 'principle of informed consent'. It assumes, that it is possible to obtain the informed consent to the HIV information disclosure only when a person is alive, while it is impossible to get it from the deceased one. Does it mean that we should keep more strictly the confidentiality principle when a person is dead, than when he was alive? A. H. Maixner suggests this solution: exactly the same confidentiality criteria should be retained as when the person is alive; the informed consent might be given either by the representatives of the deceased, the latter being appointed for this duty, or by the relatives or his close acquaintance and spokesman. [36] In this case the deceased is treated similarly to the living person, who is not able to make his/her own decisions - and passes this right to his/her representative. No doubt, this approach might sometimes be very beneficial, but it hardly allows avoidance of all problems. The relatives, who are to make the decision may be exactly those interested people, whom the information is intended to be disclosed to. In such situation, they cannot give the consent. On the other hand, when a decision is being made, it is often only supposed, how the patient himself/herself might have behaved in such circumstances. Deciding for another person, it is necessary to be aware of his/her values, his attitudes towards health, and the value of human life. J. Blustein suggests that it is possible to make a correct decision only knowing how the deceased would precisely behave in the situation. For example, when the person feeling responsible for the other's health and life has already imparted to someone the information about his/her disease: or the facts indicated that he/she intended to inform a certain person, but it was too late. [37] On the other hand, this knowledge might be very subjective

and the behaviour based on it might cause problems, if the relatives appeal to the court demanding moral damages for the disclosed information or asking to protect the honor and dignity of the deceased.

Yet, after examining (see above!) the issues of disclosure, when the HIV infected person refuses to inform the third party, it is evident that confidentiality, as a value, is not something absolute. In clinical practice, when the patient's rights come into conflict with the third party's 'anxiety to know', the decision should be made in favor of the patient, except for the cases of real danger to the health or life of the third party. Then the exception is made, known as "the duty to warn". For example, the Code of Medical Ethics, which regulates the HIV autopsy results' disclosure, acknowledges the facts when the physician informing the third party performs his ethical duty. However, confidentiality keeping should not be stricter when the person is dead, than when he/she is alive. [38]

When the HIV infected person dies, there are two reasons to inform the third party. First, when the information is presented directly to the person exposed to the danger of HIV infection because of his/her contacts with the deceased. Of course, it is allowed to inform the spouse or relatives, who have been taking care of the sick person and had contacts with the body liquids.

Second, when the information is disclosed with the purpose of testing, epidemiological prognosis, or education of the third party. As the third party had no personal contacts with the infected individual, there is no danger to his/her health or life. A person is interested in this kind of information not because of any personal involvement, but for the sake of science, research, or development of a prevention program(s). In this case, there is no question about the third party's vital interests and no reason to disclose the personality of the infected individual. The real name and surname of the person have no effect on the epidemiological, or other research. Usually, the general data about the person is required (age, sex, way of contamination, etc.). The confidentiality can be guaranteed using the codes, conventional names, abbreviations. For example, the simplest way to present the confidential information on HIV to a person or a group is an anonymous report disclosing the fact of HIV infection, the region/area of living and sex. This method usually does not deny the patient's rights and satisfies the community demand to be informed about the spread of HIV infection. [39]

Seeking to keep the deceased secret of HIV contamination, there is no need to indicate in the *post mortem* certificate the real reason - HIV; it is enough to name the diseases which are associated with AIDS. [40] As the *post mortem* certificate is an official and public document, such a record would prevent the family of the deceased from the disturbance and possible discrimination. For exactly the same reason it would not be appropriate to disclose the truth in the biographical studies, if the HIV infected person himself/herself did not make it public. In this case, there must be no place for simple curiosity, popularity or even benefits, which might appear as soon as the scandalous biography is published. [41] Making a decision both a physician and relatives should respect the deceased, mind their responsibility for the confidential information and keep loyalty to the patient.

### **Confidentiality issue while choosing the post-exposure prophylaxis**

With the introduction of new medicines a question is being posed to the researchers and clinicians, whether it

is possible to stave off, or at least to stop the progression of HIV infection, if immediately after the suspected (anticipated) contamination a person starts taking the anti-HIV drugs. The circumstances, under which the suspicion of HIV infection might arise can be very different: beginning with the accident at the workplace, in medical practice (a prick with a used syringe or the body liquids contact with the skin) and finishing with the sexual assault.

Sometimes it is known that the contact person is surely infected with HIV. In this case it is obligatory to keep confidentiality, especially if the infected individual was aggressive and has provoked or created such a situation? What are the limits of the physician's responsibility in this situation? How much is he morally obliged to report, knowing that it will possibly determine the beginning of post-exposure prophylactics?

The answers to these questions are dependent on the character of the post-exposure prophylactics. It has been proven that the HIV-drugs definitely stabilize the course of HIV infection, when it is confirmed (diagnosed). However, the effectiveness of the HIV-drugs for the post-exposure prophylaxis is not fully tested yet. Also, the consequences of such post-exposure drug use are not yet known in detail, or at all. In addition, HIV is a comparatively new infection, and it is difficult to discuss the long-term consequences. On the other hand, a lot is already known about the toxic effects of anti-HIV drugs, when used by the HIV infected individuals. [42] [43] [44] Then it becomes possible to predict their effects in a non-infected person. The post-exposure prophylactics and confidentiality problems become even more acute, as the decision to treat (or not to treat) has to be made very quickly, within 72 hours after the accident. It is considered that at latter stages the use of anti-HIV drugs has no effect. [45] This medical factor proves that the injured person must know if the other individual is a HIV carrier. Knowledge that the danger is real and the contact person is actually a HIV-carrier would help the victim – and the physician, to make the decision about the use of prophylactics. So, it is necessary to inform. Yet, it would be sufficient to state the fact of a potential HIV danger, without disclosing the identity of the HIV-infected patient. Under the threat of a complete identity disclosure, the HIV-infected person has to be warned, and his/her consent has to be obtained.

The situation would be different if the HIV infected individual demonstrated aggressive behavior. Some ethicists strongly doubt, if the attacking individual has the right to confidentiality. The assaulter violates the rights of the other person and this case has to be clearly separated from the accidents at workplace or the situations when a person puts himself in danger (e.g. using the same syringe). We might speak here about the assaulter's duty to reduce harm caused to the victim. The assaulter's confession that he is a HIV carrier or belongs to a risk group would be his moral duty. [46] However, very few criminals realize their moral duties... Then it should not be considered as a violation of confidentiality, if in such assaulter the HIV testing is performed even without of his consent according to the requirements of law. [47] In this case, it is clear from the beginning that the test results will be disclosed and presented to the victim.

## Conclusion

In his/her professional communication, the physician frequently learns the facts and details of the private lives both of the patient, his/her friends, family and relations. Then the right to confidentiality keeping should be respected not only for the patient, but for all those mentioned as well (keeping the professional secrecy). The

vital interests of the patient and of the other people involved in the situation of the HIV infection threat oblige the physician to make responsible decisions and to inform the 'third party' to prevent serious harm to his/her life or health. On making a decision about the disclosure and presentation of the confidential information to the third party, the physician must consider all *pros* and *cons*, and also learn to anticipate and thoroughly consider the consequences, which would follow the disclosure of the highly sensitive information (i.e. the HIV status of the patient).

Yet, confidentiality is not an absolute value, when there exists a real and serious danger to the health or even life of the third party (e.g. a spouse, a care-taking relative, a child, a victim). If the HIV infected individual categorically refuses to inform these people, the physician has the duty to do so. This requirement holds also when the infected individual has died, or when there is a real chance for the third party to start early the post-exposure prophylactics (especially, after the sexual assault).

## References

1. UN press release, AIDS epidemic still outpacing response. 2 June 2005, www.unaids.org Accessed 9 June 2005.
2. J. P. Tomes, "Healthcare Privacy and Confidentiality: The Complete Legal Guide," Chicago, Probus Publishers 1994:213-214.
3. Nr. IX-2361, 2004-07-13, Valstybes Žinios, 2004, Nr. 115-4284.
4. "Ethical and Religious Directives for Catholic Health Care Services (with Commentary)," New York 1994: 152.
5. R Gilbar, "Medical confidentiality within the family: the doctors duty reconsidered," International Journal of Law, Policy and the Family 18 (2004): 196-197.
6. R Bennett, H Draper, L Frith, "Ignorance is bliss? HIV and moral duties and legal duties to forewarn," Journal of Medical Ethics 26 (February 2000): 13.
7. M Beaupre, "Confidentiality, HIV/AIDS and prison health care services," Medical Law Review 2 (summer 1994): 149.
8. N Thomas, E Murray, KE Rogstad, "If confidentiality is lost will young people still access sexual health services?" International Journal of STD & AIDS 15 (May 2004): 420.
9. Ch Verity, A Nicoll, D Manning, "Consent, confidentiality, and the threat to public health surveillance," British Medical Journal 324,7347 (18 May 2002):1211.
10. UNAIDS, "Guidance on Encouraging Beneficial Disclosure, Ethical Partner Counseling & Appropriate Use of HIV Case-Reporting," Geneva 2000: 20.
11. See art. 135 of Lithuanian Penal Code, according to which a person could be imputed for an intentional transmission of serious or fatal disease.
12. UNAIDS, "2004 report on the global AIDS epidemic. Executive summary," Geneva 2004: 3.
13. G Landau, AS York, "Keeping and disclosing a secret among people with HIV in Israel," Health & Social Work 29 (May 2004): 116-26.
14. UNAIDS, "Guidance on Encouraging Beneficial Disclosure, Ethical Partner Counseling & Appropriate Use of HIV Case-Reporting," Geneva 2000: 22.
15. United Nations, "HIV/AIDS and Human Rights. International Guidelines," New York 1998: 13.
16. R Gilbar, "Medical confidentiality within the family: the doctors duty reconsidered," International Journal of Law, Policy and the Family 18 (2004): 17.
17. R Doughty, "The Confidentiality of HIV related information: responding to the resurgence of Aggressive public health interventions in the AIDS epidemic," California Law Review 82 (1994): 18.
18. Creighton working group on HIV confidentiality, "Confidentiality and its limits. Ethical guidelines for maternal/pediatric HIVinfection," Creighton Law Review 25 (1992).
19. C.H.R. res., "The Protection of Human Rights in the Context of Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS), U.N. Doc. E/CN.4/RES/1999/49 (1999).
20. C Jones, "The utilitarian argument for medical confidentiality: a pilot study of patients' view," Journal of Medical Ethics, (December 2003): 348-352.
21. J McComb, "Tarasoff v. Regents of University of California, SupremeCourt of California 1974," Source book in bioethics. A documentary history (ed AR Jonsn, RM Veatch, LR Walters) Washington, Georgetown university press 1998: 500.
22. R Bennett, H Draper, L Frith, "Ignorance is bliss? HIV and moral duties and legal duties to forewarn," Journal of Medical Ethics 26 (February 2000): 10.
23. 551 P.2d 334 (Cal. 1976)
24. KE Labowitz, "Beyond Tarasoff: AIDS and the Obligation to Breach Confidentiality," Saint Louis University Public Law Review 9 (1990):495-517.
25. J McComb, "Tarasoff v. Regents of University of California, SupremeCourt of California 1974," Source book in bioethics. A documentary history (ed AR Jonsn, RM Veatch, LR Walters) Washington, Georgetown university press 1998: 496.
26. Ch E Stenger, "Taking Tarasoff Where No One Has Gone Before: Looking at Duty to Warn under the AIDS Crisis," St. Louis University Public Law Review 15. (1995-1996): 471-504.
27. JD Rivas, DP Sulmasy, "Sexually transmitted disease: A private matter?" *American Family Physician* 66/7 (1 October 2002):1352.
28. T Myers, C Worthington, DJ Haubrich, K Ryder, L Cal, "HIV testing and counseling: Test providers' experiences of best practices," *AIDS Education and Prevention* 15 (August 2003):4.
29. PL Allen, "The vages of sin. Sex and disease, past and present," Chicago, The University of Chicago Press 2000: 42.50-51.
30. RC Turkington, "Confidentiality policy for HIV related information: an analytical framework for sorting out hard and easy cases," *Villanova Law Review*. 34 (1989):902-905.
31. Al Laiskonis, "Zmogaus imunodeficitu viruso infekcijos diagnostika, gydymas ir profilaktika," Kaunas, Spindulys 2000: 84.
32. C Dyer, "Health authority employing HIV positive dentist was anonymous," *British Medical Journal* 324 (9 March 2002):5640.
33. "AMA Ethical Opinions on HIV/AIDS Issue," www.ama-assn.org/special/hiv/policy/amapol.htm Accessed 10. 12. 2002.
34. D Nelkin, L Andrews, "Do the Dead Have Interests? Policy issues for the research after life," *American Journal of Medical Law* 24/2-3 (1998): 265-267.
35. AH Maixner, K Morin, "Confidentiality of health information postmortem," *Archives of Pathology and Laboratory Medicine* 125/9 (2001):1990.
36. *ibid*, 1991.
37. J Blustein, "Choosing for others as continuing a life story. The problem of personal identity revisited," *Journal of Law and Medical Ethics* 27 (1999).
38. "Code of medical ethics: current opinions and annotations," Chicago 2000:5.057.
39. UNAIDS, "Guidance on Encouraging Beneficial Disclosure, Ethical Partner Counseling & Appropriate Use of HIV Case-Reporting," Geneva 2000:24-26.
40. "Confidentiality of HIV Status on Autopsy Reports," *Archives of Pathological Laboratory Medicine* 116 (1992): 1120-1123.
41. ED Pel-Igri-no, "Secrets of the couch and the grave: the Anne Sexton case," *On moral Medicine. Theological Perspectives in Medical Ethics* (ed. StE Lammers, A Verhey) Grand Rapids, William B. Eerdmans Publishing Company 1998: 875.
42. C Maisonneuve, A Igoudjil et al., "Effects of zidovudine, stavudine and beta-aminoisobutyric acid on lipid homeostasis in mice: possible role in human fat wasting," *Antiviral Therapy* 9/5 (October 2004):

801-10. **43.** A Bozzi, F Brisdelli et al., "Effects of AZT on cellular iron homeostasis," *Biometals* 17/4 (August 2004): 443-50. **44.** IT Mak, MG Goldfarb et al., "Cardiac pathologic effects of azidothymidine (AZT) in Mg-deficient mice," *Cardiovascular Toxicology* 4/2 (Spring 2004):169-77. **45.** F Baylis, D Ginn, "Expanding access to PEP: Ethical and legal issues," *AIDS and Public Policy Journal* 13/3 (1998): 153. **46.** L Gostin, "HIV testing, counselling and prophylaxis after sexual assault," *Journal of American Medical Association* 271 (1996): 1439. **47.** F Baylis, D Ginn, "Expanding access to PEP: Ethical and legal issues," *AIDS and Public Policy Journal* 13/3 (1998): 154-155.

Širinskiene, A., Juškevičius, J., Narbekovas, A.: **Confidentiality and Duty to Warn the Third Parties in HIV/AIDS Context.** [Mlčanlivosť a povinnosť varovať tretiu stranu v kontexte HIV/AIDS.] *Med. Eth. Bioet.*, Vol. 12, 2005, No. 1, p. 2 – 7.

### Abstract

Generally, physicians have a legal and ethical obligation of keeping confidentiality regarding their communications with patients. So, the most complicated ethical and legal questions arise when the HIV-infected person deliberately avoids to report to the interested individuals about the possibility of HIV transmission. The decisive factor, which emphasizes the need of such a discussion about confidentiality in HIV cases, is the character of the HIV: HIV is incurable, causes the danger of fatal outcome, discrimination etc. The aim of the paper is to explore the limits of confidentiality, as there is a duty to warn the third party about the danger of HIV transmission in that case on the part of the physician, even when the HIV-infected individual categorically refuses doing so. The paper analyses some specificities of confidentiality keeping in HIV pandemic, the responsibilities of a physician concerning the third party and his duty to warn him/her. Special attention is paid to those cases, when the fact of HIV infection has to be reported upon the patient's death or when the disclosure of the confidential information is connected with the possibility to start the post-exposure prophylactics. The paper presumes that confidentiality is not an absolute value, when there exists a real danger to the third party (e.g. a spouse, a care-taking relative, a victim).

**Keywords:** HIV, AIDS, confidentiality, duty to warn, third party, disclosure.

### Abstrakt

Lekár má v zásade vždy etické i zo zákona vyplývajúcu povinnosť dodržiavať mlčanlivosť o skutočnostiach, o ktorých sa dozvie v komunikácii so svojimi pacientmi. Najzložitejšie etické a právne situácie vznikajú, keď osoba infikovaná HIV odmieta informovať tretiu stranu o možnosti prenosu infekcie, ba dokonca nesúhlasí, aby túto informáciu ohrozeným osobám poskytol lekár. Potreba diskusia o probléme mlčanlivosti v kontexte HIV je daná zvláštnosťami samotnej infekcie HIV: nateraz ide o nevyliciteľné ochorenie s nebezpečenstvom smrti a diskriminácie pacienta zo strany okolia. Cieľom práce je preskúmať ohrozenia povinnosti lekára zachovávať mlčanlivosť o záležitostiach dôverného charakteru v kontraste s povinnosťou informovať o nebezpečenstve infekcie HIV tretiu stranu, a to aj v prípade, že to HIV-infikovaná osoba odmieta. Práca analyzuje špecifiká uplatnenia princípu profesionálnej mlčanlivosti v čase pandémie HIV infekcie a povinnosti lekára voči tretej strane. Zvlášť si všima situáciu, kedy by sa informácia o HIV infekcii oznamovala po smrti pacienta, alebo keď sa rozhoduje o aplikácii post-expozičnej profylaxie. Práca poukazuje na to, že zachovávanie mlčanlivosti nie je absolútnou hodnotou v situácii, keď existuje reálne nebezpečenstvo HIV infekcie pre tretiu stránku (napr. manžel/ka, príbuzná/ý v spoločnej domácnosti).

**Kľúčové slová:** HIV, AIDS, mlčanlivosť, povinnosť varovať, tretia stránka, odtajnenie.

## KRÁTKE PRÍSPEVKY

### BRIEF COMMUNICATIONS

#### TRAINING AND DISSEMINATION OF GOOD PRACTICES FOR RESEARCH ETHICS COMMITTEES Standardization, Harmonization and Collaboration [1]

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Research Ethics Committees (RECs) as collective bodies, and thus some or all of their members should possess a certain, rather broad body of *necessary knowledge* and skills to be able to deal appropriately with their tasks and responsibilities. First of all, to review, give their opinion on, and to monitor the conduct of biomedical research projects involving human beings/subjects, including clinical trials (CTs) of medicinal drugs.

The spectrum of necessary knowledge and skills of RECs' (and their members) could be seen by some as either a more 'substantial' (e.g. general or particular scientific insight, expertise in ethics, law) or more 'procedural' in their nature (e.g. standard operating procedures, 'bureaucratic' aspects, group dynamics). Good practices (GPs) could then be referred to as broadly accepted/international *scientific, ethical and procedural standards* aimed to ensure, also to the general public, that all biomedical research involving human subjects is ethically acceptable and data generated by it are credible (see e.g. the GCP definition).

One of the means that are available to RECs, when aiming to meet the increasing expectations of sponsors, researchers, research subjects, 'the society' (and expectations of RECs' members themselves), is to learn and *implement consistently* GPs in their work. Though this would not guarantee there are no gaps in their knowledge in the areas of science, law or ethics, it would still help at least to satisfy RECs and their 'users' (other parties involved) that the procedures used are transparent and fair. And this is not a little issue at all. In the end of the day, hopefully, implementation and observance by RECs of GPs could provide more room for 'the science' and 'the ethics' in their research review and monitoring work.

Demands upon RECs and their members in the above mentioned respects are increasing. This is at the same time connected with an increasing complexity of the research projects and CTs protocols themselves. Thus the logical consequence: an increase in (recently perhaps more clearly perceived, profiled, though still much underserved or unmet) needs and demands for *introductory and continuous education* (aimed at increasing 'the knowledge') and *training* (increasing 'the skills') of RECs (as bodies, and of their members).

It is expected by many that the desired and fostered increase of performance within the European Research Area (ERA) (and possibly beyond) shall stem from and be enhanced by a more diverse, flexible and, at the same time, by a more tight and open regional and *international collaboration* in research. This obviously puts some emphasis also on *harmonization* (and standardization) in the area of GPs, including the ones used/implemented by RECs. Altogether, this logically increases further the needs and

demands for education and training of RECs and their members, and also – for definition (standardization) and harmonization of GPs concerning these very educational and training activities offered to them.

By defining (standard setting) and harmonization of GPs, a considerable part of the *content*, and also the *goals* of RECs' education and training are defined. Then, the best *educational and training means* (didactical methods, techniques) to meet these goals are to be chosen (then tried, evaluated, and, if effective – recommended).

Fortunately enough, though we explore here so far a rather (or seemingly) under-developed field, one has not 'to invent the wheel' in the area of RECs training and education. On the contrary: much has already been developed, tried, evaluated and found useful/effective – or discarded as mistaken or 'not working', in several places in Europe (on local, regional, or even international basis), or elsewhere. There seems to be a very opportune time just now to collect, share, discuss - evaluate, and (later on) – to possibly build further upon the *already existing experience*, which, in the course of time, could be enriched and developed in a concerted international (or regional) action. Some of the '*old member states*' (OMs) could surely provide interesting models in this respect to be learned from and, possibly, more widely adapted or followed.

In most of the '*new member states*' (NMs to EU) (and in the '*candidate countries*' (CCs)) the education and training activities for RECs have faced considerable problems (2). Those stemmed from the aftermath of the political, economic and cultural developments in these countries before and after the World War II, and from the burdens and hurdles of the necessary transformation processes started after breaking down of the totalitarian regimes in the relatively recent past. Some of these countries, however, despite having to build many of their structures 'from the scratch', were doing surprisingly well. Struggling with very limited (or almost 'non-existent') *resources problem*, the situation was many times perceived and tackled by interested individuals or groups from merely self-conscious and enthusiastic motivations. Later on, however, a lot of help was offered, and also given by various international organizations and bodies to interested professionals or groups, and even to governmental and non-governmental structures. Initiatives of the Council of Europe (e.g. the work of CDBI, COMETH, Program DEBRA, etc.), WHO, EF GCP, WMA, and, later on (and especially during the latest 3-4 years) also of the European Commission (DG Research), should gratefully be remembered and honoured. In the area of CTs and GCP implementation, the activities of pharmaceutical industry were also very helpful. The development (and later on 'institutionalisation') of 'bioethics' in NMs (and some CCs) was much helped and supported by the work of various European, or US bioethics centres or networks. Among those e.g. The Hastings Center (US), EACME, Linacre Centre (UK), Lindeboom Institute (NL), Albert Schweitzer Fdn., OSF (US) and CEU (US + HU), and possibly many others should be mentioned.

In Slovakia, education activities in 'bioethics' started in early 90-ies (3). The national plan for 're-vitalisation' and development of the system of ethics committees (ECs) in the Slovak Republic (in place since 2002, elaborated and fostered by the Central Ethics Committee at the Ministry of Health), as well as the new, comprehensive 'health care reform' legislation recently passed (in force since January 1, 2005) pay due attention to education and training of (R)ECs members ('introductory' and continuous), which is to be specifically required by pending ministerial regulation.

On the other hand, even in the regions/*countries with a well-developed system* of education/training for

RECs' members, several open questions (and new problems) still exist. Among those, in addition to the whats and whys mentioned above, one could list the following queries: How much regulation versus free initiative of RECs should be involved in the national (European) system(s)? How much of 'procedural/formal' versus 'substantial' (scientific, ethical) issues should be included into an 'optimised' educational or training program? How to educate or train the 'lay members'? How to deal with ethics pluralism in education and training? Which ethics to teach? Which models of ethical reasoning to offer or prefer? Should the mere 'pragmatism' be sought and taught, or should we expect and strive for 'something more' (or better) in the research ethics review by RECs in Europe? What interpersonal and group dynamics issues should be dealt with in education/training – and how to teach those to RECs members? How much 'law' and how much 'ethics' should a REC member master? And how much 'science'? How can the RECs members be motivated? Etc. Some, or almost all of these questions, however, are common, or similar (though the responses may more or less differ) for RECs working in all countries of Europe.

In conclusion, I believe an international collaboration and exchange of know-how and practical experience among RECs and their members in Europe and beyond should be encouraged and helped in the near future. Besides the 'grass root' initiatives of RECs themselves, the concrete support and help from relevant international organisation and agencies would be necessary, as well as the allocation of appropriate financial and manpower resources. A considerable part of these efforts should be focused on setting up and promoting effective RECs education and training strategies.

## References

1. The previous version of this paper was delivered as an introductory speech to the Workshop 4 of the International Conference "Research Ethics Committees in Europe: Facing the Future Together", 27. - 28. 1. 2005, Brussels (Belgium). 2. See e.g. Glasa, J. (Ed.): Ethics Committees in Central and Eastern Europe. Council of Europe, Charis - IMEB Fdn., Bratislava, 2000, 266 pp; Glasa, J.: Establishment and work of ethics committees in Central and Eastern European countries. *Med. Eth. Bioet.*, 9, 2002, No. 1-2, 9 - 12; Glasa, J.: The challenges to the new EU member states in sharing ethical review systems. In: Forum Discussion "The Implementation of the Clinical Trials Directive and the Evolving Role of European Ethics Committees." EFGCP, Brussels, Oct. 7, 2003, 20 pp; Glasa, J.: Challenges for ethics committees in the new EU member states. The approach in the Slovak Republic. In: An EMEA/EFGCP Workshop on Ethics in Clinical Development - From Legislation to Implementation. EMEA, London (UK), Dec. 11 - 12, 2003, 11 pp. 3. See e.g. Glasa, J., Bielik, J., Dačok, J., Glasová, M., Porubský, J.: Ethics committees in the Slovak Republic. In: Glasa, J. (Ed.): Ethics Committees..., 2000, 229 - 238; Glasa, J.: Bioethics and the society in transition: The birth and development of bioethics in posttotalitarian Slovakia. *Kennedy Inst. Ethics J.*, 10, 2000, No. 2, 165 - 170; Glasa, J., Bielik, J., Dačok, J., Glasová, M., Porubský, J.: Ethics committees (HECs/IRBs) and health care reform in the Slovak Republic: 1990 - 2000. *HEC Forum*, 12, 2000, No. 4, 358 - 366; Glasa, J.: EUR 21255 - National Regulations on Ethics and Research in Slovak Republic. Luxembourg, Office for Official Publications of the European Communities, 2004, 30 pp.

## ACTIVITIES OF THE CENTRAL ETHICS COMMITTEE OF THE MINISTRY OF HEALTH OF THE SLOVAK REPUBLIC June 2002 - May 2005

### Brief Historical Perspective (1990-2002)

**Central Ethics Committee (CEC)** of the Ministry of Health (MH) was originally established by the Slovak minister of health in 1990. It was given a mission was to advise the minister, and also other ministries and top

country institutions on ethical questions in connection with health care and with biomedical research. It was only few months after major political changes had taken place in Slovakia (sc. Velvet Revolution of November 1989).

From the very beginning, CEC took upon itself the role of a „national bioethics committee“. CEC was very active in helping to establish the discipline of bioethics in Slovakia. This included concrete help and support in founding 'bioethics institutions', such as ethics committees in major hospitals and research institutions, and of the leading bioethics teaching and research centre - Institute of Medical Ethics and Bioethics (IMEB) in Bratislava (1, 2).

An important part of CEC work was devoted to the international collaboration and networking, establishing working contacts with leading international institutions active in the field (e.g. CDBI, UNESCO, EGE,...), with other national bioethics bodies, and - in collaboration with IMEB, with many medical ethics / bioethics centres in Europe, and beyond. CEC and IMEB were co-organisers of several international conferences/congresses and other meetings in Bratislava, in particular those in collaboration with the DEBRA Program of the Council of Europe (CoE), and also with the DG Research (Department 'Science and Society') of the European Commission (EuC).

During the 15 years of its existence, CEC was several times thoroughly 'reconstructed' concerning its membership, and also its statutes. Not all periods were marked by the same intensity of activities; there were even some of quite passive ones. In 2002, the present CEC was appointed with a brand new membership and presidium. It also got an administrative secretary, and its own office with the necessary equipment located in at MH. The new CEC Statutes were for the first time published in the official journal of MH (3). MH shall issue the amended Statutes this year (2005), and also some personal changes to achieve the necessary CEC membership renewal are expected.

## Priorities and Activities 2002 - May 2005

Since its appointment in June 2002, CEC has been working in several priority fields. They can briefly be summarised as follows:

1. Advising the minister and various departments of MH on ethical issues connected with health care, and with biomedical research. An intensive collaboration and exchange has been established, especially with the department of health care, department of control, and the one of foreign affairs. During the period indicated, many informal consultations, as well as brief opinions to concrete cases or problems were produced in writing by the CEC presidium.

2. Providing comments on the new legislation prepared by MH. This was one of the major tasks of CEC and it occupied most of its working time and capacity. In September 2004, a major bulk of brand new health care legislation was passed by the Slovak parliament (Slovak National Council). Altogether 7 new bills - approximately 2500 pages. They were aimed to found a new legal basis for health care in Slovakia as a result of a profound and ambitious reform of the national health care system. Besides other crucial issues, also the new legislation on biomedical research and on ethics committees was elaborated and included into the new health care act (law No. 576/2004 Coll. on health care). CEC has also been provided for in this law (before it was established by ministerial decree only), as well as for the system of ethics committees (ECs) in Slovakia (regional, local - both reviewing research projects, including drug clinical trials protocols, but they also could advice on the issues of 'clinical bioethics').

3. Revitalising and development of the system of ECs in Slovakia. CEC elaborated and approved a special program to this effect already in June 2002. The program has been published in major health professional journals in Slovakia. Since 2002 annual meetings of ECs have been reintroduced. CEC also directly contributed to drafting of the parts of new health law (law 576/2004 Coll., cited above) devoted to the problems of ethics committees, biomedical research, medical genetics, transplantation of organs, tissues and cells, informed consent, etc. At present CEC is working on a draft ministerial regulation on ethics committees. It should cover both ECs for research (regional and local), and the 'clinical ethics' ECs.

4. Advising and providing guidance on case-by-case basis for ECs in Slovakia. CEC became a point of reference for members and chairs of ECs - providing informal (including telephone or e-mail) consultations and advice, and also brief written responses to questions posed to it by ECs. Reserved for exceptional cases only, CEC also reviewed several research protocols (e.g. a gene therapy trial proposal, some international research projects co-sponsored by WHO, etc.).

5. International collaboration and participation. CEC through its chairperson took an active role in several European bodies concerned with bioethics and related areas (e.g. membership in CDBI of CoE and its Bureau; membership in the Bureau of COMETH; participation in various activities of the Department 'Science and Society' of DG Research of EuC, including NECs Forum and various international conferences; collaboration with European Forum of GCP, etc.). The chairperson of CEC authored a EuC sponsored brochure on legislation in the area of biomedical research in the Slovak Republic (4).

6. Co-sponsoring international conferences and meetings in bioethics that took place in Bratislava. These activities were developing further already existing 'tradition' of international bioethics meetings, congresses and courses held in Bratislava since 1991. The most important of those in 2002 - 2005 period were the following:

- Ethics of Science and Research (together with Department Science and Society, DG Research, EuC), April 2002 (book of proceedings in press - EuC),
- Ethics of Human Genetics: Challenges of the (Post) Genomic Era (together with Debra Program of CoE and supported by EuC), October 2002 (book of proceedings (5)),
- Ethical Support in Clinical Practice: Present State and Perspectives in Europe (Debra Program of CoE), November 2004 (book of proceedings (6)).

**Assoc. Prof. Jozef Glasa, M.D., PhD.**  
Chairman

## References

1. Glasa, J.: Bioethics and challenges of a society in transition: The birth and development of bioethics on post - totalitarian Slovakia. *Kennedy Institute of Ethics Journal*, Vol. 10, 2000, No. 2, p. 165 - 170.
2. Glasa, J., Bielik, J., Dačok, J., Glasová, M., Porubský, J.: Ethics committees (HECs/IRBs) and health care reform in the Slovak Republic: 1990 - 2000. *HEC Forum*, Vol. 12, 2000, No. 4, p. 358 - 366.
3. *Vestník MZ SR*, Vol. 51, Part 20 - 21, July 21, 2003, p. 146 - 150.
4. Glasa, J.: National Regulations on Ethics and Research in Slovak Republic. Office of the Official Publications of European Communities, Luxembourg, 2003, 2 x 30 pp (English and Slovak part).
5. Glasa, J. (Ed.): *Ethics of Human Genetics: Challenges of the (Post)Genomic Era*. Council of Europe - Charis - IMEB Fdn., Bratislava, 2002, 228 pp.
6. Glasa, J. (Ed.): *Ethics Support in Clinical Practice: Status Quo and Perspectives in Europe*. *Medical Ethics & Bioethics*, Vol. 11, 2004, Supplement 1, 23 pp.

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## DOCUMENTS

## INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA [1]

United Nations Educational, Scientific and Cultural Organization  
Organisation des Nations Unies pour l'éducation, la science et la culture

*The General Conference,*

*Recalling* the Universal Declaration of Human Rights of 10 December 1948, the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Economic and Social Council Resolutions 2001/39 on Genetic Privacy and Non-Discrimination of 26 July 2001 and 2003/232 on Genetic Privacy and Non-Discrimination of 22 July 2003, the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001 and the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

*Recalling more particularly* the Universal Declaration on the Human Genome and Human Rights which it adopted, unanimously and by acclamation, on 11 November 1997 and which was endorsed by the United Nations General Assembly on 9 December 1998 and the Guidelines for the implementation of the Universal Declaration on the Human Genome and Human Rights which it endorsed on 16 November 1999 by 30 C/Resolution 23,

*Welcoming* the broad public interest worldwide in the Universal Declaration on the Human Genome and Human Rights, the firm support it has received from the international community and its impact in Member States drawing upon it for their legislation, regulations, norms and standards, and ethical codes of conduct and guidelines,

*Bearing in mind* the international and regional instruments, national laws, regulations and ethical texts relating to the protection of human rights and fundamental freedoms and to respect for human dignity as regards the collection, processing, use and storage of scientific data, as well as of medical data and personal data,

*Recognizing* that genetic information is part of the overall spectrum of medical data and that the information content of any medical data, including genetic data and proteomic data, is highly contextual and dependent on the particular circumstances,

*Also recognizing* that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some

instances on the whole group; they may contain information the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups,

*Emphasizing* that all medical data, including genetic data and proteomic data, regardless of their apparent information content, should be treated with the same high standards of confidentiality,

*Noting* the increasing importance of human genetic data for economic and commercial purposes,

*Having regard* to the special needs and vulnerabilities of developing countries and the need to reinforce international cooperation in the field of human genetics,

*Considering* that the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications and for the use of such data for non-medical purposes,

*Also considering* that the growing amount of personal data collected makes genuine irretrievability increasingly difficult,

*Aware* that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms and respect for human dignity,

*Noting* that the interests and welfare of the individual should have priority over the rights and interests of society and research,

*Reaffirming* the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research, and privacy and security of the person, which must underlie the collection, processing, use and storage of human genetic data,

*Proclaims* the principles that follow and adopts the present Declaration.

**A. GENERAL PROVISIONS****Article 1: Aims and scope**

(a) The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived, referred to hereinafter as "biological samples", in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles, which should guide States in the formulation of their legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for the institutions and individuals concerned.

(b) Any collection, processing, use and storage of human genetic data, human proteomic data and biological samples shall be consistent with the international law of human rights.

(c) The provisions of this Declaration apply to the collection, processing, use and storage of human genetic data, human proteomic data and biological samples, except in the investigation, detection and prosecution of criminal offences and in parentage testing that are subject to domestic law that is consistent with the international law of human rights.

**Article 2: Use of terms**

For the purposes of this Declaration, the terms used have the following meanings:

(i) Human genetic data: Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis.

(ii) Human proteomic data: Information pertaining to an individual's proteins including their expression, modification and interaction.

(iii) Consent: Any freely given specific, informed and express agreement of an individual to his or her genetic data being collected, processed, used and stored.

(iv) Biological samples: Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual.

(v) Population-based genetic study: A study which aims at understanding the nature and extent of genetic variation among a population or individuals within a group or between individuals across different groups.

(vi) Behavioural genetic study: A study that aims at establishing possible connections between genetic characteristics and behaviour.

(vii) Invasive procedure: Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe.

(viii) Non-invasive procedure: Biological sampling using a method which does not involve intrusion into the human body, such as oral smears.

(ix) Data linked to an identifiable person: Data that contain information, such as name, birth date and address, by which the person from whom the data were derived can be identified.

(x) Data unlinked to an identifiable person: Data that are not linked to an identifiable person, through the replacement of, or separation from, all identifying information about that person by use of a code.

(xi) Data irretrievably unlinked to an identifiable person: Data that cannot be linked to an identifiable person, through destruction of the link to any identifying information about the person who provided the sample.

(xii) Genetic testing: A procedure to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change.

(xiii) Genetic screening: Large-scale systematic genetic testing offered in a programme to a population or subsection thereof intended to detect genetic characteristics in asymptomatic people.

(xiv) Genetic counselling: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences. It takes place before and after genetic testing and screening.

(xv) Cross-matching: Matching of information about an individual or a group contained in various data files set up for different purposes.

### **Article 3: Person's identity**

Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.

### **Article 4: Special status**

(a) Human genetic data have a special status because:

(i) they can be predictive of genetic predispositions concerning individuals;

(ii) they may have a significant impact on the family, including offspring, extending over generations, and in

some instances on the whole group to which the person concerned belongs;

(iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;

(iv) they may have cultural significance for persons or groups.

(b) Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established.

### **Article 5: Purposes**

Human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of:

(i) diagnosis and health care, including screening and predictive testing;

(ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as "medical and scientific research";

(iii) forensic medicine and civil, criminal and other legal proceedings, taking into account the provisions of Article 1(c);

(iv) or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and the international law of human rights.

### **Article 6: Procedures**

(a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

(c) When the collection, processing, use and storage of human genetic data, human proteomic data or biological samples are carried out in two or more States, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.

(d) It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are

used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a penalty for the person concerned.

#### **Article 7: Non-discrimination and non-stigmatization**

(a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.

(b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.

### **B. COLLECTION**

#### **Article 8: Consent**

(a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights.

(b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.

(c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

(d) In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when it has important implications for the health of the person and has regard to his or her best interest.

#### **Article 9: Withdrawal of consent**

(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.

(b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.

(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.

#### **Article 10: The right to decide whether or not to be informed about research results**

When human genetic data, human proteomic data or

biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.

#### **Article 11: Genetic counselling**

It is ethically imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate manner. Genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned.

#### **Article 12: Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings**

When human genetic data or human proteomic data are collected for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, the collection of biological samples, in vivo or post-mortem, should be made only in accordance with domestic law consistent with the international law of human rights.

### **C. PROCESSING**

#### **Article 13: Access**

No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security.

#### **Article 14: Privacy and Confidentiality**

(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, a family or, where appropriate, a group, in accordance with domestic law consistent with the international law of human rights.

(b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.

(c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.

(d) Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes can remain linked to an identifiable

person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law.

(e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.

#### **Article 15: Accuracy, reliability, quality and security**

The persons and entities responsible for the processing of human genetic data, human proteomic data and biological samples should take the necessary measures to ensure the accuracy, reliability, quality and security of these data and the processing of biological samples. They should exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, human proteomic data or biological samples, in view of their ethical, legal and social implications.

### **D. USE**

#### **Article 16: Change of purpose**

(a) Human genetic data, human proteomic data and the biological samples collected for one of the purposes set out in Article 5 should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or unless the proposed use, decided by domestic law, corresponds to an important public interest reason and is consistent with the international law of human rights. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) should apply *mutatis mutandis*.

(b) When prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an identifiable person, human genetic data may be used in accordance with domestic law or following the consultation procedures set out in Article 6(b).

#### **Article 17: Stored biological samples**

(a) Stored biological samples collected for purposes other than set out in Article 5 may be used to produce human genetic data or human proteomic data with the prior, free, informed and express consent of the person concerned. However, domestic law may provide that if such data have significance for medical and scientific research purposes e.g. epidemiological studies, or public health purposes, they may be used for those purposes, following the consultation procedures set out in Article 6(b).

(b) The provisions of Article 12 should apply *mutatis mutandis* to stored biological samples used to produce human genetic data for forensic medicine.

#### **Article 18: Circulation and international cooperation**

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to this data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning human genetic data and human proteomic data and, in that

regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

(c) Researchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and, subject to the provisions of Article 14, should encourage the free circulation of human genetic data and human proteomic data in order to foster the sharing of scientific knowledge, provided that the principles set out in this Declaration are observed by the parties concerned. To this end, they should also endeavour to publish in due course the results of their research.

#### **Article 19: Sharing of benefits**

(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:

(i) special assistance to the persons and groups that have taken part in the research;

(ii) access to medical care;

(iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;

(iv) support for health services;

(v) capacity-building facilities for research purposes;

(vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;

(vii) any other form consistent with the principles set out in this Declaration.

(b) Limitations in this respect could be provided by domestic law and international agreements.

### **E. STORAGE**

#### **Article 20: Monitoring and management framework**

States may consider establishing a framework for the monitoring and management of human genetic data, human proteomic data and biological samples based on the principles of independence, multidisciplinary, pluralism and transparency as well as the principles set out in this Declaration. This framework could also deal with the nature and purposes of the storage of these data.

#### **Article 21: Destruction**

(a) The provisions of Article 9 apply *mutatis mutandis* in the case of stored human genetic data, human proteomic data and biological samples.

(b) Human genetic data, human proteomic data and the biological samples collected from a suspect in the course of a criminal investigation should be destroyed when they are no longer necessary, unless otherwise provided for by domestic law consistent with the international law of human rights.

(c) Human genetic data, human proteomic data and biological samples should be available for forensic purposes and civil proceedings only for as long as they are necessary for those proceedings, unless otherwise provided for by domestic law consistent with the international law of human rights.

#### **Article 22: Cross-matching**

Consent should be essential for the cross-matching of human genetic data, human proteomic data or biological samples stored for diagnostic and health care purposes and for medical and other scientific research purposes,

unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights.

## F. PROMOTION AND IMPLEMENTATION

### Article 23: Implementation

(a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the sphere of education, training and public information.

(b) In the framework of international cooperation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge concerning human genetic data and of the related know-how.

### Article 24: Ethics education, training and information

In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

### Article 25: Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, inter alia, on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration.

They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.

### Article 26: Follow-up action by UNESCO

UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of the life sciences and their applications through technologies, based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.

### Article 27: Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.

## IMPERATIVE OF "SIGNS OF CLINICAL DEATH" FOR ORGAN TRANSPLANTS Message to the Pontifical Academy of Sciences [1]

Distinguished Ladies and Gentlemen,

1. To all of you I offer cordial greetings and I would like to express my appreciation for the Pontifical Academy of Sciences, ever devoted to its traditional task of study and reflection on the delicate scientific questions facing contemporary society.

The Pontifical Academy has chosen to dedicate this session of the Study Group – as on two earlier occasions during the 1980s – to a theme of particular complexity and importance: that of the "signs of death," in the context of the practice of transplanting organs from deceased persons.

2. You know that the Church's Magisterium has maintained from the outset a constant and informed interest in the development of the surgical practice of organ transplant, intended to save human lives from imminent death and to allow the sick to continue living for a further period of years.

Since the time of my venerable predecessor, Pius XII, during whose pontificate the surgical practice of organ transplant began, the Church's Magisterium has continually made contributions in this field.

On the one hand, the Church has encouraged the free donation of organs and on the other hand she has underlined the ethical conditions for such donation, emphasizing the obligation to defend the life and dignity of both donor and recipient; she has also indicated the duties of the specialists who carry out this procedure of organ transplant. The aim is to favor a complex service to life, harmonizing technical progress with ethical rigor, humanizing relationships between people and correctly informing the public.

3. Because of the constant progress of experimental scientific knowledge, all those who carry out organ transplants need to pursue ongoing research on the technical-scientific level, so as to ensure the maximum success of the operation and the best possible life expectancy for the patient. At the same time, a constant dialogue is needed with experts in anthropological and ethical disciplines, so as to guarantee respect for life and for the human person and to provide the legislators with the data needed for establishing rigorous norms in this field.

In this perspective, you have chosen to explore once again, in a serious interdisciplinary study, the particular question of the "signs of death," on the basis of which a person's clinical death can be established with moral certainty, in order to proceed with the removal of organs for transplant.

4. Within the horizon of Christian anthropology, it is well known that the moment of death for each person consists in the definitive loss of the constitutive unity of body and spirit. Each human being, in fact, is alive precisely insofar as he or she is "corpore et anima unus" ("Gaudium et Spes," 14), and he or she remains so for as long as this substantial unity-in-totality subsists. In the light of this anthropological truth, it is clear, as I have already had occasion to observe, that "the death of the person, understood in this primary sense, is an event which no scientific technique or empirical method can identify directly" (Address of 29 August 2000, 4, in: AAS 92 [2000], 824).

From the clinical point of view, however, the only correct way – and also the only possible way – to address the problem of ascertaining the death of a human being is by devoting attention and research to the indi-

[1] Adopted unanimously and by acclamation on 16 October 2003 by the 32nd session of the General Conference of UNESCO. (SHS-2004/DECLAR.BIOETHIQUE CIB/4)

viduation of adequate "signs of death," known through their physical manifestation in the individual subject.

This is evidently a topic of fundamental importance, for which the well-considered and rigorous position of science must therefore be listened to in the first instance, as Pius XII taught when he declared that "it is for the doctor to give a clear and precise definition of 'death' and of the 'moment of death' of a patient who lapses into a state of unconsciousness" (Address of 24 November 1957, in: AAS 49 [1957], 1031).

5. Building upon the data supplied by science, anthropological considerations and ethical reflection have the duty to put forward an equally rigorous analysis, listening attentively to the Church's Magisterium.

I wish to assure you that your efforts are laudable and will certainly be of assistance to the competent Dicasteries of the Apostolic See - especially the Congregation for the Doctrine of the Faith - which will not fail to ponder the results of your reflection, and then to offer the necessary clarifications for the good of the community, in particular that of the patients and the specialists who are called to dedicate their professional expertise to the service of life.

In exhorting you to persevere in this joint commitment to pursue the genuine good of man, I invoke the Lord's copious gifts of light upon you and your research, as a pledge of which I affectionately impart my Blessing to you all.

From the Vatican, 1 February 2005 **Ioannes Paulus II**

[1] The Message John Paul II sent to the participants in the study session on the "Signs of Death," in the context of transplanting organs from the deceased, organized by the Pontifical Academy of Sciences on February 3 - 4, 2005. Taken from the Zenit Agency web site - www.zenit.org, document No. ZE05020320.

## O KNIHÁCH / BOOK REVIEWS

**BAUMANS; P.: KANT UND DIE BIOETHIK**  
**Königshausen & Neuman GmbH,**  
**Würzburg 2004, 84 str., ISBN: 3-8260-2911-9**

V kontexte úvah autorov rôznych filozofických systémov získava problematika statusu ľudského embrya v spoločnosti plastický charakter. Interdisciplinárny charakter diskusie o bioetických problémoch potrebuje vnútorný terminologický vŕhad, aby dialóg mohol vychádzať z jasne formulovaných definícií. Pyramída argumentačnej výstavby stanoviska k problému a vážnosť jednotlivých podporných definícií, úzko súvisí s filozofickým pozadím diskutujúcich a definovaním pojmov. Ak sa v priestore diskusie etickej komisie naraz stretnú napr. pragmatik, personalista, konštruktivista, komunitarista, existencialista, atď., vzniká veľmi zaujímavá debata, ktorá môže viesť k hlbšiemu pochopeniu aktuálnej morálnej dilemy a k neočakávaným výsledkom. Na druhej strane, takéto stretnutie predpokladá osobnú zrelosť diskutujúcich a vôľu k dialógu. Filozofický dialóg je jedným zo základných nástrojov etickej komisie, či už si to jej členovia uvedomujú, alebo nie.

Peter Baumans, vo svojej štúdií *Kant a bioetika* (Königshausen & Neuman GmbH, Würzburg 2004), rozpracováva základné bioetické argumentačné modely, ktoré ponúka Kantova kritická filozofia. Spomedzi mnohých bioetických problémov sa autor v tejto štúdií ilustračne sústreďuje najmä na určenie statusu ľudského embrya v spoločnosti, ako ju chápe Kant.

Kantov komplexný pohľad na človeka, ktorý sa na jednej strane aposteriórne predstavuje svetu ako *phaenomenon*, a na druhej strane je svetu apriori daný ako *noumenon*, ponúka dokonca možnosť vyriešiť niektoré zásadné bioetické problémy. Na základe Kantovej kritickej filozofickej reflexie človek, vo svojej dôstojnosti, získava uznanie ako morálna rozumná autonómna bytosť, od počiatku svojej existencie.

Prejav úcty k osobnej autonómii navyiac zvýrazňuje pojem tzv. spoločensvo autonómii. V súvislosti s Kantovým jedinečným chápaním človeka, na pozadí pojmov slobody a povinnosti, ktorý je začlenený do tohoto spoločensva autonómii, a to celkom jedinečným a unikátnym spôsobom (tzv. *Eingebürgerungsmodel*), nachádza ľudské embryo svoj spoločenský status.

Ľudskému embryu je takto, **od počiatku ľudskej existencie**, priznaný osobný a morálny status. Problémom ostáva určenie počiatku práve tejto **ľudskej** existencie embrya. Ak by sme však podrobne analyzovali Kantov pojem sloboda, podľa Baumansa, sa ľudskému embryu dopredu potvrdzuje jeho ľudská existencia v tom zmysle, že sa v ňom predpokladá **subjekt** - bytosť obdarená rozumom a slobodnou vôľou.

Odborná filozofická štúdia Petra Baumansa si zaslúži pozornosť širokého spektra záujemcov o problémy bioetiky. A to aj napriek tomu, že náročnosťou výkladu je adresovaná najmä filozofom, etikom, bioetikom, teológom. Riešenie morálnych dilem v klinickej praxi a na pôde etických komisií, a či dokonca pri tvorbe zákonov a legislatívnych usmernení, prináša otázky, ktoré vo svetle Kantovej filozofie môžu nájsť svoju presnejšiu formuláciu, a tým relevantnú odpoveď.

**Mgr. Katarína Glasová**  
ÚMEB n. f., Bratislava

**Seglow, J. (Ed.): The Ethics of Altruism**  
**Frank Cass & Co. Ltd., London, 2004,**  
**204 strán, ISBN: 0-7146-5594-5**

Altruizmus, sebaobetovanie... Pojem stále aktuálny aj v dnešnej dobe. Spoločensky uznané a docenené hrdinstvo... Ako však chápať transformáciu tohoto pojmu v praxi medicínskej etiky? Dá sa ešte povedať, že terminologické ohraničenie obsahu tohoto pojmu stále korešponduje s definíciou zaužívanou v praxi filozofických smerov? Ako je to s darcovstvom organov, paliatívnu starostlivosťou a inými bioetickými problémami, kde práve altruizmus našich „susedov v žití“ pomáha prekonať prvotné bariéry a nezriedka aj vyriešiť životne dôležité otázky?

Publikácia *Etika altruizmu*, tematický zborník prác, predstavuje pohľad na terminológiu a realitu altruizmu v dennej praxi lekára, pacienta a právnik, a to v kontexte anglofónnej politickej filozofie. Ako píše editor, cieľom tejto knižky je poukázať na to, že aj keď altruizmus terminologicky úzko súvisí s takými pojmami ako sú sloboda, morálna povinnosť, spravodlivosť, stále má isté svoje zákonitosti, ktoré by sa nemali v praxi prehliadať. Úvodných päť esejí sa zaoberá terminológiou altruizmu v rámci rôznych filozofických koncepcií. Ďalších päť esejí sa už díva priamo na problematiku altruistického konania v praxi.

Z hľadiska bioetiky je azda najzaujímavejším príspevkom filozofická reflexia *„Canaries in the Mines?“* Autor, Alasdair Maclean, profesor lekárskeho práva na Univerzite v Glasgowe, sa k štúdiu práva dostal po dlhoročnej lekárskej praxi v oblasti pediatrie. V centre jeho záujmu rezonuje problematika ľudských práv v súvislosti so zdravotnou starostlivosťou a informovaného súhlasu v pediatrii. Vo svojom príspevku sa zaoberá problémom aplikácie tzv. *pravidla najlepšieho záujmu* (angl. *the rule of the best interest*) v súdnych procesoch prípadov darcovstva orgánov maloletých detí, alebo mentálne postihnutých detí a dospelých. Na pozadí reálnych príkladov rozoberá ako sporný hlavný argument, tzv. psychologické odobrenie altruistickej obete donora v prípadoch mentálnej nespô-

sobilosti na morálne rozhodovanie. Utilitaristické argumenty *pravidla najlepšieho záujmu* totiž presahujú túto vekovú (mentálnu) hranicu a sústreďujú sa na posudzovanie altruistického činu u človeka spôsobilého morálne sa rozhodovať (teda dospelého, alebo nachádzajúceho sa v neskoršom štádiu puberty). Presne formulované, dieťaťu z právnického hľadiska nie je dovolené konať altruisticky, ale egoisticky.

Podľa autora by súd nemal izolovať ani darcu, ani príjemcu od komunity kam patria, teda od vlastnej rodiny. Zvlášť, ak ide o dieťa alebo mentálne postihnutého človeka, ktorý je bytostne s touto komunitou zviazaný a na ňu odkázaný. Problém osobnej autonómie by sa mal vyvíjať integritou vzťahov v rodine, odkiaľ dieťa, alebo mentálne postihnutý prichádza (týka sa to aj tých, ktorí sú dlhodo- bo v opatere ústavnej starostlivosti). Keďže dobro detí je previazané s dobrom komunity, v ktorej žijú – s dobrom rodiny, autor sa zasadzuje za uznanie autonómie rodiny v prípadoch rozhodovania o zdôvodnení dobra detí a mentálne postihnutých donorov. Rodinu charakterizuje ako autonómnu komunitu ľudí, ktorá navonok zdieľa spoločné hodnoty, záujmy, ciele a životné osudy.

Publikácia **Etika altruizmu** ponúka široké spektrum pohľadov na prax altruistického rozhodovania, a to ako pre právnickú obec, lekárov a zdravotníkov, členov etických komisií, filozofov a teológov, tak aj pre širšiu verejnosť.

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## RATIONALITÄT IN DER ANGEWANDTEN ETHIK

P. Fobel, G. Banse, A. Kiepas, G. Zecha (Eds.)

Vydavateľstvo Knižiareň – Ján Bernát,  
Banská Bystrica (Slovenská republika),

1. vydanie, 2004, 246 s., ISBN 80-969014-1-9

The book of proceedings of the international collaborative conference "Rationality in Applied Ethics", which took place at Matej Bell University in Banská Bystrica in September 2003 (22 – 25), should be considered as an extraordinary achievement in itself. The volume not only puts together the papers of renowned authors from 5 countries (Austria, Czech Republic, Germany, Poland and Slovakia) on a very needy and dynamic topics, but also offers all paper texts in a good quality German language, supplemented with Slovak – English summaries, chapter outlines, and general introduction to the book in all 3 languages (Slovak, English, German). This will surely make the book more accessible to the broader interested German speaking audience in Europe, and beyond. The books of similar scope and quality are still quite scarce so far.

It is to be agreed with the editors of the book, as stated in their introductory remarks, that the applied ethics today has many faces. They belong to different branches, making up a multitude of discourses, and also a plurality of rational viewpoints and procedures. Descriptive part of ethical discourse is nowadays, sometimes in a much too oversimplifying manner, cut off, or put in a contradiction to its prescriptive or normative part. However, for both of these parts rationality is required, especially in the context of justification. It surely will remain an open issue for a good time to come, which type of rationality should be applied to which kind of applied ethics.

In this situation, the analysis of the relationships between applied ethics and rationality is to be considered a highly relevant and timely endeavour. The aim of the conference, and of the resulting book of proceedings, obviously has been to pursue this analysis, especially with respect to rationality in applied ethics, in order to find consensual (if at all possible) answers to some of the pressing moral problems of our time. The general message of the book, finally, points not only to the relevance of rationality in ethics, but also underlines the importance of ethics as a necessary element in our reasoning.

The papers in the book are divided into two major parts: the first chapter "Foundations, Chances and Limits" contains contributions dedicated to the general relationships between rationality and applied ethics; the second chapter "Applications and Significant Topics" contains papers focusing on particular disciplines of applied ethics: bioethics, environmental ethics, ethics of technology and media, business ethics, and ethics of professions. The papers presented are well written and informative, referenced as necessary with relevant and actual literature. The international dimension of the discourse undertaken at the conference and the plurality of suggested solutions to the challenging issues of contemporary applied ethics, are very well reflected and commented upon in the papers. I believe this contributes in particular to the informative value and interest provoking qualities of the book.

The efforts of editors to give a fresh and interesting account of „a viable applied ethics, which is both conscious of local as well as of international moral problems“ will surely be attractive to a broader interested audience. I believe, the book will be of interest, and highly informative, to all scholars that study and develop a „European perspective“ in today's applied ethics, to students of philosophy, theology, and other humanities, and also for those interested in ethical problems of their respective disciplines that have been the focus of papers collected in this excellent volume.

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**Medicínska etika & bioetika - Medical Ethics & Bioethics**, founded as the journal of the Institute of Medical Ethics & Bioethics in Bratislava. It aims to serve the informational and educational needs of the members of ethics committees in the Slovak Republic and the broadest medical and health audience as well. It aims also to enhance the international exchange of information in the field of medical ethics and bioethics. The information published comprises news, original papers, review articles, reprints of national and international regulatory materials, letters, reviews. Contributions and materials are published in Slovak or English. Chosen materials are published in both languages. Scientific papers published in ME&B must respect the usual international standards (see Instructions for authors)