The major question that underlies concerns regarding biotechnology (and both meanings behind the phrase make life better) involves our basic definition of human life. What does it mean to be human? To whom do we choose to assign value? Who decides, and who benefits?

However, this assumption is questionable. Designers know that what is manufactured is truly better than the original and that the implication that there can be an aspect of designing life, of manufacturing humans, is the cultivation of molds for antibiotics such as penicillin. In more recent times, including humans. The creation of human life in the laboratory, starting with the birth of the first in vitro fertilisation (IVF) baby in 1978, has ushered in an era where biotechnologies related to human life itself, with an idea of creating, manipulating, even controlling technology can be brought to bear directly on humans. 

The major issue regarding the science and the biotechnologies is forcing us to ask the basic question of just what it means to be human. 

D. A. Prentice, Ph.D.
THE ETHICS OF FRIENDSHIP RECONSIDERED FOR MEDICINE
Part I – Aristotle’s Ethics of Friendship

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The traditional characterization of the patient-physician relationship as a friendship has been given vast attention in the ethics literature. [1] Negative critiques of this view attest to the growing alienation between the physician and the patient. [2] Aristotle’s work on the ethics of virtue friendship offers a unique perspective on defining the term “friendship,” thereby providing a more robust analogy to characterize the patient-physician relationship. This more robust characterization of friendship is grounded in the nature of the virtue friendship via eudamonia. [10] Because, for Aristotle, friendship is one in which interest is found in another’s character through benevolence, mutual concord and beneficence.

The goal of part one of this essay is twofold: (1) to examine the concept of friendship in Aristotle’s ethics, relying heavily on the Nichomachean Ethics and (2) to recover the nuances in Aristotle’s ethics through an examination of virtue friendship. This analysis will lay the foundation for part two of this work, which will examine Aristotle’s ethics of virtue friendship as an appropriate analogy for the patient-physician relationship.

Statement of the Problem

The patient-physician relationship can be traditionally characterized as a relationship based on healing. [3] The inherent demands of the therapeutic relationship are the bases for the virtues internal to the practice – virtues such as, fidelity to trust, benevolence, courage, compassion, intellectual honesty, competence, prudence, and self-criticism. [5] However, as authority, power, and bureaucratization influence these “internal virtues,” the ability to heal may not necessarily create a patient-physician relationship. [6] An inadequate understanding of human relationships, especially friendships, can set the stage for inadequate relationships between the physician and the patient in the health profession. [7] That is, a patient-physician relationship characterized solely by the ability to utilize the physician’s skills to alleviate the patient’s isolated symptoms is reduced to mere utility. [8] This essay will begin to recover an understanding of the patient-physician relationship through an examination of Aristotle’s conception of the virtue friendship in the Nichomachean Ethics. [9]

The Role of Friendship in the Nicomachean Ethics

Any discussion of a relationship between two individuals in accord with human flourishing involves a discussion of friendship as an essential component of the pursuit of eudaimonia. [10] Because, for Aristotle, friendship is a specific relationship conceived of teleologically, [11] a good is sought. Three specific goods pursued include: useful good, pleasurable good, and the good of virtue. [12] Aristotle characterizes a friendship based on utility as essentially instrumental—one that quickly fades once the goal has been achieved. Such relationships are established for the purposes of some desirable end and therefore only serve to reach that end. [13] Friendships characterized by pleasure are less easily defined and are subject to the whims and interests of those entertained by the relationship. They too quickly fade once the pleasure or entertainment is absent from the relationship. [14] Virtue friendships, however, are a true and absolute good; they are essential. [15] It is friendship founded upon this last good that is friendship in the perfect sense, since, for Aristotle, it alone comprises the essential element of being for the sake of another. [16]

Aristotle is quick to point out that although useful and pleasurable friendships are incomplete and unstable, they are still friendships. [17] These friendships are characterized solely by the ability to utilize the physics or pleasure, may be problematic for the physician who finds it worthwhile to know his or her patient’s conception of the good, the patient’s desires and plans for realizing elements of the good, especially as the pursuit of such goods may relate to the patient’s health. [19] Likewise, such characterization may be problematic for the patient, insofar as he or she regards as irrelevant matters outside the narrowly circumscribed context of utility or pleasure. [20] At the very least, these latter forms of friendship “instrumentalize” that which could be a profound opportunity for human flourishing. [21]

Virtue friendship, on the other hand, when exercised appropriately, is characterized by the excellence of each other’s character through benevolence, mutual concord and beneficence. [22] Persons engaged in such friendships are attracted by virtue, compelled by each other’s conception of the good, plans and means to actualize the good and the habitual patterns of virtue directed toward the good. [23] In order to understand the patient-physician relationship in a model other than utility or pleasure, the essay must further examine benevolence, mutual concord and beneficence as they relate to the virtue model.

Benevolence in the Model of Virtue Friendship

Benevolence or goodwill is centered on knowing an “other self” as well as self. As stated previously, happiness is living virtuously in proper accord with reason. A major concern for achieving happiness, therefore, is knowledge of virtue. Here, friendship widens the person’s familiarity with virtue. [24] That is to say, for Aristotle, the virtuous friendship is one in which interest is found in another’s virtuous action. Seeking virtue in another fosters understanding of virtue in oneself, thus making the case for “other selfhood as a source of cognitive, as well as moral actualization for those engaged in it.” [25] In other words, Aristotle contends that the amount of self-knowledge or noetic insight gained from friendship is directly related to the quality of the friendship. [26]

The implications for benevolence in terms of the virtue friendship are therefore based in noetic claims. That is, claims revealed to the individual through self-knowledge and virtue. [27] Therefore, if a virtue friendship is formed, then virtue may be better understood by both persons. This does imply, however, that the persons who seek a virtue friendship have a prior awareness of what “constitutes the best good for a human being.” [28] Aristotle’s understanding of the term phronesis has specific relevance here. Terence Irwin translates phronesis...
as prudence, suggesting a “good sense about one’s welfare,” a “practical wisdom.” [29] This necessarily notes an understanding of ends, more specifically good ends—hence, the obligatory relationship between phronesis and virtue. Therefore, as one engages in the virtuous friendship, benevolence or goodwill is understood in the self prior to the relationship, but yet is fostered, nurtured and brought to fruition because of the virtuous friendship. [30] In other words, the virtuous friendship not only has an intimate knowledge of the good internal to self, but also is keenly aware of the good in another such that the virtuous friendship can be pursued. C.H. Kahn states this dynamic more explicitly noting that virtue friends “recognize in their common humanity and common rationality unifying principles that makes their concern for one another possible.” [31] Thus benevolence, understood in the self as well as in the “other self” as a unifying principle among friends, is necessarily a prerequisite for the virtue friendship. How this dynamic relates the self and the “other self” toward mutual flourishing in the virtue friendship is revealed in Aristotle’s understanding of mutual concord.

Mutual Concord in the Model of Virtue Friendship

Aristotle’s use of the term “concord” reference a set of conditions in which action should take place among persons or states in order to function peaceable, thereby allowing minimal interference in the affairs of the individuals pursuing happiness. [32] It is a means by which to foster a general well-being of a community.

Among virtue friends, the good is noticed in another reflecting on one’s own awareness of their journey toward the good. Mutual concord is the state of harmony in which the mutual search for the good among virtue friends can be exercised peaceably—allowing for persons to work together toward eudaimonia. Aristotle stresses the importance of mutual concord most directly with regard to civic friendship. [33] He does so to articulate the necessary cooperation that persons of virtue must possess in order to elect leaders, make political decisions, or draft treaties. [34] However, of significance to this essay is the role of mutual concord within virtue friendship. Namely, the context mutual concord creates to allow the virtues to manifest.

Recall virtue friendship requires a certain level of self-understanding of benevolence before one can search it out in others. This is also true of mutual concord. Concord with oneself is narrowly construed, that is, cooperating with oneself; concord with others necessitates mutuality, that is, an active participation toward cooperation. More explicitly, cooperation will only work if the friendship is characterized by certain virtues (e.g., trust, generosity); these virtues then manifest themselves when mutual concord creates the effective context to do so. [35]

While virtue friendship is characterized by benevolence and mutual concord, a final component remains. That is, virtue friendship characterized only by benevolence and mutual concord does not articulate a method by which one shares purpose with another toward a common good—hence, the need for beneficence.

Beneficence in the Model of Virtue Friendship

Aristotle defines beneficence within the context of a virtue friendship in specific manner. Beneficence implies good will for the sake of another essentially, that is, developing the good of another as an end. In other words, beneficence is acting essentially for the sake of an end and accidentally for the sake of the means. [36]

Aristotle views such virtue friendship as a practical necessity for life. [37] For humanity not only envisages its ultimate end in terms of an association, but also relies, whether consciously or not, on association with others for the fullest possible flourishing of daily life. [38] That said, an understanding of how one is to act out shared goods and purposes is not clear. For example, Paul Schollmeier’s account of Aristotle’s friendship leaves out the manner by which “good friends [are to] act with the intention of advancing the happiness of one another.” [39] Schollmeier’s read of Aristotle implies that this is simply what is done by good friends. His circular reasoning omits how virtuous friends act toward achieving the good.

James Bernard Murphy struggles too with this nuance in Aristotle’s characterization of friendship noting that although altruism is a part of friendship, it is not such in totality. [40] Beneficence is not merely acted out, it is guided by virtue, both internally and externally recognized. Murphy points out the inadequacy of friendship seen as pure altruism, stating:

Aristotle’s analysis takes us beyond egoism and altruism when he says that true friendship cannot be reciprocal altruism because I could wish the good for another and the other could wish good for me but we would not be friends unless we both are aware of and acknowledge our mutual good-will—otherwise, we would have a mere coincidence of unrequited friendship. [41]

Virtue friendship then, seen as differing from mere mutual altruism, utilizes the self-awareness of beneficence in mutual concord to coordinate activities such that these activities move toward a mutually recognized good. Therein, the experience of cooperation guides both to happiness. True friendship, therefore, begins as a search for the good in another in order to broaden the depth and scope of one’s own understanding of virtue. [42] As activities continue between persons amidst the friendship, goods develop internal to the friendship itself, goods that would not have come to fruition in any other way. [43] True friendship, then, experiences goods onto itself flowing from a self-awareness of benevolence when persons act in mutual concord with each other.

In this manner, benevolence, mutual concord, and beneficence necessarily act in harmony to allow distinct and individual persons to come together in friendship. In other words, when one recognizes virtue in oneself and can establish mutual concord to engage another person peaceable, beneficence will have a telos by which to guide action. Stated more succinctly, Murphy notes:

Virtues alone make it possible for two quite different and separate persons to open themselves up—or better, to let down their guard—to a degree of communion that would otherwise be far too risky. In the intimate mutuality of friendship, we are extraordinarily vulnerable to harm by a partner who is unjust, intemperate, dishonest, or selfish...For those who have acquired the proper virtues, the goods common to friends...are their own reasons for acting. [44]

Friendships that include benevolence, mutual concord and beneficence are then seen as an opportunity for human flourishing through participation in a good common to all persons.

Part one of this essay asserts it is this understanding of friendship that most appropriately provides an analogy to the patient-physician relationship. To this end, part two of this essay will make two concomitant claims: (1) that the ends of medicine provide the teleology that characterizes the strengths of the patient-physician relation-

**List of References**


**Abstract**


Use of the term friendship to characterize the patient-physician relationship has been strongly criticized in articles in the medical literature. Critics have sought to undermine use of this analogy by strongly cautioning against friendship between patients and physicians, others have blamed a health care system that no longer affords physicians time for a friendship to develop, others see the model as simply unhelpful. Sensitive to these critiques, part one of this two-part essay examines a nuance in Aristotle’s understanding of virtue friendship via benevolence, mutual concord and beneficence. Part two of this essay will apply Aristotle’s model of virtue friendship to the patient-physician relationship to argue this model warrants reconsideration as a valid analogy.

**Keywords**: Aristotle, friendship, virtue, patient-physician relationship
THE ETHICS OF FRIENDSHIP RECONSIDERED FOR MEDICINE
Part II – Application to the Patient-Physician Relationship
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Part one of this two-part essay examined the concept of friendship in Aristotle’s ethics, relying heavily on the Nichomachean Ethics and recovered the nuances in Aristotle’s ethics through an examination of virtue friendship. To that end, part one offered a more robust characterization of friendship grounded in the nature of the virtue friendship via benevolence, mutual concord and beneficence. Part two of this essay will apply Aristotle’s model of virtue friendship to the patient-physician relationship to argue this model warrants reconsideration as an appropriate analogy for the patient-physician relationship while drawing a distinction between “friendship” and “friendship-like” behavior.

The Contribution of Aristotle’s Ethics of Friendship to the Patient-Physician Relationship
Proposing the model of friendship as an analogy for the patient-physician relationship emphasizes the physician’s character as trustworthy, wise, good-willed, loyal and of an unwavering integrity guided by the teleology of his/her patient’s health. [1] That is, the parameters of the patient-physician relationship are qualified in some sense by the nature of the physician as expert; however, this expertise is in turn governed by the patient’s symptoms and hope of relief. [2] The dynamic of friendship therefore may be appropriate given that the patient-physician relationship bespeaks shared activity. In other words, friendship in this sense creates a normative framework that orders the moral good of the relationship in accord with the goals specific to the patient-physician relationship—the good of health. [3] Friendship governs the shared activity such that participants mutually commit to the goal, understand their individual efforts toward this end, and agree to participate fully to the extent they each understand the commitment and goal. [4]

It is also important to highlight the implications of using the word “analogous.” An analogy is inherently more different than similar to the object it seeks to describe. [5] Therefore, this essay does not suggest that patients and physicians be friends as this term is popularly understood, but rather that the nature of the relationship fosters friendship-like behavior. That is, behavior motivated by the common pursuit of healing. [6] To this end this essay will utilize Aristotle’s construction of the virtue friendship—benevolence, mutual concord, and beneficence—to demonstrate its contribution to an understanding of the nature of the patient-physician relationship. In order to demonstrate this contribution the essay will relate each of the characteristics of Aristotle’s friendship and its corresponding good within the patient-physician relationship—namely, the good of the patient, the good of a social nature to medicine, and the good of health for human flourishing, respectively.

Benevolence and the Good of the Patient
To begin a discussion on the contribution of Aristotle’s ethics of friendship to the nature of the patient-physician relationship, it must first be established that there is in fact a relationship. Namely, one must address the matter of whether there is a social dynamic to the patient-physician relationship. This essay makes the claim such a relationship does exist by recognizing that a patient seeks health through certain means judged prudent by the patient himself or herself. [7] The physician, in turn, is the expert whose training and licensing is directed toward the explicit purpose of health. [8] The context for practicing medicine, then, demands a patient and a physician engage in a relationship that will be organized around these circumstances. [9] Therefore, the patient is, at the very least, necessary and central to the practice of medicine in general and additionally may be primary to other concerns. [10]

Moving from the patient-physician relationship understood as a social relationship to one characterized by benevolence necessitates understanding a patient’s illness, as well as the patient’s vulnerability and anxiety related to the encounter. That is, benevolence moves the relationship from a presentation of medical knowledge to alleviate symptoms to a consideration of treatment or cure within the interests of the one who is ill. As such, good medical decisions serve to restore, “to the extent possible, those human capacities eroded by illness” with a consideration of the means used and ends served. [11] Understood this way, the relationship between the patient and the physician is characterized by a delicate balance between the patient’s vision of the good life and the reality of his or her illness. [12] Here, the patient, as the central concern of medicine, demands benevolence on the part of the physician because all events surrounding the clinical encounter relate to the good of the patient’s health. [13] Yet, to understand how specific events are ordered toward this end, this essay considers mutual concord within the patient-physician relationship.

Mutual Concord and the Social Nature of Medicine
Recall that Aristotle’s use of the term “concord” references a set of conditions in which action should take place among persons in order to function peaceably. [14] Application of this term to the social nature of medicine, as utilized in Aristotle’s construction of a virtue friend-
ship, recognizes mutual concord is an expectation of both the physician and the patient. Mutual concord therefore sets the context for understanding the social dynamic of medicine and its ability to function virtuously.

The array of activities inherent to the practice of medicine (e.g., diagnosis, prognosis, counseling, and education) require that persons engage in relationship. [15] Diagnoses, sound therapy and the use of medical technology require engagement with the patient in terms of disclosure, consent and compliance. Mutual concord highlights the cooperation that must be present for virtue friendship to manifest toward specific ends. As such, understanding the relationship between mutual concord and the relational nature of medicine means the same must be true of the patient-physician relationship. That is, where a virtue friendship is understood to be characterized by trust, goodwill, loyalty and unwavering integrity, so too this holds true for the patient-physician relationship.

In this way, mutual concord as the context for understanding the relational dynamic of medicine (i.e., the patient-physician relationship) demands the patient be truthful (e.g., disclosing accurate and pertinent information to the physician); collaborative (e.g., meeting compliance recommendations from the physician); and trustworthy (e.g., avoiding threatening the physician with lawsuits and meeting financial obligations regarding insurance and payment). [16] In turn, mutual concord demands the physician be truthful (e.g., disclosing to the patient his or her skill with regard to a specific illness as well as proper diagnoses and prognoses); collaborative (e.g., committing a certain visible compassion and loyalty to the good of the patient as well as to his or her health); and trustworthy (e.g., articulating a commitment to serving the needs of the sick patient as primary to other dimensions of his or her practice). [17] What remains however, is how the patient-physician relationship acts out shared goods and purposes to enable human flourishing. This final component will be addressed by exploring the relationship between beneficence and the good of health for human flourishing.

Beneficence and the Good of Health for Human Flourishing

Aristotle characterizes beneficence as a shared sense of good will for the sake of another. Virtue friendship utilizes this concept to recognize the good of another as an end in itself as a mutual good. [18] For the patient-physician relationship, this is the shared good of restoring the patient’s health. [19] This structure of the patient-physician relationship highlights a concept of human flourishing to “organize important moral goods and ideals which physicians and patients strive to attain.” [20] Although the virtue friendship model is the ideal analogy, not all patient-physician relationships will approximate this model. Beneficence will minimize the interests of the physician toward that of restoring the patient’s health. [21] In other words, it is at this point where the patient’s interests and goals converge with the physician’s clinical decision. [22] That clinical decision involves more than simply applying a biological remedy to a symptomatic ailment. Beneficence, understood in the context of the patient-physician relationship, does not resort to this “biological reductionism,” but rather seeks to treat disease in the context of the whole person. [23] Obligations to the individual patient’s health, to foster his or her flourishing, orient beneficent clinical decisions in a profoundly personal manner. As such, efforts must be made to “assure that the patient understands alternatives, burdens and benefits, costs, chances of success, [and] limitations of the procedures or treatment” [24] in the context of the individual patient’s values, desires, beliefs and interests. Such a position enables the physician to understand both the patient’s illness and the illness’ effect on the patient’s ability to flourish. [25] This reinforces advocating a patient-physician model different than that of utility or pleasure—where utility and pleasure fail to recognize the medical profession “as a unique vocation and a way of life dominated not by self-interests but by care and benevolence.” [26]

Beneficence coordinates the medical relationship by highlighting the inherent good of the patient in a relational context to further the good of health for human flourishing. Relating Aristotle’s discussion on the role of friendship in the Nicomachean Ethics to the patient-physician relationship, it is in the exercise of acting virtuously that the patient and the physician acquire virtue within. [27] As such, as both acquire virtue within, trust, cooperation, and truthfulness develop outwardly and dynamically amidst the shared good of the patient’s health. Therefore, as the relationship develops and a deeper understanding of these virtues is communicated within the patient-physician relationship, an understanding of the patient’s health and ability to flourish may be deepened. [28] This dynamic becomes a shared context in which the good of human health and flourishing is the reason for acting beneficently within the patient-physician relationship; that is, the properly acquired virtues, common to the patient and the physician, are the reason for acting. [29]

The patient-physician relationship is often understood as analogous to friendship, an understanding of the patient-physician relationship is aided by a foundational claim that a human person cannot attain a full and perfect life alone, therefore one naturally moves into society. Aristotle argues from this premise that the human being is naturally a political animal, since his or her full, natural perfection as an individual is attained, not alone, but in society. Friendship is therefore not something that one can dismiss but something one naturally needs for full perfection. Consequently, the patient-physician relationship seen as analogous to friendship appears not as something that restricts the free development of the individual, but as the indispensable means of bringing the human person to full perfection in times of illness.

Further analysis clarifies the analogy drawing on a specific form of friendship, that is, virtue friendship. Here, benevolence, mutual concord, and beneficence operate in a unique manner to serve the good of the patient, the inherent social nature of medicine, and the good of health for human flourishing, respectively. This effort serves to define more clearly how the patient-physician relationship ought to operate, what ends it should serve, and what obligations fall on both patient and physician.
Endnotes


List of References


KRÁTKE PRÍSPEVKY

BRIEF COMMUNICATIONS

NATIONAL REGULATION OF HEALTH CARE ETHICS COMMITTEES – SLOVAK REPUBLIC [1]

Jozef Glasa, Katarína Glasová

Institute of Medical Ethics and Bioethics n.f., Bratislava, Slovak Republic

1. An outlook of the recent developments of clinical ethics support services in the Slovak Republic (1990 – 2005)

The “Velvet Revolution” of November 1989 marked a brand new start for the development of bioethics in Slovakia (SR), which was taking place amidst the profound transformation of health care system and other major, unprecedented and complicated ‘transition’ processes finally taking the country to the full membership of the European Union (May 1, 2004).

Since the very beginning, the idea of ethics committees in general was strongly supported by the Ministry of Health (MH) SR: ethics review was deemed necessary for an optimisation and supervision of the ongoing health care reform processes. Therefore, the Central Ethics Committee (CEC) was founded at MH SR in autumn 1990.

At the same time, in the reform atmosphere that followed the „Velvet Revolution“, several informal working groups on medical ethical issues were formed at the Faculties of Medicine, as well as in the teaching hospitals, research institutes, and also within several member societies of the Slovak Medical Association (SMA – association of scientific medical societies in SR), and the Slovak Medical Chamber (SMC – professional association of physicians in SR).

Those groups were, later on, transformed into the „hospital“, research („institutional“), or mixed-type ethics committees (ECs). The “know-how” support for these ethics review and advisory bodies was provided mostly by CEC: by means of consultations, informal recommendations and professional guidance. No reporting or hierarchical relationships were introduced. In June 1992, the „Guidelines on Establishment and Work of Ethics Committees in Health Care Facilities and Biomedical Research Institutions“ (Guidelines) were elaborated by CEC, and published in the form of MH’s recommendation. The Guidelines asked for and gave a specific guidance on the establishment and work of local ECs, both of a hospital, research („institutional“) or mixed type (English translation of the Guidelines available).

Legal developments were started by several partial amendments of existing health legislature based on the Law No. 20/1960 on health care. The new health law was adopted in 1994 (Law No. 277/1994 on Health Care). Together with subsequent legislature, it helped to create a new legal milieu for medicine and health care in SR.

The next period of extensive legal developments was connected with Slovakia’s accession processes to EU as well as with a profound, almost ‘revolutionary’ transformation of the whole health care system in SR.

The “reform health legislation”, approved in September 2004 by the Slovakian parliament, consisted of 7 brand new laws. Further amendments and several other laws passed by the parliament later completed the most profound legal transformation of health care related legislature ever seen in SR. The most important for ethics committees’ issues were two of the mentioned laws: the Law No. 576/2004 Coll. on health care and the Law 140/1998 Coll. on drugs and medical devices as later amended (see below).

Establishment and work of local ECs in Slovakia contributed to the positive moral atmosphere and overall progress of the health care system reform, especially through their awareness building and local education activities directed toward health care professionals and to the general public. Their role in institutional policy development and clinical ethics consultation service has been so far limited. A clear appreciation of ECs’ contribution has been witnessed in review of clinical research, including clinical trials of new drugs, especially in promoting and contributing to the observance of GCP and related international ethical standards.

Thus, the first 15 years of ECs’ existence in Slovakia may be seen as a period of many positive achievements, and building of the foundations for the more structured developments provided for by the recently approved legal backing.

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### Section 1: Legal Prerequisites

The new health legislation (the Law No. 576/2004 Coll. on health care; which has entered into force on January 1, 2005) does ask all inpatient health care facilities in SR to have ECs established to deal with the ethical problems connected with the health care provision. It also asks the regional health authorities (the whole SR is divided into 8 regions with their own political/municipal/self-governance structures) to establish “regional” ethics committees for the same purpose, i.e. to oversee and deal with ethical problems of health care, public health and biomedical research at the territory of their respective regions.

Ministry’s of Health regulation on ethics committees is under preparation (to be issued under the new law). It is supposed that it will require the registration of ethics committees, and thereby also their fulfilling of certain criteria, newly reset by it (e.g. detailed requirements concerning statutes, membership, education and training of ethics committees members, etc.).

### Table 1
Text of §5 of the Law No. 576/2004 Coll. on Health Care

#### English translation

**§ 5 Dealing with ethical questions connected with health care provision**

1. Ethical questions arising in connection with provision of health care and ethical acceptability of biomedical research projects (§ 2 ind. 12) are reviewed by an independent ethics committee (further on „ethics committee”).

2. Ethics committee is established by:
   - a) ministry of health to review ethical questions arising in connection with provision of the health care, including those of biomedical research, and
   - b) self-governing region to review the ethical acceptability of biomedical research projects and ethical questions arising in connection with provision of the outpatient health care.

3. Health care provider that provides inpatient health care to review the ethical acceptability of biomedical research projects and ethical questions arising in connection with provision of the inpatient health care.

4. Ethics committee consists of a minimum of five members; those are health care professionals, representatives of other professions, whose qualification is required for the work of the ethics committee, and persons without a professional qualification for the work of a health professional or the work in biomedical research. There is also a member nominated as a representative by the professional organizations of health care professionals.

5. The number of members without a professional qualification for the work of a health professional or the work in biomedical research should not exceed the simple majority of all members of the ethics committee.

6. The members of ethics committee are obliged to:
   - a) report to the authority that has established the ethics committee all facts that could constitute or actually constitute a conflict of interest in the case of review of a particular project; if a member of ethics committee finds himself or herself in the conflict of interest, he or she must not take part in the ethics committee’s review and approval of this project,
   - b) keep confidentiality concerning all facts about which they learned in connection with their work as the ethics committee’s members; the obligation of keeping confidentiality is waived in cases, where the information is revealed after the person concerned has consented to this effect.

7. Ethics committee must keep records about its activities, minutes from its meetings, its conclusions, opinions and recommendations. The authority that has established the ethics committee is obliged to secure keeping these documents on file for 20 years.

8. Ethics committee issues its opinions in a written form, in each opinion it must provide justification of its conclusion. For the adoption of an opinion of the ethics committee, the two-thirds majority of all of its members is necessary.

9. The activities of an ethics committee are governed by its statutes. The statutes are issued by the authority that establishes the ethics committee.

(Translation by J. Glasa)

### Original text in Slovak

**§ 5 Posudzovanie etických otázok pri poskytovaní zdravotnej starostlivosti**

1. Etické otázky vznikajúce pri poskytovaní zdravotnej starostlivosti a etickú prijateľnosť projektov biomedicínského výskumu (§ 2 ods. 12) posúva je nezávislá etická komisia (ďalej len „etická komisia”).

2. Etickú komisiu zriadzuje
   a) ministerstvo zdravotníctva na posuzovanie etických otázok vznikajúcich pri poskytovaní zdravotnej starostlivosti vrátane biomedicínskeho výskumu,
   b) samosprávny kraj na posuzovanie etickej prijateľnosti projektov biomedicínskeho výskumu a etických otázok vznikajúcich pri poskytovaní ambulantnej starostlivosti,
   c) poskytovateľ ústavej starostlivosti na posuzovanie etickej prijateľnosti projektov biomedicínskeho výskumu a etických otázok vznikajúcich pri poskytovaní ústavej starostlivosti.

3. Etická komisia má najmenej piatich členov; skladá sa zo zdravotníckych pracovníkov, z pracovníkov iných profesí, ktorých odbornosť sa vyžaduje pre činnosť etickej komisie, a z osôb bez odbornej spôsobilosti na výkon zdravotníckeho povolania alebo v oblasti výskumu. Členom každej etickej komisie je aj zástupca menovaný stavovskými organizáciami v zdravotníctve.

Počet členov etickej komisie bez odbornej spôsobilosti na výkon zdravotníckeho povolania alebo v oblasti výskumu nesmie presiahnuť nadpolovičnú väčšinu všetkých členov etickej komisie.

4. Členovia etickej komisie sú povinní
   a) označiť zriaďovateľa etickej komisie skutočnosti, ktoré predstavujú alebo by mohli predstavovať konflikt záujmov v prípade konkrétneho posudzovaného projektu; ak člen etickej komisie je v konflikte záujmov, nesmie sa zúčastniť na posuzovaní a na príjmi stanoviska etickej komisie k takému projektu,
   b) zachovávať mliečavnosť o všetkých skutočnosťach, o ktorých sa dozvedeli pri výkone svojej funkcie; povinnosť mliečavnosti sa nevzťahuje na prípady, ak tieto skutočnosti oznamujú so súhlasom toho, koho sa týkajú.

5. Etická komisia je povinná viest záznamy o činnosti, zápissnice z rokovania, závery, stanoviska a odporúčania. Zriaďovateľ príslušnej etickej komisie je po povinný zabezpečiť ich uchovávanie počas 20 rokov.

6. Etická komisia vydáva svoje stanoviska v písomnej forme; v každom stanovisku je povinná uviesť odôvodnenie jeho záveru. Na príjmi stanoviska etickej komisie je potrebná dvojretinová väčšina všetkých členov komisie.

7. Činnosť etickej komisie upravuje štatút, ktorý vydá zriaďovateľ príslušnej etickej komisie.
The most important provisions of the Law 576/2004 - from the point of view of ECs established in the health care facilities and at the level of the regional health authorities in SR - are contained in §5 (the full English translation given in Table 1).

The other most relevant questions are dealt with primarily in the following paragraphs of the law (given here as mere examples):

§2 - important definitions (e.g. health care, health care intervention, good care, biomedical research, health care provider, outpatient and inpatient health care provision, etc.);

§6 - informed consent issues (quite detailed treatment);

§11 - rights of persons and their obligations with regard to health care (rather extensive paragraph containing also the list of patients' rights);

§26 - 34 - biomedical research (rather extensive treatment of the issues involved in biomedical research review and authorization in SR, including the provisions concerning informed consent, vulnerable groups and research in emergency situations);

§35 - 39 - provisions concerning organ, tissue and cell transplantations (procurement, storage and use of human organs, tissues and cells for transplantation purposes);

§40 - sterilization.

The specific legal provisions concerning drug clinical trials (CTs) are given in the Law. No. 140/1998 Coll. on drugs and medical devices. These include provisions with regard to CTs' scientific and ethical review, authorization or notification procedures before the competent state authorities, as well as the provisions concerning the application of the Good Clinical Practice standards.

3. The present situation in SR and outlook for the future

Clinical ethics support services at local or regional level are still scarce in SR. The outline of existing structures (ethics committees) is given in Table 2. There are no single-working “ethics consultants” appointed in the hospitals or other health care facilities in SR.

At present, there are (“local”) ECs established at the major hospitals and at the medical research institutes that provide also the highly specialized inpatient medical/health care (approximate number of ECs for the whole country: 40-50; more accurate data are so far missing). They occasionally (so far quite rarely) take on the consultation of ethically difficult cases, or, even more seldom, reviewing and providing advice on local/regional health policies (e.g. they are required to review occasionally the ‘compassionate’ use of new drugs not yet ‘registered’ (i.e. given an marketing authorization) in SR).

The same is basically true with regard to (“regional”) EGs established by the regional health authorities in 8 SR’s regions. These EGs are supposed to review and give advice on ethical issues connected with outpatient medical/health care.

The Central Ethics Committee, located at the Ministry of Health, has been much involved in the preparation work on the regulation, and the accompanying guidelines. It also was very active in drafting of the new health legislation mentioned above (especially the chapters on informed consent, ethics committees, biomedical research, transplantation, etc.). It has also been very supportive in developing, or re-activation of EGs’ system throughout the country (e.g. by organising annual meetings of EGs (since 2002), contributing to the journal “Medical Ethics & Bioethics”, providing consultations and guidance on difficult cases (either in writing, or as telephone consultations), starting a web page for EGs within its own web page hosted by the server of the Ministry, etc.).

Ethics support in clinical practice is felt being a necessary pre-requisite, and of growing importance, for the development and reform of the Slovakia’s health care system, which is still struggling nowadays with results of the profound transformation undertaken during past recent years. It is becoming to be spotted on the horizon of needs of clinicians and health care administrators.

The publication of the pending ministerial regulation on ECs should provide a more comprehensive legal backing for further development of “clinical” ECs and improvement of quality of their work. In this process, education and training of ECs’ members and ECs’ users is of paramount importance, as well as the recognition of the role, responsibility and potential for help of, and partnership in action with ECs by health care professionals, and also by the society in SR in general (especially by the patients and their relatives).

4. Health care professionals’ education and training in clinical bio/ethics

Undergraduate level

Medical ethics is taught as a compulsory discipline at all 3 faculties of medicine in Slovakia (only in one of them, however, a specialized department has been established (Bratislava)). Ethics is also a compulsory discipline within the education and training of nurses and other health care pro-

Table 2 Ethics committees' system in SR with regard to clinical ethics support

<table>
<thead>
<tr>
<th>Types of ethics committees and their tasks with regard to clinical ethics support</th>
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<tbody>
<tr>
<td>Ethics Committee of the Ministry of Health</td>
</tr>
<tr>
<td>(formerly “Central”)</td>
</tr>
<tr>
<td>- conceptual work, legislation review and drafting,</td>
</tr>
<tr>
<td>- advisory role for state institutions (parliament, government),</td>
</tr>
<tr>
<td>- consulting and advisory help to ”regional” and “local” ethics committees, organization of annual national meetings of ethics committee’s members,</td>
</tr>
<tr>
<td>- health policies ethical review,</td>
</tr>
<tr>
<td>- opinions on concrete ethical issues,</td>
</tr>
<tr>
<td>- only seldom review of concrete cases (upon the request of the minister).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethics committees established by regional health authorities (“regional”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- review of and advice on ethical issues arising in connection with provision of the outpatient health care in the region,</td>
</tr>
<tr>
<td>- review of the ethical acceptability of biomedical research projects (including drug clinical trials protocols) to be conducted or co-ordinated in the region’s territory.</td>
</tr>
</tbody>
</table>
fessionals, in advanced studies in nursing (MA, PhD.), and in the study of public health (MPH, PhD.). Corresponding curricula have been developed and are being stepwise state-accredited within the state accreditation process of the universities and faculties (provided for in the law). Teaching activities usually comprise lectures, discussions, small groups activities, and essay writing. Some education materials (texts, textbooks) were produced in Slovak language. The students from abroad, enrolled into the international university programmes, are usually taught in English.

Postgraduate level

The availability of training in clinical ethics for health professionals already in practice is still insufficient. There are no specific training programs at the hospital level for doctors, nurses, or other health care workers (2). Seldom lectures, seminars, or small conferences are held in university teaching hospitals settings, or within the activities of the Institute of Medical Ethics and Bioethics in Bratislava (in 1991, postgraduate courses in medical ethics started at the Postgraduate Medical Institute, where the first country’s Chair of Medical Ethics was established; these very well attended, popular events, attracting health professionals from all around the country).

In the recent years, a steady progress is being made in the continuous medical education field, where lectures on bioethics are frequently included into the programs of specialized courses of various medical disciplines, and courses for nurses. The courses on Good Clinical Practice are held regularly at the Slovak Medical University (since 1996). Specific education for members of ethics committees is being prepared and should be offered soon (2006). It is to be required by the new, pending ministerial regulation on ethics committees.

Notes


(2) Results of the study undertaken under the “European Hospital-based Bioethics Education Program” (EHBP) – the Project of 5th Framework Program of the European Commission, in 2003 (details by the author).

Abstract

Glassa, J.: National Regulation of Healthcare Ethics Committees – Slovak Republic. [Predpisy o etických komisiách v zdravotníckej starostlivosti – Slovenská republika.] Med. Eth. Bioet., Vol. 13, 2006, No. 1 – 2, 9 – 12. Paper outlines more than 15 years of development of ethics review services within the health care system in the Slovak Republic (SR). Though the emphasis was put so far mainly on the ethics committees (ECs) established to review projects of biomedical research (including drug clinical trials), clinical ethics, since the very beginning, has been the part of ECs' deliberations and work. In 1992, this was reflected in the first national guidelines for ECs published by the SR Ministry of Health. New health legislation (especially the law No. 576/2004 Coll. On health care), which has been approved in 2004, requires all hospitals in SR to have an EC established to give advice on ethical problems connected with provision of health care, as well as provides for the establishment and work of regional ECs to support, among their other duties, the work of ECs in a particular region (SR is divided altogether into 8 territorial regions).

Key words: clinical ethics, ethics committees, health care

Abstrakt


Kľúčové slová: klinická etika, etické komisié, zdravotnícka starostlivosť

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Človek tíži vždy po novom obdarovaní životom, aby mohol vyčerpať, čo mu okamih dáva i berie. Nechte sa vzdať toho, čo ho napĺňa a najradšej by bol nekonečný a bezhraničný, aby mu život patril úplne a bez konca.

Večná blaženosť je radosť bez konca, šťastie bez tietra, láskas bez hraníc, plný život bez ochabnutia, činorodosť, ktorá je zároveň dokonalým pokojom a uvoľnením od všetkého napätia.

To je bytie, o ktoré človeku v tomto živote ide.

Edith Stein, 1891-1942
PRIORITISING OF WHO TARGETS - - PROGRAM „HEALTH FOR ALL IN 21st CENTURY".
The views of medical students

Vojtech Ozorovský, Ladislav Badalík

Institute of Social Medicine and Medical Ethics, Faculty of Medicine, Comenius University, Bratislava, Slovak Republic

The education of health professionals should be designed in accordance with health needs of the society and aimed at ensuring that they acquire the necessary knowledge. The education of health professionals at different levels should be strongly interlinked to create a continuous process. The strategies and content of education at different levels and branches should be defined accordingly.

In this paper, authors report on their repeated evaluation of the attitudes of different groups of students of the Faculty of Medicine, Comenius University in Bratislava, to the targets of the WHO strategy “Health for all in the 21st century” (1, 2, 3, 4, 5).

Material and methods

The sample of 17 students (English speaking foreign students) of the 4th class of general medicine studies at the Faculty of Medicine, Comenius University in Bratislava took part in a workshop and case study (Harward’s type) organized by the Institute of Social Medicine and Medical Ethics. Students were from 8 different countries (Norway 3, Greece 6, Spain 2, Sweden 1, United Arab Emirates 1, Kuwait 2, Canada 1, and Libya 1). The work in workshop was organized in 4 stages: 1. Forming, 2. Storming, 3. Norming, Performing. Among various other tasks at the workshop, each participant was asked to select for himself/herself three targets of those of the WHO strategy “Health for all in the 21st century” and to link them to the following categories (prioritize): 1. the most important, 2. very important, 3. important. After a thorough group discussion (2 hours) a consensus statement of the group was reported by a designated the reporter in the plenary session.

Results

The group of 17 medical students from 8 different countries was able to reach the following consensus with regard to prioritizing, from their perspective, the importance of the targets set in the WHO strategy “Health for all in the 21st century”:

1. Out of 21 targets of the WHO program, the target No. 4 “Health of young people” was evaluated as the “most important” by all students. Young people in the region should be healthier and better able to fulfill their roles in the society. In particular: a) Children and adolescents should have better life skills and the capacity to make healthy choices. b) Mortality and disability from violence and accidents involving young people should be reduced by at least 50%.

2. At the second place, as “very important”, the target No. 12 “Reducing harm from alcohol, drugs and tobacco” was picked up (“By the year 2015, the adverse health effects from the consumption of addictive substances such as tobacco, alcohol and psychoactive drugs should have been significantly reduced in all member states. In particular: 12.1. In all countries, the proportion of non-smokers should be at least 80% in over 15-years-olds and close to 100% in under 15-year-olds. 12.2. In all countries, per capita alcohol consumption should not increase or exceed 6 litres per annum, and should be close to zero in under 15-year-olds. 12.3. In all countries, the prevalence of illicit psychoactive drug use should be reduced by at least 25% and mortality by at least 50%).

3. In the third place, as “important”, the target No. 19 “Research and knowledge for health” was seen by the students (“By the year 2005, all member states should have health research, information and communication systems that better support the acquisition, effective utilization, and dissemination of knowledge to support health for all.”).

Discussion

The prioritising results achieved in our relatively small multinational group of students of medicine clearly cannot be generalized. However, we were pleased to see the interest and vigour the students exhibited when engaging in the discussion. They were bringing in their experience and also their more-less “lay” knowledge of the health problems present in their respective communities. We believe it was at least a good motivating exercise for these bright young people.

Our next positive experience was the very fact of reaching a consensus in this rather heterogeneous group of young people. Even if dealing with rather complex and difficult subject - medically, culturally, or even emotionally.

The weight, which the students were able to give to different priorities, should not be seen with regard of their background and prevailing interests. On the first sight, the chosen “top priority” may seem selfish. However, it also could be seen as a valid, prospective looking mental exercise, prioritizing prevention and good foundation for future health in productive age and, later on, also in a healthy aging. It is perhaps not a big surprise that these young adepts of contemporary and future medicine were mostly in a strong belief in research and medical knowledge.

Last, quite an obvious observation, does tell us that students change over time – new generations bringing in different positions, fresh thinking and new attitudes. At least this could be seen in comparing the present results with those of our previous surveys among the medical students of similar age. The targets, evaluated as the “most important”, were: No. 11 - Healthier living, No. 2 - Equity in health, No. 3 - Healthy start in life and No. 17 - Funding health services and allocating resources. No one was picked up by their peers, just one year younger. Qualitative research (QR) consists of a family of approaches to understanding human social activity. It is growing in popularity in the health related fields (6).

In conclusion, it may be observed that the issue of prioritizing the targets concerned with medical practice, health care and public health are of important interest to the medical students. The students are able to engage actively in lively discussions on these topics, while they are also able to reach consensus on these complicated and culturally/historically charged issues when working in a discussion group. Besides of the active learning and abilities developing benefit to students stemming from the teaching approach described in our paper, this “mental exercise” is also useful for planning of the teaching strategy for medical students and may well be used as a motivational and activation tool in undergraduate teaching of social medicine and ethics.

References

Abstract


Authors report the results of a small survey among the foreign medical students of the 4th class at Comenius University in Bratislava, concerning their subjective evaluation of the relative importance of the targets set in the WHO strategy “Health for all in the 21st century”. Altogether 17 English speaking students from 8 countries of the 4th class took part in the workshop and case study (Harward’s type). Of the 21 targets, the highest priority was given by the students to the target No. 4 – Health of the young people, which was followed by target No. 12 – Reducing harm from alcohol, drugs and tobacco, and target No. 19 “Research and knowledge for health”. Besides the other learning benefits to students, the teaching approach described in the paper is useful also for education planning purposes, and it may be used as a motivational and activation tool in undergraduate and postgraduate teaching of the social medicine and ethics.

Key words: WHO Strategy – Health for all in the 21st Century, targets, prioritising, views of medical students.

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Council of Europe

Committee of Ministers

Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin

Adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers' Deputies

The Committee of Ministers, under the terms of Articles 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that one of the aims of the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5) is the protection of private life;

Considering that the aim of the Convention on Human Rights and Biomedicine (ETS No. 164, hereinafter referred to as „the Convention“) and of its Additional Protocol concerning biomedical research (ETS No. 195), as defined in Article 1 of both instruments, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Considering that progress in medical and biological sciences, in particular advances obtained through biomedical research, including research using biological materials donated in a spirit of solidarity, contributes to saving lives and improving their quality;

Conscious of the fact that the advancement of biomedical science and practice is dependent on knowledge and discovery which necessitates research on human beings and research involving the use of biological materials of human origin;

Stressing that such research is often transdisciplinary and international;

Taking into account the current and planned development of collections and banks of biological materials at national level;

Taking into account national and international professional standards in the area of biomedical research and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Convinced that biomedical research that is contrary to human dignity and human rights should never be carried out;

Stressing that the paramount concern should be the protection of the human being whose biological materials are removed, stored or used for research;

Recalling that research on biological materials should be carried out freely subject to the provisions of this recommendation and the other legal provisions ensuring the protection of the human being;

Emphasising that the interests and welfare of the human being whose biological materials are used in research shall prevail over the sole interest of society or science;

Affirming that particular protection shall be given to human beings who may be vulnerable in the context of research;
Recognising that every person has the right to accept or refuse to contribute to biomedical research and that no one should be forced to contribute to it:

Stressing the importance of appropriate and transparent governance of biological materials stored for research purposes;

Stressing that population biobanks developed on the basis of donations of biological materials made in a spirit of solidarity should not be monopolised by small groups of researchers;

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to biomedical research on biological materials of human origin,

Recommend that the governments of member states adopt their laws and practices to the guidelines contained in appendix to this recommendation and promote the establishment of practice guidelines to ensure compliance with the provisions contained in this appendix:

Entrust the Secretary General of the Council of Europe to transmit this recommendation to the governments of the non-member states of the Council of Europe which have been invited to sign the Convention on Human Rights and Biomedicine, to the European Community and to the international organisations participating in the work of the Council of Europe in the fields of bioethics.

Appendix to Recommendation Rec(2006)4

Guidelines

CHAPTER I
Object, scope and definitions

Article 1 – Object
Member states should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, right to private life and other rights and fundamental freedoms with regard to any research governed by this recommendation.

Article 2 – Scope
1. This recommendation applies to the full range of research activities in the health field involving the removal of biological materials of human origin to be stored for research use.
2. It also applies to the full range of research activities in the health field involving the use of biological materials of human origin that were removed for a purpose other than that mentioned in the previous paragraph; this includes material removed for a previous research project.
3. This recommendation does not apply to embryonic and foetal tissues.
4. The use of biological material of human origin may be accompanied by the use of associated personal data.

Article 3 – Identifiability of biological materials
Biological materials referred to in Article 2 may be identifiable or non-identifiable:

i. Identifiable biological materials are those biological materials which, alone or in combination with associated data, allow the identification of the persons concerned either directly or through the use of a code.

   In the latter case the user of the biological materials may either:
   a. have access to the code: the materials are hereafter referred to as „coded materials“; or
   b. not have access to the code, which is under the control of a third party: the materials are hereafter referred to as „linked anonymised materials“.

ii. Non-identifiable biological materials, hereafter referred to as „unlinked anonymised materials“, are those biological materials which, alone or in combination with associated data, do not allow, with reasonable efforts, the identification of the persons concerned.

CHAPTER II
General provisions

Article 4 – Codes of good practice
Member states should promote the establishment of codes of good practice to ensure compliance with the provisions of this recommendation.

Article 5 – Risks and benefits
1. The risks for the persons concerned and, where appropriate, for their family, related to research activities, in particular the risks to private life, should be minimised, taking into account the nature of the research activity. Furthermore, those risks should not be disproportionate to the potential benefit of the research activities.
2. Possible risks for the individuals in the same group as the person concerned should also be taken into consideration in this context.

Article 6 – Non-discrimination
Appropriate measures should be taken, in the full range of research activities, to avoid discrimination against, or stigmatisation of, a person, family or group.

Article 7 – Prohibition of financial gain
Biological materials should not, as such, give rise to financial gain.

Article 8 – Justification of identifiability
1. Biological materials and associated data should be anonymised as far as appropriate to the research activities concerned.
2. Any use of biological materials and associated data in an identified, coded, or linked anonymised form should be justified by the researcher.

Article 9 – Wider protection
None of the provisions of this recommendation should be interpreted as limiting or otherwise affecting the possibility for a member state to grant a wider measure of protection than is stipulated in this recommendation.

CHAPTER III
Obtaining biological materials for research

Article 10 – Obtaining biological materials for research
1. Biological materials should be obtained for research in accordance with the provisions of this chapter.
2. Information and consent or authorisation to obtain such materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect.

Article 11 – Interventions on a person
An intervention should only be carried out to obtain biological materials for storage for research purposes if it complies with the Additional Protocol concerning biomedical research (CETS No. 195, 2005).

Article 12 – Residual biological materials
1. Biological materials removed for purposes other than storage for research should only be made available for research activities with appropriate consent or authorisation, or in accordance with the provisions of Article 22 paragraph 1.ii.
2. Whenever possible, information should be given and consent or authorisation requested before biological materials are removed.

Article 13 – Biological materials removed after death
1. Biological materials should not be removed from the body of a deceased person for research activities without appropriate consent or authorisation.
2. Biological materials should not be removed or supplied for research activities if the deceased person is known to have objected to it.

CHAPTER IV
Collections of biological materials

Article 14 – Principles applicable to all collections of biological materials
1. The person and/or institution responsible for the collection should be designated.
2. The purpose(s) of a collection should be specified. The principles of transparency and accountability should govern its management, including access to and use and transfer of its biological materials and disclosure of information.
3. Each sample of biological material in the collection should be appropriately documented, including information on any relevant consent or authorisation.
4. Clear conditions governing access to, and use of, the samples should be established.
5. Quality assurance measures should be in place, including conditions to ensure security and confidentiality during storage and handling of the biological materials.

Article 15 – Right to change the scope of, or to withdraw, consent or authorisation
1. When a person has provided consent to storage of identifiable biological materials for research purposes, the person should retain the right to withdraw or alter the scope of that consent. The withdrawal or alteration of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

When identifiable biological materials are stored for research purposes only, the person who has withdrawn consent should have the right to have, in the manner reseen by national law, the materials either destroyed or rendered unlinked anonymised.

2. Where authorisation has been given on behalf of a person not able to consent, the representative, authority, person or body provided for by law should have the rights referred to in paragraph 1 above.

4. Where a person on whose behalf authorisation has been given attains the capacity to give consent, that person should have the rights referred to in paragraph 1 above.

Article 16 – Transborder flows
Biological materials and associated personal data should only be transferred to another state if that state ensures an adequate level of protection.

CHAPTER V
Population biobanks

Article 17 – Scope of chapter V
1. A population biobank is a collection of biological materials that has the following characteristics:
   i. the collection has a population basis;
   ii. it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;
   iii. it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;
   iv. it receives and supplies materials in an organised manner.

2. Population biobanks should meet the requirements set out in this chapter in addition to those of chapter IV.
3. Member states should consider applying the provisions of this chapter to collections that have some, but not all, of the characteristics specified in paragraph 1.

Article 18 – Independent examination
A proposal to establish, or to convert a collection to, a population biobank should be subject to an independent examination of its compliance with the provisions of this recommendation.

Article 19 – Oversight of population biobanks
1. Each population biobank should be subject to independent oversight, in particular to safeguard the interests and rights of the persons concerned in the context of the activities of the biobank.
2. Regular audits should be conducted of the implementation of procedures on access to, and use of, samples.
3. Procedures should be developed for the transfer and for the closure of a population biobank.
4. Population biobanks should publish reports on their past and planned activities at least annually, or more frequently if appropriate.

Article 20 – Access to population biobanks
1. Member states should take appropriate measures to facilitate access by researchers to biological materials and associated data stored in population biobanks.
2. Such access should be subject to the conditions laid down in this recommendation; it may also be subject to other appropriate conditions.

CHAPTER VI
Use of biological materials in research projects

Article 21 – General rule
Research on biological materials should only be undertaken if it is within the scope of the consent given by the person concerned. The person concerned may place restrictions on the use of his or her biological materials.

Article 22 – Identifiable biological materials
i. If the proposed use of identifiable biological materials in a research project is not within the scope of prior consent, if any, given by the person concerned, reasonable efforts should be made to contact the person in order to obtain consent to the proposed use.

ii. If contacting the person concerned is not possible with reasonable efforts, these biological materials should only be used in the research project subject to independent evaluation of the fulfilment of the following conditions: the research addresses an important scientific interest; the aims of the research could not reasonably be achieved using biological materials for which consent can be obtained; and there is no evidence that the person concerned has expressly opposed such research use.

2. The person concerned may freely refuse consent for the use in a research project of his or her identifiable biological materials, or withdraw consent, at any time. Refusal to give consent or the withdrawal of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.
Article 23 – Unlinked anonymised biological materials
1. Unlinked anonymised biological materials may be used in research provided that such use does not violate any restrictions placed by the person concerned prior to the anonymisation of the materials.
2. Anonymisation should be verified by an appropriate review procedure.

Article 24 - Independent review
1. Research should only be undertaken if the research project has been subject to an independent examination of its scientific merit, including assessment of the importance of the aim of the research, and verification of its ethical acceptability. National law may additionally require approval by a competent body.
2. Member states should apply the provisions concerning ethics committees contained in chapter III of the Additional Protocol concerning biomedical research (CETS No. 195, 2005) to the review of research within the scope of this recommendation.
3. Review procedures may be adapted to the nature of the research and the extent to which the persons concerned could be identified from their biological materials or associated data.

Article 25 – Confidentiality and right to information
The principles of chapter VIII (confidentiality and right to information) of the Additional Protocol concerning biomedical research should be applied to any research project using biological materials and associated personal data.

CHAPTER VII
Review-examination of the recommendation

Article 26 – Re-examination of the recommendation
This recommendation should be re-examined not more than five years after its adoption, notably in the light of the experience acquired in the implementation of its guidelines.

Text of the Recommendation is taken from the official web page of Council of Europe at http://www.coe.int, where also Explanatory Report to the Recommendation could be found and downloaded.
Veľmi potrebná a originálna monografia predstavuje viac, ako púšť úvod do problematiky štúdia demografie, ako autor skromne uvádza v názve i úvodnej kapitole. Ide o očišťovacie a veľmi vydaný pokus poskytnúť v našich podmienkach ucelený a prakticky orientovaný príehľad demografickej problematiky pre všetkých záujemcov o serióznu orientáciu v týchto zložitých otázkach a v ich súťaži súvislostiach.

Aktuálnosť témy podčiarujú aj závažné dôsledky demografických procesov, ktoré začali v rozvinutých (i rozvojových) krajínach EÚ a sveta v minulom storočí – a v súčasnosti predstavujú základné existenčné problémy života a budúcnosti (post)moderných spoločností týchto krajín (a tiež významnú agendu ich vlád, parlamentov i medzinárodnej organizácie a inštitúcií – až po úroveň OSN). Pritom účinne riešenia týchto postupne nahromaďujú sa podobne ako ucelené a prakticky orientované príehľady demografickej problematiky pre študiu významných (v)kladov môže podarovať, že sa snažili zaplniť túto právdu všetkým možným spôsobom. Otočenie (i gratulácia), že sa pousilovali zaplniť túto príležitosť a vo svetle práve náležite domyslených a podstatné zmeny v sociálno-ekonomickej, ale predovšetkým v kulturnej a mravnnej oblasti (ako sa pri rozličných príležitostiach a vo svetle práve náležite domyslených a správne interpretovaných vyššej štúdia demografických procesov zreteľne ukázalo).

Zodpovedná spoločnosť, zvláštne jej „intelektuálna vrstva“ a zodpovedné verejné predstaviteľia nesmú (a dnes vlastne už ani nemôžu) tieto skutočnosti a procesy neviedieť (a dôjazne aj „neriešiť“). Dnes aplikované riešenia, optatnosti, progamy a sociálno-kultúrne zmeny, ktoré by sa využívalo nové strategické myslenie a komplexné zvládnutie problematiky na jej teoretickej i aplikačnej úrovni, a ktoré by sa v našej súčasnosti využívalo zásadné a nemále investicie (materiálne i ľudske) a tiež výraznú zmenu vzorcov individuálnego i spoločenského správania (vrátane správania sexuálneho a reprodukčného), však môžu priniesť svoje plody a úžitok až v dlhodobejších súvislostiach. Zodpovednosť voči budúcnosti sa však nevyzriatí, nevyhnutí, nie sa bude dobro spravovať, ale až sama zadávať na svet, ktorému sa tehdejšie pokusí poviniť svoje praktické úlohy – v štátnej správe, pastoračnej službe, vede, či politike – komunálnej i „veľkej“) získatť spopáľhivú orientáciu a hlubší príehľad demografickej problematiky v jej najvýznamnejších praktických súvislostiach.

Publikáciu možno odporúčať nielen studentom huminých disciplín (vrátane štúdia sociálnej práce, sociálnej a rodinné politiky), ale aj všetkým, ktorí potrebujeť (či už pre svoje praktické úlohy v štátnej správe, pastoračnej službe, vede, či politike – komunálnej i „veľkej“) získať spopáľhivú orientáciu a hlubší príehľad demografickej problematiky v jej najvýznamnejších praktických súvislostiach.

Doc. MUDr. Jozef Glass, CSc. ÚMEB n.f., Bratislava

Etika, sex, reprodukce


Útla svojimi rozmermi, prináša táto pozoruhodná knižka neobyčajné pôsobivý a hlbozí pohľad na celý rad kľúčových problémov súčasnej bioetiky – a to práve na tie, ktoré súvisia s počiatkom ľudskeho života a novými možnosťami technologie a vedy do týchto tajomných, a dosiahť zvýjčajne pred ľudským zrakom a pozornosťou ukrývajúce takých procesov, ktoré ľudia pre svoje práctické úlohy – v štátnej správe, pastoračnej službe, vede, či politike – komunálnej i „veľkej“) získatť spopáľhivú orientáciu a hlubší príehľad demografickej problematiky v jej najvýznamnejších praktických súvislostiach.

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(doc. MUDr. Jozef Glass, CSc.)

Konferencie, kongresy v roku 2006–7
Conferences, Congresses in 2006–7

- Beyond Therapy: Ethical and Social Aspects of Medical and Genetic Enhancement of Human Properties, Pre-dispositions and Capabilities, 24 March – 2 April 2006, Bonn (Germany), contact: The Institute of Science and Ethics at the University of Bonn, web: www.iwe.uni-bonn.de.
- Genomics and Society - Towards a Socially Robust Science, 20 – 21 April 2006, Amsterdam (The Netherlands), contact: e-mail: info@management-forum.co.uk , web: www.management-forum.co.uk.
- The EU Clinical Trial and GCP Directives, 25 - 26 April 2006, London (UK), contact: Management Forum Ltd, 48 Woodbridge Rd, Guildford, GU1 4RJ, United Kingdom, e-mail: info@management-forum.co.uk , web: www.management-forum.co.uk.
- Death without Suffering: Advanced Bioethics Course, 27 - 29 April 2006, Nijmegen (The Netherlands), contact: N. Steinkamp, V. Hulsman, University Medical Centre Nijmegen, 2232 Department of Ethics, Philosophy and History of Medicine, P.O. Box 9101, 6500 HB Nijmegen, NL, tel: +31-24-5615320, fax: +31-24-3540254, e-mail: n.steinkamp@efg.umcn.nl.
- European Society for Philosophy of Medicine and Healthcare, 23-26 August 2006, Helsinki (Finland), contact: Dr. Bert Gordijn, Department of Ethics, Philosophy, and History of Medicine, Radboud University Nijmegen Medical Centre, P.O. Box 9101, 6500 HB Nijmegen, NL, e-mail: b.gordijn@efg.umcn.nl.