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An issue, mainly for those countries and perhaps less pertinent now than in the past, has been the extent to which ethical principles are considered universal or as culturally relative – the universalist versus the pluralist view. The challenge to international research ethics is to apply universal ethical principles to biomedical research in a multicultural world with a multiplicity of health-care systems and considerable variation in standards of health care. The Guidelines take the position that research involving human subjects must not violate any universally applicable ethical standards, but acknowledge that, in superficial aspects, the application of the ethical principles, e.g., in relation to individual autonomy and informed consent, needs to take account of cultural values, while respecting absolutely the ethical standards.

Related to this issue is that of the human rights of research subjects, as well as of health professionals as researchers in a variety of sociocultural contexts, and the contribution that international human rights instruments can make in the application of the general principles of ethics to research involving human subjects. The issue concerns largely, though not exclusively, two principles: respect for autonomy and protection of dependent or vulnerable persons and populations. In the preparation of the Guidelines the potential contribution in these respects of human rights instruments and norms was discussed, and the Guideline drafters have represented the views of commentators on safeguarding the corresponding rights of subjects.

CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva, 2002, p. 11.

BIOETHICS, SPORT AND THE GENETICALLY ENHANCED ATHLETE

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Abstract

This paper begins by acknowledging the interest taken by various international organisations in genetic enhancement and sport, including the US President's Council on Bioethics (July, 2002) and the World Anti-Doping Agency (March, 2002). It is noticed how sporting organisations have been particularly concerned to emphasise the 'threat' of genetics to sport, whereas other institutions have recognised the broader bioethical issues arising from this prospect, which do not readily reject the use of genetic technology in sport. Sports are identified as necessarily 'human' and 'moral' practices, the exploration of which can reveal greater insight into the intuitive fears about genetic modification. It is argued that anti-doping testing measures and sanctions unacceptably persecute the athlete. While there are substantial reasons to be concerned about the use of genetic modification in sport, the desire for policy ought not diminish the need for ethical research; nor ought such research embody the similar guise of traditional 'anti' doping strategies. Rather, the approach to genetics in sport must be informed more by broader social policies in bioethics and recognition of the greater goods arising from genetic technology.

Key words: bioethics, sport, gene doping, athlete, fair play, enhancement

Introduction

The prospect of using genetic technology to augment athletic performance is, for many, an abhorrent misuse of science. Prima facie, there are far more worthwhile uses to which genetics can be put. Additionally, the genetic science does not yet seem anywhere near being able to enhance humans safely, or with any certainty of the effects. Yet, the climate of performance modification in sport has provoked concerns about whether athletes will now seek the use of genetic modification (GM) to evade anti-doping testing procedures. Consequently, the topic has given rise to questioning the merits of genetically modified athletes and, particularly, how we can ensure that such humans do not emerge. To this extent, the emerging discourse about GM in sport has already become one of prevention, not of reflective value questioning. GM sport has already been concluded by key sporting organisations such as the International Olympic Committee (IOC) and the World Anti-Doping Agency (WADA) as unethical, nay, immoral. Their strategy is to establish the means by which it is possible to maintain a distance between GM and sport.

While recognising that there are good reasons to be weary of GM in sport, I argue that this approach overlooks a significant philosophical opportunity, which is provided by the prospect of genetically modifying athletes. Such a possibility offers a tangible human and social context within which it is possible to question the value of genetic technologies more deeply. Sport is a context about which many people have strong feelings of there being a valued 'human' and 'moral' component that seems threatened by genetically modifying people. Exploring what these components are, I suggest, can provide greater insights into our understanding of what is valuable about being human and why this is challenged by genetic manipulation. It is partly for this reason that I critique the 'anti' position in regard to GM in sport. However, my rationale for considering this topic is also based upon the specific ethical issues, which are facing sporting authorities, as well as emerging scientific research that indicates why genetically modified athletes are imminent.

Who Cares About GM Sport?

It is only in the last 2 years that any serious attention has been given to the prospect of GM in sport both in the academic literature and in the organisation of sport. Yet, a significant amount of research has taken place in sport regarding the ethics of performance enhancement in sport generally. This work has emerged largely out of the sporting side of ethics, rather than biomedicine, emanating significantly from post-1980 volumes of the *Journal of the Philosophy of Sport*, journal of the International Association for the Philosophy of Sport, established 1972. These articles range in their method of argumentation, a number of which include the following:

1. Coercion: Permitting drug use is permitting an environment that forces athletes into choosing drugs to remain competitive, thus risking harm to their life. (8, 11, 29, 34, 36).

2. Unfair: Permitting drug use has some unfair consequence for either the participating athletes, other members of the sporting community, or over the sport itself. (8, 11, 14, 28, 31, 34, 35, 36).

3. Health Risk: Permitting drug use entails a substantial risk to the biological constitution of an athlete, which is unacceptable, unnecessary, and undesirable. (3, 11, 28, 31, 34-36).

4. Unnatural: drugs are unethical because sporting performances are supposed to be natural, which drugs are not. (9-11, 28, 30, 35).

5. Rule Breaking / Cheating / Respect: Drug taking is unacceptable because it is against the rules. Thus, using them is cheating and demonstrates a lack of respect for other participants and the sport. (1, 10, 33, 34).

6. Unearned advantage: Because drugs are not permitted, using prohibited drugs provides an unfair advantage over other competitors and the sport (5).

7. Contrary to / Does not promote the internal goods of sport: Sport is valued because of the 'internal goods' (16) and the use of drugs does not contribute and is contrary to such goods. As such, it is unethical. (30).

8. Contrary to the nature of sport: Sport has an internal essence that is compromised by the use of drugs. As such, their use is unethical. (34, 36).

9. Contract Violation: Entering into sporting competition entails making a tacit contract with one's opponent to play under the same conditions, failing to do this by using drugs which are not agreed upon means, breaks this contract. (4, 6, 7, 13, 22, 36).

However, bioethics writers such as Thomas H. Murray (25-27), Christian Munthe (23, 24) and Michael Shapiro (32) have given some time to considering the ethics of performance modification in sport, even mentioning the prospects of GM. Indeed, Shapiro's extensive consideration of performance modification in sport provides a very useful conceptual framework from which to depart in

understanding why GM is alarming in sport, both for athletes and the broader social community.

This work has focused largely on drug use, though the broader category of 'doping' has also been included. The definition of doping seems important to clarify, though is a somewhat befuddling term. Of course, organisations such as the IOC and WADA do give it a specific definition, as have governmental organisations, such as the Council of Europe (CoE) and UNESCO. For example, one of the earliest definitions, given by the IOC was that doping is,

The administration of or use by a competing athlete of any substance foreign to the body or any physiologic substance taken in abnormal quantity or taken by an abnormal route of entry into the body with the sole intention of increasing in an artificial and unfair manner his/her performance in competition. (IOC, 1963, cited in 10, 39).

This remains a useful definition to critique in order to understand why it is that anti-doping policy began on a route that has been lacking in philosophical rigour, since its employment of such terms as 'abnormal', 'intention', 'artificial' and 'unfair' have been challenged in all manner of ways. The definition is useful also because these terms tend often to be used as intuitive reactions to why drug use is wrong.

Importantly, the new international body WADA has recently revised its anti-doping code, distinguishing bet-ween substances that are performance enhancing (illegal) and those that are not (legal). This comes in reaction to anti-doping critics who claim that the role of sporting organisations in prohibiting the freedoms of athletes (qua humans) has long been overstated by the restrictions within the anti-doping code.

However, its definition remains unclear and philosophically suspicious. For example, it is not often considered that one solution to the argument of fairness could be to make all forms of doping legal. On this basis, nobody would have an advantage over others. Alternatively, the concept of what is artificial or natural seems to have little strength when the training regime of non-doping athlete is, itself, highly unnatural. For some sport ethicists, it is not evident that the anti-doping efforts are anything more than a political wrangling and media circus, given the vast inconsistencies between, for example, the rejection of drugs and the acceptance of new sports equipment, which each seem to be used for the same purpose. This problem is exacerbated by the prospect of genetic modification.

Outside of sport, the Australian Law Reforms Commission (ALRC) published a paper in 2001 about the legal concerns for the use of genetic information. Within this document, they devoted a section specifically to such concerns in the context of sport. Here the ALRC is worried about the potential for discrimination against athletes on the basis of their genetic disposition. They state, genetic testing may lead to discrimination against certain athletes. For example, an athlete with a susceptibility to a particular injury may never in fact develop the injury, but may be dropped from the team by management in an effort to avoid potential liability if the injury manifests. Alternatively, a sports co-ordination body may seek to impose certain conditions on players to minimise its own liability for any injuries they may suffer. For example, the Professional Boxing and Martial Arts Board (Vic) has proposed the genetic testing of all professional boxers in Victoria as a condition of their license to fight (2, section 12.29, HTML).

The most recent institution to take an interest in genetic enhancement in sport has been the United States President's Council on Bioethics (38). On 11 July 2002, the Council met and received a paper from Dr. Ted Friedmann, who also sits on the WADA Executive Board and who has been active in WADA to raise the genetics issue. The meeting was titled the 'Potential for Genetic Enhancements in Sports' and the conclusions varied significantly from arguing that GM threatens a 'romantic' view of sport, to arguing GM as integral of the 'technological-rationality' of contemporary elite sport.

Is GM for Sport Possible?

It is widely recognised that the present level of sophistication in genetic research is such that the applications to sport are highly unlikely. With relatively few successes in gene therapy, the prospects for genetic enhancement seem uncertain, though pessimistic. However, this is not any basis on which to conclude, therefore, that the possible applications to sport are of no serious ethical concern. It is possible to identify a number of emerging studies in genetic science, which could lead into sporting applications. For example, two of the major concerns for the US President's Council on Bioethics were IGF-1 or insulin-like growth factor, which has the medical purpose of treating muscle wasting disease, though might be used by athletes for boosting muscle mass. Research in this area is being undertaken by Dr. H. Lee Sweeney at University of Pennslyvania (USA) and separately, Geoffrey Goldspink at the Royal Free and University College Medical School in London, who have made similar findings. Using a form of IGF-1 called mechano growth factor (MGF) with mice, which is used to treat muscle-wasting diseases such as muscular dystrophy, Goldspink's team were able to isolate muscle tissue and insert the MGF gene. The results showed an increase in muscle mass by approximately 20 percent after two weeks.

At Harvard University, Dr. Nadia Rosenthal used IGF-1 in gene therapy in mice to halt depletion of muscle strength that comes with old age. As Rosenthal notes, „Older mice increased their muscle strength by as much as 27 percent in the experiment, which suggested possibilities for athletes as well as for preserving muscle strength in elderly people and increasing muscle power in those who suffer from muscular dystrophy" (cited in 15).

The other concern of the US President's Council on Bioethics was genetically engineered erythropoietin (EPO), which has the potential to increase endurance capabilities, though its medical application is to increase the hematocrit level in patients with chronic renal disease. Research identifies the effects of inserting genes into a virus to produce a specific bodily effect. For example, at the University of Chicago, Jeffrey Leiden used an adenovirus to deliver EPO to mice and monkeys, to observe whether it would render a difference in biological capabilities. By inserting the gene into a virus strand, it was transported throughout the body and did, indeed, have the effect of increasing the level of red blood cells that were being pumped around the body. In performance, this produces a similar effect to that of blooddoping, which operates on a similar principle by reintroducing blood into the body to boost the amount of oxygen being transported around the body, to off set fatigue. Thus, genetically inserting EPO into an athlete could increase the capabilities for endurance when active, which would be useful for any long distance event. Similar work has been conducted by Dr. Steven Rudich, of University of Michigan, where inserting EPO into the leg muscles of monkeys produced a significantly elevated red blood cell level for 20 to 30 weeks (15).

Other emerging research from Lin et al. (12) includes the gene 'PGC-1', which is known to tell other genes in muscle whether they should be turned on or off. The implications of manipulating this gene entail the possibility of being able to switch on those muscle fibres (fast or slow twitch) which are most conducive to an athlete's

chosen sport. Alternatively, the ACE gene (angiotension-converting enzyme) has been received by Montgomery et al. (20, 21) and is claimed to be associated with endurance capabilities. Collectively, these findings are providing a scientific basis for arguing why there are serious concerns about the ethical status of sport in the era of genetic modification and this seems reflected by the breadth of institutions, which are taking this matter seriously.

Could Genetically Modified Sport be Good?

Engaging with the suggestion that GM might actually be good for sport is absent from any of the opinions in international sport. To suggest that GM is a legitimate means, by which an athlete could enhance their performance, seems incomprehensible by most. However, a deeper account of the rationale behind anti-doping policies in general and subsequently applied to genetics reveals some inconsistencies and some basis for seeking genetically modified athletes.

One of the major criticisms of organisations like WADA (it is one of many other bodies, such as the Australian Sports Drug Agency or the United States Anti-Doping Agency) is that it unfairly persecutes the athlete through its policies. Even if one has moral concerns about the athlete's using drugs, there are even more serious moral issues regarding how an athlete becomes nationally and internationally persecuted through relatively minor acts within sport. Such concerns for the athlete's well being are equally, if not more, alarming than the fact of them taking some banned substance. For example, the ingestion of minute amounts of banned substance or the taking of cold remedies are among the 'drugs' that can produce a scandal in many newspapers. From a moral perspective, it seems excessive (and harmful) to demonise a person so very much on account of using such soft substances to try and beat others in sport. This concern is comparable to that which is also highlighted by the ALRC (2) document on genetic information.

Additionally, anti-doping policies have been criticised because they *only* target the athlete. Regarded as an independent, rational, free-choosing agent, the athlete is seen as having sole responsibility for ingesting banned substances. Yet, athletes do not act alone. Rather they are part of a larger entourage and system of significant others including coaches, sponsors, family, and other supporting scientists - including medical doctors who have been known to prescribe the drugs needed to boost an athlete's performance or to treat the individual as an athlete rather than as a patient. Such people do have some part to play in having created this 'culture' of doping, as it is widely regarded.

Certainly, public opinion is against drugs in sport, but it can be questioned how much of this opinion is based upon sound engagement with the ethical and moral issues the matter raises rather than the broad, social ambivalence towards drugs in general. Many societies embody an anti-drug taking attitude, despite readily accepting the use of some stimulants and depressants as part of their daily life. It is worth noting that caffeine is regarded as unacceptable if an athlete is found with too much of it in their body. It is also worth noting that very little scientific evidence is available to demonstrate whether performance-enhancing drugs do actually have any effect on performance. If the response by anti-doping policy makers is the 'health' argument (as noted above), then they must also be able to justify why certain kinds of health risks are acceptable over others. As well, it must be considered why it is that an approach of paternalism is warranted in the case of sports, where it is not in other professions.

Thus, with GM looming, the basis for forming ethical policy might not best be informed by the approach described as 'anti-doping'. Indeed, it might not do to be 'anti-genetics' at all. As with any new technology, rational persons are rightfully concerned about potential abuses. However, the critical question facing WADA ought to be what constitutes an abuse of such technology and why. The controversial conclusions are whether any kinds of GM or use of genetic technology at all are acceptable in sport. The perspectives of key figures in world sport are already relating the technology to drugs and so a similar way of approaching these performance enhancers is beginning to ensue. Yet, it is not clear that GM is analogous to the drug issue, especially since the ethical issues arising from genetics outside of sport seem qualitatively different from ethical issues concerning drug use. At most, there are some forms of GM that are comparable to other forms of doping in sport. For example, somatic-cell modification can confer similar benefits to the blood-boosting process of blood doping, where blood is removed from the body and then introduced at a later date to boost the red blood-cell count and promote endurance capacity.

However, while I have set out some reasons for doubting the unethical status of GM in sport, it is not clear whether genetics might actually be 'good' for sport. In response, it is necessary to question the role of genes in sport. Currently, sport is an activity where 'genetic-luck' is accepted as a given circumstance of competition. Thus, even if one cannot claim that genetic variance enhances sporting value, it seems evident that it most certainly does not enhance such value for the genetically disadvantaged. However, sport can be seen as being partly a test of what is humanly possible and that this involves a genetic component. On this view, sport performances have value partly for them being a reflection of what a human being can achieve biologically and without artifice. As such, in a similar way to how drug use is unacceptable, GM is unacceptable because it prevents us appraising a performance as being human. This approach can be criticised on account of having *never* been clear that such claims are at all possible. Indeed, this argument is comparable to the 'romantic' view of sport, articulated within the U.S. President's Council on Bioethics meeting on genetics and sport. Yet, an athlete's performance has always been tainted by the technology they employ, whether it is new running shoes, faster swimming costumes, or drugs.

On another view, genetic difference is negative and - following the 'level playing field' argument where the ethical ideal is to ensure all athletes begin from the same starting point - it is desirable to try and omit such inequalities to ensure that only characteristics such as 'effort' or 'training hours' are evaluated. Accepting this, GM might be useful to try and promote genetic parity between competitors, though the argument must also recognise that GM might not confer similar effects on different persons. As such, the argument might have only to be libertarian rather than egalitarian, ensuring that, at least, people have the chance to lessen their disadvantages, even if their final circumstances might not ensure equality for all.

A further matter arises in respect to the prospect of GM outside of sport and how this might impact upon sport. So far, the discussion has focused primarily upon post-natal GM, though it has not yet been considered what ought to be the position of sporting authorities if faced with a human being who has been engineered before birth and who has a particularly advantageous genetic disposition for a particular kind of sport. It does not seem justifiable to exclude such persons from competition on account of them having transgressed some ethical rules since they will not have done anything wrong. Rather, if there is any wrong that has been done, then it will have been done on their behalf by those who

decided to enhance them. The exclusion of such persons from sport implies a discrimination of persons based upon their genetic disposition that does not sit well with broader policy about genetics.

These arguments, which loosely seem to be in favour of engaging with the possibility that GM is *not* inconsistent with sport, can be contrasted with other bioethical concerns about such applications. The appeal to the rights of the unborn not to be disadvantaged by sporting policy that prevents their participation in competitive sport must be balanced with the concern about what it means to engineer a life for a given purpose. If, as an extreme (and unlikely) case, it is possible to engineer an embryo to become a better tennis player, then we would rightly be concerned for the motivations of a parent or guardian for seeking to engineer their child for such a specific future. Thus, one of the major concerns about engineering a child for sport, or any highly specialised pursuit, is that it implies a sense of objectifying life - treating that life as a means to an end, rather than an end in itself. In sport, this problem is particularly acute, as it seems many parents are overly influential in their children's choices to train quite as hard as is necessary to become elite. At a deeper level, one can question whether a parent or guardian should have the authority to modify the genes of their future offspring in such cases.

More likely than not, this is an immediate and insurmountable ethical issue within medicine, which would prohibit the freedom to make such choices. However, there are important fuzzy boundaries to this matter, as has been indicated by the recent questioning of sex selection and its legitimacy. Potentially, the modification of embryos for sporting reasons could be justified on similar 'parental freedom' bases as might be argued in the case of sex selection and it need not imply that the parents are overly objectifying their future child. It might simply entail that they have a clear and defensible vision about what is best for the future of their child and this is more problematic to criticise. Additionally, it does not dismiss the possible circumstances whereby a 'health related' GM gives rise to a potential performance advantage for sporting competition. In such instances, further argumentation would be necessary for considering whether this is acceptable, since it would be very difficult to argue the modification as being ethically unacceptable. Indeed, in such circumstances, any discussion about sport would be secondary.

Conclusion

It can be quite popular to agree with WADA and feel an affinity with what it is trying to prevent. Similarly, it is understandable that people feel sympathy with anti-drug campaigns in general, regardless of whether it is drugs in sport. However, there is an ethical component to the sporting issue that demands an adherence to philosophically rigorous arguments. While there seems to be a lot of fuss made about the use of drugs in sport, it is not always the case that such anti-doping policies are well formulated or that they only prohibit the kinds of drugs that we are really concerned about. Thus, it is not just anabolic steroids that are prohibited; it is also caffeine and alcohol or nasal decongestants. It is not necessarily the case that an athlete who has been found guilty of having ingested a banned substance is trying to cheat their fellow competitors or has no respect for sport. As well, it need not be the case that the genetically modified athlete is cheating sport or other athletes. If such technology is made safe, or if a person finds himself or herself to be genetically modified in a manner that is conducive to being good at a particular sport, then this does not justify their being disqualified from competition on account of some prescribed concept of fair play.

Equally, the use of performance modification in sport must be re-appraised. As I indicated at the outset of the paper, one of the more interesting reasons for considering GM in sport is that it can reveal some greater insight into the use of enhancement technologies more generally. In respect of sport, the case of GM calls for an entire re-evaluation of enhancement in sport, bringing into focus a number of taken-for-granted assumptions about elite sport. It ought not be construed solely as an extension of anti-doping policy. From such a perspective GM is a small part of a general obsession with enhancement, which sport participants and fans seems to value. Thus, GM in sport is an opportunity to question the development of technology aimed at enhancing the performance of the athlete, which might demand the conclusion that performance-based sport as an indication of value, is highly impoverished. It might, for example, give rise to re-questioning the moral limits of 'parental autonomy', a particularly entrenched value within Western society.

By extension, the role of bioethics in this debate can be to inform the scope of sports ethical discussions. It is not sufficient for this discussion to remain at the sporting value, though its rich context of contested values can provide a means for grounding bioethical debates about genetic engineering in a social context. Until now, the discussions in sport have focused largely upon sport as a self-contained system of logic and ethics. Sports operate through their own internal logic and rules, without much recourse to broader social values, although overlaps can be identified. Nevertheless, questioning what it means to be a technological-human remains largely un-touched (9). Moreover, the context of genetic technology has been explored only recently in sports ethical discussions (17-19, 23, 24, 37). Genetics in sport is providing a welcome departure from this internal logic, making explicit the broader ethical links with, for example, medicine, which has also been under-researched in relation to the drug issue. However, in so doing the approach must also be to recognise that genetically modified athletes might actually be desirable in sports or, at least, impossible to disqualify.

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Miah, A.: Bioethics, Sport and the Genetically Enhanced Athlete. [Bioetika, šport a geneticky zvýhodnený atlét.] Med. Eth. Bioet., 9, 2002, No. 3 - 4, p. 2 - 6. Práca začína konštatovaním záujmu, ktorý o problematiku „genetického zlepšovania" (angl. genetic enhancement) vo vzťahu k športu prejavujú viaceré medzinárodné inštitúcie, vrátane Rady prezidenta Spojených štátov amerických pre bioetiku (júl 2002) a Svetovej protidopingovej agentúry (marec 2002). Všíma si, ako športové organizácie v tejto súvislosti predovšetkým zdôrazňujú „hrozbu" zo strany genetiky pre šport, kým iné organizácie si viac všímajú širšie bioetické skutočnosti, ktoré súvisia s touto problematikou, pričom ich odsúdenie použitia genetickej technológie v oblasti športu nie je také jednoznačné. Športové odvetvia treba považovať za nutne „ľudské" a „morálne" činnosti, pričom analýza týchto ich aspektov môže lepšie osvetliť intuitívne obavy z genetickej modifikácie v oblasti športu. Autor tvrdí, že protidopingové testovacie opatrenia a sankcie neakceptovateľne prenasledujú športovcov. Hoci existujú podstatné dôvody pre obavy zo zneužitia genetickej modifikácie v oblasti športu, snaha o rýchle zavedenie určitých smerníc by nemala znamenať zníženie potreby ďalšieho bioetického skúmania tohto problému; pričom takéto skúmanie by sa nemalo obmedziť iba na prístupy tradičného „antidopingového" pohľadu. Naopak, skúmanie vzťahu genetiky a športu by malo byť informované širším bioetickým hľadiskom a poznaním väčších dobier, ktoré prináša genetická technológia. ***Kľúčové slová***: bioetika, šport, génový (genetický) doping, športovec, fair play, „genetické zlepšovanie" (genetic enhancement).

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BORDERLINE VIABILITY RESUSCITATION CASES

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Abstract

Decisions on whether to resuscitate severely premature infants are especially difficult in „borderline viability" cases - those cases where the probability of survival is slim, and where, if survival is possible, multiple co-morbidities and severe disabilities are likely. The 2000 *International Guidelines on Cardiopulmonary Resuscitation* are comprehensive, yet leave open some of the more difficult ethical questions that must be addressed by decision-makers. This paper recommends evidence-based, clinical ethical guidelines for neonatal resuscitation, drawing on one large Catholic health system's approach, arguing from the perspective of the Catholic moral tradition and the *Ethical and Religious Directives for Catholic Health Care Services* (the ERD are policy for all of Catholic health care in the U.S). The paper presumes that there is an inherent dignity of the human person to be respected and protected regardless of the nature of the person's health problem or social status. But it also presumes and argues that treatments can be justified only by a proportionate benefit to the patient. In maintaining a holistic view of the human person, two extremes are avoided: a „vitalistic" approach where life is preserved at all costs; and the „easy" alternative of euthanasia. Several principles of medicine, theology, ethics and Anglo-American common law are applied to three categories of preterm infants, each of which calls for a different basic response: Category I - infants with a confirmed gestational age of < 23-0/7 weeks; Category II - infants with a confirmed gestational age between 23-0/7 and 25-0/7 weeks; and Category III - infants with a gestational age > 25-0/7 weeks. Studies show that survival rates and outcomes vary dramatically for these three groups, even with the availability of the latest technologies.

Key Words: neonatal resuscitation; guidelines; severely premature infants; borderline viability; evidence-based; treatment decisions; Catholic moral tradition; inherent dignity; human person; holistic view; proportionate and disproportionate means; medical futility; euthanasia

Introduction

Sometimes a decision about whether to resuscitate a premature infant is relatively simple to make. In one case, the newborn is relatively far along in gestational age (>26 weeks), is of good weight, and will be delivered at a fully equipped level II or III NICU (Neonatal Intensive Care Unit) with a skilled team of professionals standing by who have anticipated the delivery, and have made adequate preparations and accurate evaluations. In another case, the baby is below 20 weeks gestation - no special facility or amount of technical skills will save the baby. Then there are those cases of borderline viability - e.g., babies born at 23-0/7 weeks gestation. The outcomes are far less predictable in such cases, and the appropriateness of a resuscitation decision more ambiguous.

The International Guidelines Conference on Cardiopulmonary Resuscitation, gathering in February of 2000, assembled experts from many fields from all over the world, including neonatal resuscitation, producing strong

evidence-based *International Guidelines for Neonatal Resuscitation*.[1] The ethics segment of those guidelines argue that changes in resuscitation and intensive care practices and neonatal outcomes make it imperative that all protocols be reviewed regularly and modified as necessary. This paper considers what the ethics portion of such protocols might contain to facilitate decision-makers. Should a live-born infant always be resuscitated? Should professionals always acquiesce to parental demands for resuscitation or non-resuscitation? When would it be ethically appropriate not to resuscitate? Although the law will vary from state to state, a dialogue with the Catholic moral tradition can shed some meaningful light on these questions.

Principles

Neonatal resuscitation decisions should take into account the intrinsic value of the individual infant, the reasonable wishes of the parents (if known), normative principles, and concrete circumstances including the likelihood of the infant's survival, known or expected co-morbidities and anomalies, expected burdens and benefits and risks of treatment or non-treatment, and expected outcomes-all within the realistic limits of medical practice.

Consistent with Catholic moral teaching, as summarized by the *Ethical and Religious Directives for Catholic Health Care Services* (ERD)[2], Catholic health care facilities are committed to the claim that „the inherent dignity of the human person must be respected and protected regardless of the nature of the person's health problem or social status" (ERD, 23). Rooted in this inherent dignity and fundamental value is the right to life to which every person, no matter how vulnerable, has an inalienable claim.[3] However, although this right to life is inviolable, our obligation to preserve life by the application of a particular treatment is limited and „can be justified only by a proportionate benefit to the patient" (ERD, 33). If physical life were the highest value of the human person, what would constitute a „proportionate benefit" could be measured simply by the likelihood of survival. Some might assume that any *chance* of survival would demand a decision to resuscitate. But the Catholic moral tradition suggests otherwise. Physical life is not, we believe, the highest value of the human person, to be protected or preserved at all costs. As Pope Pius XII reminds us, „life, health, all temporal activities are in fact subordinated to spiritual ends."[4] Maintaining a holistic view of the human person, therefore, must inform all decisions concerning the preservation of physical life. A failure to appreciate this holistic view of the human person can too easily lead to a „vitalistic" understanding of our moral duty to preserve life, giving euthanasia or infanticide the appearance of being the only „reasonable" alternatives.

A decision to use a particular treatment for the preservation of physical life must also not be driven by a „technological imperative." Simply because we *can* employ a certain therapy does not necessarily mean that we *ought* to do so in every case. Rather, decisions to resuscitate or to use any life-sustaining treatment must take into account the physical, emotional, intellectual and spiritual condition of the particular individual, including the prospects for survival and any co-morbidities that are likely to occur with or without medical intervention. Still, no matter what course of treatment or non-treatment is chosen, continuous *care* should persist even when resuscitation is no longer a realistic option. A decision not to resuscitate requires a continuous commitment to compassionate care no less than a decision to resuscitate. Other principles and judgments to consider include but are not necessarily limited to the following.

„**First, do no harm."** Every treatment carries with it expected benefits, burdens, risks and harms. The question for us is whether the expected benefits of a treatment will justify its concomitant burdens or harms. This first principle in the practice of medicine is difficult to apply with „borderline" neonates, where the outcome is so uncertain and unpredictable. „First, do no harm" necessarily requires the virtue of Prudence. According to St. Thomas Aquinas, *Prudence*, or the capacity for discernment, is the moral virtue by which the individual translates general principles and demands of morality into concrete action. It is not simply a matter of knowing what is *generally* good, but of knowing what is the best thing to do in the particular case. The virtue of Prudence normally can only be acquired through reflection and experience. In the context of our borderline cases and the Catholic moral tradition, prudential judgments must at least preclude actions intended to harm or to devalue the life of a newborn (ERD, 23). Concern for justice, or giving to each what is *due* on account of his or her humanity, will take into account what it means to flourish in a truly human way. There can come a point when treatments to preserve life become more harmful than beneficial. When that point is thought to be reached will depend on the particular circumstances and condition of the patient involved, as well as a realistic appreciation for the current limits and capabilities of medical practice. Such a judgment certainly involves scientific knowledge and technical skill, but also moves into the realm of art. This is where the knowledge, experience and virtue of the physician become so critical for helping to guide the parents when a decision has to be made.

Proportionate and disproportionate means. „Proportionate means" are those treatments that in the judgment of the infant's parents offer a reasonable hope of benefit *and* are not too burdensome for the infant or for others (ERD, 56). „Disproportionate means" are those treatments that in the judgment of the infant's parents do not offer a reasonable hope of benefit *or* entail an excessive burden, either for the infant or for others (ERD, 57). Reasonable people will not always agree on what counts as a „sufficient benefit." This is where the prudence of the physician and a well-informed ethics consultation service may be vital for assisting the parents to form their moral judgment. A decision not to initiate or to discontinue resuscitation based on these principles must not be confused with euthanasia. In order to distinguish euthanasia from the morally licit foregoing of treatment, we are reminded by Pope John Paul II to consider not only the intention of the agent but also the proportionate benefits of a treatment in the particular case:

Euthanasia must be distinguished from the decision to forego so-called „aggressive medical treatment," in other words, medical procedures which no longer correspond to the real situation of the patient either because they are by now disproportionate to any expected results or because they impose an excessive burden on the patient and his family.Certainly there is a moral obligation to care for oneself [or others].but this duty must take account of concrete circumstances. It needs to be determined whether the means of treatment available are objectively proportionate to the prospects of improvement. To forego extraordinary or disproportionate means is not the equivalent of suicide or euthanasia; it rather expresses acceptance of the human condition in the face of death. [5]

In considering how to weigh the proportionate benefits and burdens of treatment, it may be helpful to define exactly what we mean by „benefits and burdens." Benefits are the goals that a specific medical intervention in

all probability will be successful in attaining. As in concerns for justice, considering what is of sufficient benefit must also take into account an adequate view of the human person, and what it means to flourish in a human way (ERD 33). Burdens are the physical and emotional pain, discomfort, suffering and/or losses that a medical intervention will impose or fail to prevent. What the parents will consider to be a worthy risk and a tolerable burden will be influenced both by their understanding of the practice and limits of neonatal medicine as well as by their personal value system. Adequate information is vital, therefore, as many parents will first come into the decision-making process with a wholly inaccurate and inadequate set of ideas about the medical possibilities.

The „best interests" standard. A resuscitation decision must always be guided by a commitment to seek the best interests of the infant. This is the only appropriate surrogacy standard for newborns, as infants have yet to develop any particular values, intentions or beliefs of their own (see ERD, 25). Respect for the autonomy of the parents to make such decisions is generally appropriate, but we must also consider that the child is not merely an extension of its parent's values and beliefs. Rather, the child has an inherent dignity and an inherent value of its own (ERD, 23). The best interests standard is widely recognized by the courts as applicable to care decisions made for infants. It provides a positive framework for understanding the proper limits of parental autonomy. „Best interests" is a good faith determination of what treatment would promote the patient's overall greatest welfare, in accord with all relevant ethical and medical standards. Relevant factors include: present and future level of physical, sensory, emotional and cognitive functioning; the degree of pain and suffering resulting from the infant's condition with or without treatment and from the treatment itself; life expectancy, recovery and degree and/or complexity of disability; and other relative risks, benefits, burdens and alternatives of treatment.[6] Many U.S. courts and juries have accepted parental judgments to forego burdensome or futile treatment from a premature infant or catastrophically injured child as a legitimate application of the right of informed consent, made in the child's best interests. [7]

Informed consent and respect for autonomy. From the perspective of the Catholic moral tradition, a person has a moral right to advance his or her own physical and spiritual welfare, and the physical and spiritual welfare of his or her own child. On this account, respect for parental autonomy involves not only refraining from interfering with the reasonable wishes of the parents, but entails providing them with the necessary conditions and opportunities for making decisions within appropriate limits. The principle of respect for autonomy implies that one should be free from coercion in deciding to act, and that others are obligated to protect confidentiality, respect privacy, and tell the truth. In the practice of health care, a person's autonomy is exercised through the process of obtaining informed consent. The principle of respect for autonomy, however, *does not* imply that one must necessarily cooperate with another's actions in order to respect that individual's autonomy. Guidelines would be helpful for defining the limits of parental autonomy that will be respected by the institution through the process of informed consent. Quality informed consent requires four conditions: adequate disclosure of information; the freedom of the parent to decide without coercion (within appropriate limits); comprehension on the part of the parent; and the capacity of the parent to make a decision. [8] Written materials may be useful for helping the parents to examine and understand the medical and moral issues.

Medical futility. A treatment can be considered futile when there is virtual certainty that the treatment in question will not be successful in attaining the mutually agreed-upon goals of treatment or the treatment's desired physiological effect. [9] Whether a given treatment can be considered futile in the case of „borderline" neonate will not always be clear. Therefore, conversations about the futility of treatment should be the starting point of a conversation, not the blunt instrument for ending conversation. Resuscitating a 20 week infant may be medically futile, but there may also be more humane ways of informing parents of this reality.

Discussion

In applying these principles to borderline viability cases, and to all neonatal resuscitation decisions for that matter, it will be helpful to consider relevant clinical data. Take Ascension Health facilities, for example. From 1998 through 1999, in 23 Ascension Health facilities, outcomes for extremely low birth weight babies (< 499 grams) were very poor. Of 7 babies born in our Level I nurseries, 6 died. Of 21 babies born in Level II nurseries, 14 died. Of 136 babies born in Level III nurseries, 103 died. During the same period, 206 babies were born weighing between 500 and 749 grams. Both babies born in a Level I nursery died. Of 32 babies born in a Level II nursery, 9 died. Of 172 babies born in a Level III nursery, 68 died. During the same period, 246 babies were born weighing between 750 and 999 grams. Both babies born in a Level I nursery survived. Of 26 babies born in a Level II nursery, only 1 died. Of 218 babies born in a Level III nursery, 16 died.

A 1999 study in *Early Human Development* discusses survival outcomes over the course of the 1990s, examining both low birthweight (< 800 g) and gestational age (< 26 weeks) together. [10] In a review of the world literature, Hack and Fanaroff found that the survival rates for live births at 23 weeks gestation ranged from 2% to 35%. At 24 weeks, the range varies from 17% to 58%, and at 25 weeks from 35% to 85%. They speculated that differences in population descriptors, in the initiation and withdrawal of treatment and the duration of survival considered may have accounted for the wide variation. They also correlated morbidity increases with decreasing gestational age and birthweight. The rates of severe cerebral abnormalities detected by ultrasound ranged from 10% to 83% at 23 weeks; 17% to 64% at 24 weeks; and 10% to 22% at 25 weeks. At 23 weeks gestation, chronic lung disease occurred in 57% to 70% of survivors; 33% to 89% at 24 weeks; and 16% to 71% at 25 weeks. They found that the rates for neurodevelopmental disabilities (including subnormal cognitive function, cerebral palsy, blindness and deafness) did not vary significantly from babies born prior to 1990. Of 30 survivors reported at 23 weeks gestation, 9 (30%) were severely disabled. At 24 weeks, the rates range from 17% to 45%, and at 25 weeks the rates range from 12% to 35%. From these and other literature reviewed, Hack's and Fanaroff's study strongly suggests that we have reached the medical limits of viability. Those who survive birth at a lower gestational age will be very rare, and not without several developmental disabilities.

A 2000 study on developmental disabilities in surviving preterm infants in the *New England Journal of Medicine* also reveals catastrophic outcomes for babies born at 25 weeks gestation or less. [11] Wood, Marlow, *et al* evaluated all children born in this category in the United Kingdom and Ireland from March through December 1995 at the time when they reached a median age of 30 months. 283 children were formally assessed by an independent examiner, using the Bayley Scales of

Infant Development. Neurologic function was assessed by a standardized examination. The 283 children represent 92 percent of 308 surviving children in this category. Overall, 138 children had disability (49%; 95% confidence interval, 43 to 55 percent), including 64 (23%) who were severely disabled. When data from 17 assessments by local pediatricians were included, 155 of 314 infants discharged (49%) had no disability.

Motivated by the 2000 International Guidelines, by these studies above as well as others, including various model guidelines, and by the knowledge that our individual Health Ministries utilize several or even no protocols with considerable variation, Ascension's Maternal Child Clinical Excellence team convened a work group in 2001-2002, consisting of individuals with broad expertise from across the System, with the hopes of developing model clinical and ethical guidelines that would facilitate the development of consistent protocols and ethical decision-making across the System. The reader will note that gestational age is the principal indicator in the three general categories. However, this does not mean that clinicians should not consider birthweight as a factor among all the assessments. The purpose of these model guidelines is to supplement, not to replace the 2000 International Guidelines, in order to ensure consistency with Catholic values and principles. Included in the draft guidelines are discussions of the relevant ethical principles, briefer than in this article, followed by the actual treatment guidelines below:

Guidelines

In cases of emergency delivery of a preterm infant, in the absence of a complete assessment, consent for resuscitation may be presumed until the infant can be stabilized and/or further assessment is made, consistent with the ethical principles above and guidelines below, and, if applicable, until appropriate transfer can be made.

1. Decisions in the presence of severe congenital anomalies. Following on the above ethical considerations, a decision for noninitiation or discontinuation of resuscitation for live born infants with a confirmed diagnosis of Anencephaly, Trisomy 13 or 18, or for other infants with severe congenital anomalies generally considered incompatible with life is both medically and ethically appropriate. In cases of uncertain diagnosis and/or prognosis, resuscitation options include a trial of therapy and noninitiation or discontinuation of resuscitation after further assessment. In such cases, initiation of resuscitation at delivery does not mandate continued support.

2. Decisions for noninitiation or discontinuation of treatment. Following on the above ethical considerations, there will be other circumstances in which noninitiation or discontinuation of resuscitation of newborns is both clinically and ethically appropriate. Noninitiation of support and later withdrawal of support may generally be considered ethically equivalent, assuming that other appropriate clinical and ethical considerations have been made. A decision to resuscitate and then to withdraw later may allow time to gather more complete clinical information and to provide counseling to the family. Ongoing evaluation and discussion with the parents and the health care team should guide decisions for continuation or withdrawal of support. In general, there is no advantage to delayed, graded, or partial support; if the infant survives, outcome may be worsened as a result of this approach.

3. Delivery and transportation considerations. Ascension Health ministries equipped to delivery babies will have protocols and mechanisms in place for ensuring that delivery occurs at the most appropriate site, and will include a comprehensive transportation plan.

4. Legal considerations. Ascension Health ministries equipped to delivery babies will have policies and procedures for neonatal resuscitation that are consistent with Federal, State and local laws and regulations.

5. Weight and gestational age considerations. Gestational weight alone will normally not be used to decide whether to resuscitate a preterm infant. In cases of uncertain gestational age, resuscitation options include a trial of therapy and noninitiation or discontinuation of resuscitation after further assessment. Guidelines for the resuscitation of preterm infants include the categories as given in the **table 1**.

Table 1. Guidelines for the Resuscitation of Preterm Infants - Categories According to the Gestational Age

Category I
It is ethically appropriate not to resuscitate infants with a confirmed gestational age of less than 23-0/7 weeks.

Category II
Infants with a confirmed gestational age between 23-0/7 and 25-0/7 weeks:

- When there has been no pre-delivery consultation, resuscitation may be initiated when determined to be medically appropriate;
- When there has been a pre-delivery consultation, parental wishes will be respected and followed, unless contrary to these guidelines.

Category III
Infants with a gestational age greater than 25-0/7 weeks will be routinely resuscitated.

Conclusion

These guidelines will not provide pat answers for every moral dilemma. Rather, they provide a general framework for how to think morally about the issue of resuscitation for preterm newborns, consistent with the Catholic tradition and the ERD, and suggest general parameters for protocols developed at the local level. Category I clearly supports forgoing resuscitation as ethically appropriate, but does not mandate it. Parents who would want a child under this category to be resuscitated need to understand the likely consequences of such a decision. Category II could support a parental decision to forgo resuscitation, assuming that the parent is reasonable and is attempting to act in the best interests of the child. Category III would normally not support a parental decision to forgo resuscitation, unless there are other serious medical factors that would warrant such a decision. All three categories do not preclude a decision to initiate and later to forgo resuscitation after further evaluation, or after it has become more apparent that such efforts are no longer „proportionate to the prospects of improvement." A person who makes any judgment without considering the clinical facts of the particular is not acting in good conscience. A bad conscience is reflected by the tendency to make judgments without regard for moral norms or relevant information that may affect the moral character of an action. Nevertheless, people acting in good conscience will invariably disagree with each other. These guidelines allow for such disagreement. Achieving moral consensus requires hard work that no guidelines can substitute.

References

1. See S Niermeyer, J Kattwinkel, P Van Reempts, *et al*, „International Guidelines for Neonatal Resuscitation: An Excerpt From the Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: International Consensus on Science," *Pediatrics* 106:3 (September 2000): e29, on Website at: . For the complete guidelines ratified by the American Academy of Pediatrics and the American Heart Association see „International Guidelines 2000 for CPR and ECC," *Circulation* (2000; 102(suppl I): I-343-I-357. **2.** On Website at: . **3.** 1974 Vatican *Declaration on Procured Abortion*, n. 8, on Website at: . **4.** Pius XII, „The Prolongation of Life," in *Critical Choices and Critical Care*, ed. K.W. Wildes (Netherlands: Kluwer Academic Press, 1995), pp. 189-96, at 192. **5.** John Paul II, 1995 Encyclical, *The Gospel of Life*, n. 65, on Website at: . **6.** This understanding of „Best Interests" is based on the definition used in the Michigan Supreme Court Ruling, *In re Martin, a Legally Incapacitated Person*, North West Rep Second Ser. 538:399-420, 1995 Aug 22 (date of decision). Other states may employ a different variation of this legal-ethical concept. **7.** See, for example, *In re Joelle Rosebush*, 195 Mich. App. 675 (1992), on Website at: ; see also the trial of Dr. Gregory Messenger, who was acquitted of murder by a jury after removing life-supports from his infant against the wishes of the attending physician and the hospital, in „The Messenger Case: Summary and Analysis" (adopted from a chronology in the Detroit Free Press, February 4, 1995), by Howard Brody, at . **8.** See PS Applebaum and T Grisso, „Assessing Patients' Capacities to Consent to Treatment," *New E Journal Med* 319:25 (Dec 22, 1988): 1635-38. **9.** See G. Trotter, „Response to 'Bringing clarity to the futility debate: done use the wrong cases' by Howard Brody and 'Commentary: bringing clarity to the futility debate: are the cases wrong?' by L.J. Schneiderman,„ *Cambridge Quarterly of Healthcare Ethics* 1999: 8; 527-37; also JP Slosar, „." *Health Care Ethics USA* 10, 1 (Spring 2002): 26-31. **10.** M Hack and AA Fanaroff, „Outcomes of Children of Extremely Low Birthweight and Gestational Age in the 1990s," *Early Hum Dev* 53, 3 (January 1999): 193-218. **11.** NS Wood, N Marlow, *et al*, „Neurologic and Developmental Disability After Extremely Preterm Birth," *N Engl J Med* 343, 6 (August 10, 2000): 378-84.

Abstrakt

Dan O'Brien, D.: Borderline Viability Resuscitation Cases. [Resuscitácia v prípadoch hraničnej životaschopnosti.] Med. Eth. Bioet., 9, 2002, No. 3 - 4, p. 6 - 10. Rozhodnutia o resuscitácií extrémne nezrelých novorodencov sú zvlášť ťažké v prípadoch tzv. „hraničnej životaschopnosti", kde je malá pravdepodobnosť prežitia, a ak je prežitie možné, býva spojené s mnohopočetnou komorbiditou a ťažkými poškodeniami u novorodenca. *Medziná-rodné smernice o kardiopulmonálnej resuscitácii* z roku 2000 sú podrobné, avšak ponechávajú otvorené niektoré náročné etické otázky, ktoré musia riešiť priamo tí, ktorí v danom prípade rozhodujú o ďalšom postupe starostlivosti u konkrétneho dieťaťa. Táto práca odporúča klinické etické smernice (guidelines) pre resuscitáciu takýchto novorodencov založené na vedeckých dôkazoch (evidence-based), pričom sa opiera o prístup používaný v rámci jedného veľkého katolíckeho zdravotníckeho systému v USA. V etickej argumentácii sa opiera o katolícku morálnu tradíciu a o dokument *Etické a náboženské direktívy pre katolícke zdravotnícke služby* (END; ide o dokument, ktorý platí pre všetky zdravotnícke zariadenia na území USA, ktoré patria Katolíckej cirkvi). Predpokladá prítomnosť inherentnej dôstojnosti ľudskej osoby, ktorú je potrebné rešpektovať a chrániť bez ohľadu na podstatu konkrétneho zdravotného problému alebo sociálneho statusu danej osoby. Súčasne však predpokladá a zdôrazňuje, že určitý liečebný postup možno odôvodnene použiť len vtedy, ak znamená pre daného pacienta proporcionálny prospech. Pri zachovaní holistického pohľadu na ľudskú osobu sa vyhne dvom extrémom: „vitalistickému" prístupu, kedy sa život zachraňuje za každú cenu; ako aj „ľahkej" alternatíve eutanázie. Viaceré princípy medicíny, teológie, etiky a anglo-amerického práva sa aplikujú v prípade troch kategórií nezrelých novorodencov, pričom každá z nich si vyžaduje odlišný základný prístup vo vzťahu k neonatálnej resuscitácií: kategória I - novorodenci s potvrdeným gestačným vekom < 23-0/7 týždňov; kategória II - novorodenci s potvrdeným gestačným vekom medzi 23-0/7 a 25-0/7 týždňov; a kategória III - novorodenci s potvrdeným gestačným vekom > 25-0/7 týždňov. Doterajšie klinické štúdie ukázali, že prežitie a výsledky sú výrazne rozdielne u novorodencov patriacich do odlišných kategórií, a to aj pri dostupnosti najmodernejších technických prostriedkov. ***Kľúčové slová***: neonatálna resuscitácia; smernice (guidelines); ťažko nezrelí novorodenci; hraničná životaschopnosť; založený/á na dôkazoch; rozhodnutia o liečbe; katolícka morálna tradícia; inherentná dôstojnosť; ľudská osoba; holistický pohľad; proporcionálne a disproporcionálne prostriedky; eutanázia.

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K PROBLÉMU REVITALIZÁCIE ETICKÝCH KOMISIÍ V SLOVENSKEJ REPUBLIKE

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Abstrakt

Problematika etických komisií (EK) sa v Slovenskej republike (SR) začala rozvíjať až po politických zmenách v novembri 1989. Prvé EK v modernom zmysle slova vznikali ako neformálne skupiny nadšencov z radov zdravotníckych pracovníkov, teológov, psychológov a predstaviteľov ďalších humanitných disciplín a zvyčajne boli viazané na väčšie nemocnice (fakultné, krajské) alebo na tie zdravotnícke zariadenia, kde sa v minulosti, napriek určitému riziku alebo aj prenasledovaniu, udržovali isté etické tradície, nezriedka viazané na činnosť intelektuálneho alebo náboženského disentu. V roku 1990 bola na Ministerstve zdravotníctva (MZ) SR založená Centrálna etická komisia (CEK), ktorá sa ujala iniciatívy, ktorej výsledkom bolo vybudovanie základných inštitucionálnych podmienok tak pre činnosť EK v SR, ako aj pre vznik a rozvoj odboru medicínskej etiky a bioetiky. V období 1993 - 2001 prišlo k určitej stagnácií, ktorá bola zapríčinená nedostatočnou legislatívnou, politickou, odbornou a organizačnou podporou tejto problematiky. Napriek tomu činnosť EK, predovšetkým vo veľkých nemocniciach a výskumných ústavoch rezortu zdravotníctva, pokračovala, a to najmä vzhľadom na potrebu etického posudzovania protokolov klinického skúšania liečiv a projektov biomedicínskeho výskumu, ktoré striktne vyžadovali sponzorujúce farmaceutické firmy a zahraničné i domáce grantové agentúry. Po obnovení riadnej činnosti CEK v júni 2002 je v SR potrebné nadviazať na dosiaľ vybudované inštitucionálne, odborné a personálne predpoklady a revitalizovať činnosť EK ako systému, a to tak pre ich nezastupiteľnú činnosť v oblasti etického dohľadu nad klinickým skúšaním liečiv (v zmysle plnenia požiadaviek Správnej klinickej praxe) a vykonávaním biomedicínskeho výskumu (oblasť etiky biomedicínskeho výskumu), ako aj pre perspektívu ich aktívnejšej činnosti v zdravotníckych zariadeniach a liečebných ústavoch SR (oblasť klinickej etiky).

Kľúčové slová: etické komisie, história, vývoj, revitalizácia, Slovenská republika, klinické skúšanie liečiv, biomedicínsky výskum, klinická etika

1. Úvod [1]

Problematika etických komisií (EK) v modernom zmysle slova sa v Slovenskej republike (SR) začala rozvíjať až po zmenách, ktoré začali v rokoch 1989/1990. Niektoré funkcie EK v predchádzajúcom období suplovali iné štátne štruktúry (Komisia pre nové liečivá Ministerstva zdravotníctva (MZ), Štátny plán vedecko-technického rozvoja, ai.). Náplňou práce „etických komisií" v zdravotníckych zariadeniach, ak v nich vôbec EK existovali, bolo najmä riešenie občasných úplatkárskych afér. Preto tieto EK mali skôr zlú ako dobrú povesť. Iným druhom boli „interrupčné komisie" zriadené podľa zákona o umelom prerušení tehotenstva (zrušené novelizáciou zákona v roku 1986).

Po roku 1990 sa začali v SR objavovať EK v modernom zmysle slova, a to spočiatku ako neformálne skupiny

nadšencov z radov zdravotníckych pracovníkov, prípadne teológov, psychológov a predstaviteľov ďalších humanitných disciplín. Boli zvyčajne viazané na väčšie nemocnice (fakultné, krajské) alebo na zdravotnícke zariadenia, kde sa v minulosti, napriek určitému riziku alebo aj prenasledovaniu, udržovali isté etické tradície, nezriedka vychádzajúce z náboženských koreňov, prípadne viazané na činnosť intelektuálneho alebo náboženského „undergroundu“ alebo „disentu“. V tomto čase vznikli aj EK na Lekárskej fakulte UK v Bratislave (najmä vďaka aktivitám Doc. M. Babála, CSc. a spolupracovníkov a pochopeniu a záujmu vtedajšieho vedenia LF UK) a na Ústave preventívnej a klinickej medicíny (ÚPKM) v Bratislave (najmä zásluhou Prof. T. R. Niederlanda a jeho spolupracovníkov, ktorí vydali aj prvú modernú príručku o klinickom skúšaní liekov a úlohách i zodpovednosti EK [2]).

V roku 1990 bola založená prvá Centrálna etická komisia (CEK) na MZ SR (spoločne s obdobnou CEK MZ ČR). Ujala sa aktivity, ktorej výsledkom bolo vybudovanie základných inštitucionálnych podmienok pre činnosť EK v SR, ako aj pre vznik a rozvoj odboru medicínskej etiky a bioetiky. Najvýznamnejšie kroky ukazuje **tabuľka 1**.

Tabuľka 1. Vznik inštitúcií odboru medicínskej etiky a bioetiky v Slovenskej republike

Rok	Aktivita
1990	založenie Centrálnej etickej komisie MZ SR
1991	založenie Katedry medicínskej etiky IVZ v Bratislave
1992	vydanie prvých smerníc MZ SR pre zriadenie a činnosť etických komisií
1991 -1992	vznik etických komisií v zdravotníckych zariadeniach a výskumných ústavoch rezortu zdravotníctva
1992	založenie Ústavu medicínskej etiky a bioetiky IVZ a LFUK
1994	založenie časopisu *Medicínska etika & Bioetika*
1997, 2002	revitalizácia Centrálnej etickej komisie MZ SR

Dôležité boli aj početné vzdelávacie aktivity organizované najmä pod hlavičkou Ústavu medicínskej etiky a bioetiky (ÚMEB) IVZ a LFUK v Bratislave, zavedenie výuky medicínskej etiky na LF (Bratislava, v obmedzenom rozsahu aj Martin a Košice; vydanie prvých skrípt [3]) a etiky ošetrovateľstva na stredných zdravotných školách (SZŠ) na celom území SR (ako povinného predmetu; vydanie prvej učebnice [4]), ako aj viaceré medzinárodné konferencie organizované v spolupráci s Radou Európy, Medzinárodnou spoločnosťou pre etiku, právo a vedu (Milazzo group) a viacerými významnými medzinárodnými organizáciami alebo zahraničnými ústavmi medicínskej etiky a/alebo bioetiky z Európy i zo zámoria. Umožnili prepojenie odborných a vzdelávacích aktivít v SR s vývojom v Európe a vo svete a priniesli významné uznanie SR ako krajine s mimoriadne aktívnym a úspešným prístupom k rozvoju bioetiky [5].

2. Súčasný stav

V roku 1993, pri neoficiálnom orientačnom prieskume organizovanom v rámci ÚMEB sa počet EK v zdravotníckych zariadeniach a výskumných ústavoch v SR odhadoval na cca 70. Odvtedy problematika EK značne stagnovala - i z dôvodu jej nedostatočnej prioritizácie zo strany MZ SR a útlmu aktivít samotnej CEK (po personálnych zmenách v r. 1993). Činnosť EK v zdravotníckych zariadeniach prakticky ustala, s výnimkou práce tých EK, ktoré posudzovali protokoly klinického skúšania liečiv a projekty biomedicínskeho výskumu. V tomto smere významnú úlohu zohrali požiadavky a tlak zahraničných farmaceutických firiem (vyžadujúcich plnenie kritérií Správnej klinickej praxe (SKP)) a snaha výskumných pracovníkov z pracovísk SR o aktívne zapojenie do medzinárodných výskumných projektov (napr. 5FP Európskej komisie, bilaterálne projekty s krajinami Európskej únie (EÚ), USA, ai.). Niektoré aktivity EK (vrátane činnosti CEK) čiastočne suplovala činnosť ÚMEB-u a tiež iniciatíva viacerých jednotlivcov - expertov nominovaných za SR do rôznych medzinárodných komisií. Smerom k zahraničiu to bola aj činnosť Zahraničného odboru MZ SR, najmä referátu európskej integrácie, prípadne aj niektoré zahraničné aktivity SLS (najmä smerom k Svetovej asociácii lekárov (WMA), ale aj k Európskej únii medicínskych špecialistov (EUMS), ai.).

Absencia metodického vedenia EK v uplynulom období, útlm celoštátnych postgraduálnych edukačných aktivít pre členov EK, ako aj viac alebo menej deklarované „pochybnosti“ o samotnej potrebe a koncepcii EK v SR, spôsobili, že v súčasnosti chýbajú presnejšie údaje o počte, zložení (profesijnej štruktúre) a spôsobe práce EK v SR. Získanie relevantných údajov v tomto smere je nutné nielen pre plánovanie potrebných opatrení, ale aj vzhľadom na vykazovanie príslušných parametrov voči zahraničiu (s väzbou na kompetitívnosť vedeckovýskumných pracovísk v SR voči obdobným pracoviskám v zahraničí, vrátane vykonávania klinických skúšaní nových liekov a plnenia požiadaviek SKP).

Vzhľadom na rastúce nároky na odborné zabezpečenie záväzkov a aktivít SR voči medzinárodným organizáciám a inštitúciám (Rada Európy, Európska komisia, UNESCO, WHO, ai.) bolo potrebné už dávnejšie situáciu nečinnosti CEK a nedostatočnej akcieschopnosti a efektívnosti systému EK riešiť. Nedávna revitalizácia CEK MZ SR (apríl - jún 2002) bola prvým nevyhnutným krokom tohto procesu.

3. Princípy systémového riešenia

V ďalšom v stručnosti načrtneme najpotrebnejšie kroky, ktoré sú nevyhnutné na zabezpečenie revitalizácie systému EK v SR.

Legislatívne predpoklady

Základným predpokladom je zakotvenie existencie a rámcových podmienok činnosti EK v zákonnej norme. Pre špeciálnu oblasť klinického skúšania liečiv sa tak už stalo v rámci zákona o lieku (zákon č. 144/1998 Z. z. v znení neskorších predpisov). Vyhláška o klinickom skúšaní liečiv a o správnej klinickej praxi však dosiaľ nebola vydaná.

Zákonná norma upravujúca vznik, činnosť a zodpovednosť EK v ostatných oblastiach výskumu, ako aj v rámci zdravotníckych zariadení (tzv. „nemocničných EK“) nateraz chýba. V návrhu zákona o zdravotníckych zariadeniach, pripravovanom v predchádzajúcom volebnom období (avšak až k jeho koncu 2001/2002), bola čiastočne riešená aj problematika EK (vrátane CEK). Zákon mal splnomocniť MZ SR na vydanie vyhlášky o etických komisiách, ktorá by mala túto problematiku riešiť komplexne (vrátane zjednotenia príslušnej terminológie).

Prijatím potrebných zákonných noriem a vydaním príslušných vykonávacích vyhlášok by sa vytvorili nevyhnutné legislatívne predpoklady pre činnosť systému EK v SR. V ďalšom období by bolo potrebné postupne doplniť tieto právne záväzné dokumenty súborom odborných usmernení, reagujúcich na riešenie aktuálnych etických

problémov medicíny, zdravotníctva a biomedicínskeho výskumu (napr. pripravených CEK v spolupráci s ďalšími zainteresovanými inštitúciami).

Odborné riadenie systému EK

Systém EK (tabuľka 2) nepredpokladá vzájomnú „podriadenosť" miestnych EK komisiám vyššieho typu - krajské EK (KEK), CEK. Odlišnosť je v rozsahu úloh, zodpovednosti a kompetencií.

Odborné riadenie systému EK v SR musí byť **úlohou MZ SR**. Realizáciu by mala zabezpečiť metodická a konzultačná činnosť **CEK.** Dôležitú pomocnú úlohu by mali plniť výskumné a edukačné aktivity **ÚMEB** (SZU) a ďalších zainteresovaných organizácií a inštitúcií (ŠÚKL, odborné spoločnosti SLS, ai.).

Tabuľka 2. Typy etických komisií, ich činnosť a hlavné úlohy

Typ etickej komisie – Hlavná oblasť činnosti – úlohy
Centrálna (**CEK**) – legislatíva; koncepčná činnosť; konzultačná činnosť pre EK v SR; medzinárodné vzťahy a spolupráca; medzinárodné inštitúcie, organizácie a odborné komisie; stanoviská k aktuálnym problémom bioetiky, atď.
Krajská (regionálna) (**KEK**) – posudzovanie protokolov multicentrických štúdií klinického skúšania liečiv a projektov multicentrického biomedicínskeho výskumu, konzultačná činnosť pre MEK v rámci kraja/regiónu; regionálne predpisy a usmernenia; prípadne špecializácia na posudzovanie etických problémov v konkrétnej, vysokošpecializovanej oblasti; atď.;
Miestna (lokálna) (**MEK**) ***a) MEK pre biomedicínsky výskum/klinické skúšanie liečiv***: posudzovanie protokolov klinického skúšania liečiv a ďalšie činnosti podľa požiadaviek SKP; konzultácie pre výskumných pracovníkov a účastníkov výskumu; štandardné pracovné postupy na miestnej úrovni; atď.; ***b) MEK pre klinickú etiku („nemocničná")***: vzdelávanie zdravotníckych pracovníkov v medicínskej etike/bioetike; konzultácie pre zdravotníckych pracovníkov, pacientov a ich príbuzných; riešenie eticky problémových klinických prípadov; atď.

Vzájomný kontakt a spolupráca EK

Pre dobré fungovanie systému EK sa v zahraničí, a v minulosti i u nás, osvedčili pravidelné kontakty členov EK, vzájomná výmena informácií a spolupráca medzi EK, a to tak v horizontálnom (MEK-MEK, KEK-KEK; CEK v rámci Medzinárodnej konferencie národných etických komisií (COMETH) + bilaterálne vzťahy, v našich podmienkach najmä spolupráca s CEK MZ ČR) ako aj vo vertikálnom smere (MEK - KEK, KEK - CEK).

Pre tieto účely bude v budúcnosti potrebné najmä:

– vybudovať ***informačnú sieť EK*** (internet, webová stránka CEK, projekt EURETHNET, ai.),

– organizovať pravidelné „***diskusné sústredenia"*** členov EK (aspoň raz ročne, prípadne spojené s kurzom ÚMEB alebo SZU, alebo vedecko-odbornou konferenciou bioetiky),

– v budúcich ***smerniciach*** pre činnosť EK zakotviť povinnosť vzájomnej informácie EK, ako aj povinnosť predkladateľov protokolov klinického skúšania a projektov biomedicínskeho výskumu informovať EK o prípadnom predchádzajúcom etickom posúdení protokolu alebo projektu inou EK.

Motivácia a vzdelávanie členov EK

Úroveň práce EK priamo závisí od motivácie a informovanosti (vzdelania) členov EK. Obe stránky je **nevyhnutné systematicky zabezpečiť**, vrátane vytvorenia primeraných **personálnych** a **materiálnych podmienok** (a to i vzhľadom na narastajúce nároky na objem a kvalitu práce EK a jej jednotlivých členov, najmä v oblasti posudzovania protokolov klinického skúšania liečiv a projektov biomedicínskeho výskumu).

V **motivácii členov EK** bude potrebné vhodne uplatňovať:

a) nepeňažné prostriedky (napr. vytvárať vhodné podmienky pre prácu EK a priebeh zasadnutí (vhodná miestnosť, občerstvenie, technické a administratívne zabezpečenie, ai.), zvýšiť spoločenské uznanie za prácu v EK a prestíž členov EK (informovanosť, médiá, ai.), účasť členov na atraktívnych vzdelávacích aktivitách, ai.),

b) finančné prostriedky (napr. honorovanie práce pri spracovaní posudku na prejednávaný projekt, vyžiadaných písomných materiálov pre potreby EK, ai.).

Vo **vzdelávaní členov EK** sa ukazuje vhodným rozlíšiť dve etapy:

a) vstupné školenie pre nových členov EK (napr. inštruktáž na úrovni danej EK, vstupný seminár pre nových členov EK na miestnej alebo regionálnej úrovni, kurz ÚMEB, ai.),

b) kontinuálne vzdelávanie členov EK (napr. kurzy/semináre na miestnej alebo regionálnej úrovni, kurzy ÚMEB, účasť na konferenciách, ai.).

Je nevyhnutné vypracovať ucelený a otvorený **systém vzdelávania členov EK** - i vzhľadom na požiadavky SKP (viaceré zahraničné inštitúcie a firmy napr. vyžadujú informáciu o vzdelávaní členov EK pri prieskume zabezpečenia plnenia podmienok SKP na danom pracovisku/pracoviskách).

Podporiť vypracovanie **súboru informačných materiálov pre členov EK**, medzi ktoré by mali patriť:

– *príručka člena EK* (v pravidelných intervaloch inovovaná, vydaná knižne ako brožúra, prípadne aj na diskete alebo CD),

– *portfólio materiálov pre člena EK* (pripravené a pravidelne doplňované na úrovni jednotlivých EK alebo centrálne (CEK, ÚMEB) - ako jednoduchá doplňovacia príručka, prípadne (alebo len) na diskete/CD),

– *časopis „Medicínska etika & Bioetika"* (členom EK zasielať zdarma v elektronickej forme (PDF), zabezpečiť zasielanie 1 výtlačku pre jednotlivé EK v SR).

Úlohy Centrálnej etickej komisie

Úlohy, ktoré pri revitalizácii systému EK v SR má plniť CEK vyplývajú priamo z jej štatútu. Sú predovšetkým v oblasti legislatívnej, metodickej (koncepčné, konzultačné a edukačné) a motivačnej. V menšej miere, vzhľadom na aktuálne možnosti a obmedzenia, by sa CEK mohla podieľať na audite činnosti EK (v oblasti klinického skúšania liekov túto činnosť vykonáva zo strany sponzora monitor (vnútorný audit); inšpekcie SKP zo strany štátnej správy vykonáva ŠÚKL, možné sú aj kontroly/inšpekcie poverenými zástupcami medzinárodných organizácií a inštitúcií - a to aj viac rokov po ukončení klinickej štúdie, napr. FDA, EMEA, ai.).

Podľa štatútu CEK ide najmä o tieto **dlhodobé úlohy:**

◆ vykonáva odbornú konzultačnú činnosť v oblasti

medicínskej etiky, zdravotníckej etiky a bioetiky pre EK zdravotníckych zariadení a EK pre biomedicínsky výskum,

◆ spracováva stanoviská k predloženým materiálom a vyjadrenia k etickej stránke aktuálnych problémov medicíny a zdravotníctva, spracováva koncepčné materiály pre oblasť medicínskej etiky, zdravotníckej etiky a bioetiky,

◆ pripravuje vecné návrhy právnych predpisov týkajúcich sa etických aspektov problémov medicíny, zdravotníctva a biomedicínskych vied,

◆ podieľa sa na tvorbe a inovácii koncepcie vzdelávania zdravotníckych pracovníkov a členov EK v biomedicínskej etike v spolupráci s ďalšími zainteresovanými inštitúciami a organizáciami (napr. Slovenská zdravotnícka univerzita v Bratislave, lekárske fakulty, Ústav medicínskej etiky a bioetiky v Bratislave, Štátny ústav pre kontrolu liečiv, ai.),

◆ udržuje kontakty s orgánmi profesijných organizácií zdravotníckych pracovníkov, odborných lekárskych spoločností a s inými inštitúciami a organizáciami zaoberajúcimi sa etikou medicíny, zdravotníctva a bioetikou v Slovenskej republike (a v cudzine),

◆ iniciuje a podieľa sa na verejnej diskusii na aktuálne témy biomedicínskej etiky a etiky zdravotníctva, ako aj na informačných kampaniach a vzdelávacích aktivitách určených pre širokú verejnosť.

Medzi **krátkodobé úlohy** CEK by v najbližšom období mali patriť:

◆ usporiadanie (1-2 razy ročne) *diskusných sústredení pre členov EK* (prvé sa uskutočnilo 24. októbra 2002 v priebehu medzinárodnej konferencie bioetiky „Ethics of Human Genetics“ v rámci Programu DEBRA Rady Európy v Bratislave),

◆ podporiť *dotvorenie legislatívnej bázy* pre činnosť EK v SR (najmä vydanie vyhlášky o klinickom skúšaní liečiv a o správnej klinickej praxi, ako aj vyhlášky o etických komisiách),

◆ podporiť, spoluiniciovať tvorbu *informačnej siete EK* (napr. v nadväznosti na plánované zriadenie Informačného a dokumentačného centra bioetiky v Bratislave a program EURETHNET),

◆ podporiť vznik *informačných materiálov pre členov EK*.

4. Etické komisie v zdravotníckych zariadeniach (komisie pre „klinickú etiku“)

Etické komisie pre klinickú etiku sú v zdravotníckych zariadeniach v našich podmienkach pomerne novým a dosiaľ zriedkavým fenoménom. Vzhľadom k nedostatočnému záujmu a podpore zo strany zdravotníckeho manažmentu, samotných zdravotníckych pracovníkov, ako i pacientov a širšej verejnosti sa (s výnimkou spontánne vzniklých diskusných skupín lekárov v niektorých väčších nemocniciach v období po novembri 1989) takéto EK v našich nemocniciach alebo iných zdravotníckych zariadeniach zatiaľ širšie nerozvinuli. EK posudzujúce projekty biomedicínskeho výskumu alebo protokoly klinického skúšania liekov sa len výnimočne vo svojej práci zaoberajú etickými problémami medicínskej alebo ošetrovateľskej praxe. Vzhľadom na vývoj v okolitých krajinách s rozvinutým zdravotníctvom, ako aj na aktuálne trendy v globálnom meradle, však možno predpokladať, že etická problematika spojená s poskytovaním zdravotnej starostlivosti a výkonom zdravotníckych povolaní bude už v relatívne blízkej budúcnosti aj u nás významne narastať. Najčastejšie **dôvody**, ktoré sa na zriadenie EK pre klinickú etiku uvádzajú, sú súhrnne uvedené v tabuľke 3. Poslanie, účel zriadenia a náplň činnosti týchto EK sú v mnohých aspektoch odlišné od komisií pracujúcich v oblasti biomedicínskeho výskumu alebo klinického skúšania. Niektoré **odlišnosti** sú uvedené v tabuľke 4.

Tabuľka 3. Dôvody pre zriadenie etických komisií v zdravotníckych zariadeniach

- pokrok v oblasti medicíny a zdravotníctva;
- ekonomické hranice v oblasti zdravotníctva;
- tímový prístup pri poskytovaní zdravotnej starostlivosti;
- rastúca autonómia pacienta;
- komplikovanosť medicínskych rozhodnutí v praxi (pre samotných odborníkov);
- komplikovanosť medicínskej problematiky a náročnosť v rozhodovaní pre pacientov a ich rodinných príslušníkov, resp. zákonných zástupcov (pre medicínskych „laikov“);
- nové medicínske technológie s ďalekosiahlym vplyvom na osobný a rodinný život (napr. aplikácie humánnej genetiky, metódy asistovanej reprodukcie človeka, ai.);
- možný vplyv novej medicínskej technológie na okolie pacienta alebo na blízke či vzdialené budúce generácie (napr. génová terapia, xenotransplantácie);
- zvýšený výskyt eticky podmienených konfliktov v oblasti zdravotnej starostlivosti;
- pluralizmus v morálnej (etickej) oblasti;
- rastúci multikulturalizmus spoločnosti, vrátane náboženskej plurality;
- narastajúca multietnicita spoločnosti;
- potreba brať do úvahy hodnotové postoje pacienta a jeho príbuzných;
- záujmy spoločnosti, záujmy menších spoločenstiev;
- potreba „neutrálnej pôdy“ pre mediáciu, objasňovanie, rozhodovanie;
- potreba ochrany dôstojnosti, práv, integrity, identity a ďalších oprávnených záujmov pacienta;

Tabuľka 4. Porovnanie etických komisií pre klinickú etiku v zdravotníckych zariadeniach (**A**) a etických komisií pre biomedicínsky výskum (**B**)

Vlastnosť/Činnosť/Poslanie/Priorita	A	B
Vzdelávacie aktivity	+	+
Posudzovanie projektov biomedicínskeho výskumu	–/+*	+
Konzultácie pre vedenie zariadenia	+	+
Konzultácie pre pracovníkov zariadenia	+	+
Konzultácie pre pacientov	+	–/+
Konzultácie pre účastníkov výskumu	–/+*	–/+
Konzultácie pre rodinných príslušníkov	+	–/+
Problematika klinickej etiky	+	–/+
Správna klinická prax	–/+*	+
Problematika etiky biomedicínskeho výskumu	-/+*	+
Vypracovanie odporúčaného postupu, smerníc pre dané zariadenie, oddelenie	+	–
Riešenie konkrétnych klinických prípadov	+	–

* Pokiaľ sa plánuje alebo vykonáva klinický výskum.

Úlohy a činnosť etickej komisie v zdravotníckom zariadení

Úlohy, ktoré má EK plniť v zariadeniach poskytujúcich zdravotnú starostlivosť, možno rozdeliť do piatich hlav-

ných skupín. V rôznych obdobiach svojej činnosti EK, v súlade s aktuálnymi potrebami daného zdravotníckeho zariadenia, plní tieto úlohy v rôznom rozsahu a intenzite.

Ide predovšetkým o tieto oblasti činnosti:

1. Vzdelávanie v medicínskej a **ošetrovateľskej etike** (prípadne **bioetike**). Orientuje sa na aktuálne potreby **zdravotníckych pracovníkov** zdravotníckeho zariadenia, dané typom poskytovanej zdravotnej starostlivosti a spektrom i náročnosťou riešených prípadov. Cieľom je nielen informovať zdravotníckych pracovníkov o relevantných etických problémoch a plauzibilných riešeniach, o rôznych etických smerniciach, profesijných etických kódexoch, atď., ale predovšetkým zvyšovanie ich **etickej kompetencie** - t.j. schopnosti samostatne rozpoznávať, analyzovať a riešiť etické problémy, s ktorými sa vo svojej medicínskej alebo ošetrovateľskej praxi stretávajú. EK má takto prispievať k **etickej kultúre** daného zdravotníckeho zariadenia, čo má nezriedka priamy dopad na kvalitu poskytovanej zdravotnej starostlivosti.

Zvlášť na začiatku svojej činnosti má EK zamerať vzdelávacie aktivity na **svojich vlastných členov** - na nadobudnutie špeciálnych individuálnych aj „kolektívnych" schopností potrebných pre plnenie úloh v danom zariadení. Na absolvovanie určitého „vstupného minima" pre všetkých členov novej EK, i pre komisiu ako celok (najmä školenia z problematiky skupinovej dynamiky a metodológie efektívnej skupinovej práce), musí nadväzovať primeraný program kontinuálneho vzdelávania, zameraný na zvyšovanie odbornej úrovne a kompetencie jednotlivých členov i celej komisie.

2. Vypracovanie a **posudzovanie smerníc** a **štandardných pracovných postupov** v rámci daného zdravotníckeho zariadenia. Ide o účasť EK pri tvorbe rozhodovacích algoritmov pre klinicky náročné alebo hraničné situácie, kde buď dosiaľ neexistujú všeobecne prijaté diagnostické a liečebné postupy, alebo ich aplikácia v konkrétnej situácii je problematická pre zložitosť situácie alebo závislosť od konkrétnych podmienok daného zdravotníckeho zariadenia (napr. prístrojové vybavenie, dostupnosť príslušných odborníkov, ai.). Príkladom môže byť: postup pri starostlivosti o novorodencov s extrémne nízkou pôrodnou hmotnosťou, indikácie a kontraindikácie konkrétnych nedostatkových alebo finančne veľmi náročných diagnostických alebo terapeutických postupov, postup pri odmietaní život zachraňujúcej alebo predlžujúcej liečby zo strany pacienta alebo jeho rodinných príslušníkov, atď.

Významnou súčasťou činnosti EK by malo byť **posúdenie etických aspektov** novo zavádzaných **diagnostických, liečebných, preventívnych** alebo **ošetrovateľských metód a postupov,** prípadne významných zmien alebo rušenia dosiaľ zavedených metód a postupov. Cieľom tohto posúdenia – okrem posúdenia všeobecných etických a medicínskych aspektov novej metódy – je posúdenie týchto aspektov vo vzťahu ku konkrétnym podmienkam daného zdravotníckeho zariadenia (prístrojové a personálne vybavenie, nároky na služby a financie, atď.), a to aj z hľadiska prípadných morálnych záväzkov a postojov správcu alebo vlastníka tohto zdravotníckeho zariadenia (napr. zdravotnícke zariadenia spravované/vlastnené cirkvou alebo náboženskou spoločnosťou), ako aj obyvateľstva regiónu, v ktorom dané zdravotnícke zariadenie pracuje. Vyjadrenie EK by sa malo stať súčasťou procedúry zavedenia každej novej metódy alebo postupu v rámci daného zdravotníckeho zariadenia. Môže predísť závažným diskusiám a problémom v neskorších fázach implementácie novej metódy alebo postupu, a byť určitou bázou pre informovanú diskusiu aj v prípade nepredvídaných alebo nežiaducich reakcií alebo udalostí.

3. Posudzovanie a **riešenie eticky problematických klinických prípadov**. Ide o veľmi zodpovednú a náročnú činnosť EK. V našich podmienkach v najbližšom období bude pomerne zriedkavá. So vzrastajúcim povedomím lekárskej i širšej verejnosti o existencii a možnostiach EK v zdravotníckych zariadeniach (prípadne v nadväznosti na niektoré nové všeobecne záväzné predpisy alebo aj niektoré odborné smernice) bude pravdepodobne počet klinických prípadov, ku ktorým bude požadované stanovisko EK, narastať.

4. Konzultačná činnosť. EK prostredníctvom svojich poverených členov, alebo aj ako celok v rámci svojich riadnych zasadnutí, má poskytovať vo vhodnom čase a priestore odborné konzultácie z oblasti zdravotníckej, ošetrovateľskej etiky a bioetiky pre všetkých potenciálnych záujemcov. Spočiatku bude pravdepodobne táto zložka jej činnosti pomerne málo rozvinutá, resp. obmedzená na konzultácie pre vedenie a pracovníkov jednotlivých oddelení daného zdravotníckeho zaradenia. Neskôr, podobne ako v prípade riešenia konkrétnych klinických prípadov, sa okruh konzultujúcich subjektov pravdepodobne rozšíri aj na pacientov a ich rodinných príslušníkov, prípadne na zástupcov organizácií pacientov alebo aj širšej verejnosti (napr. predstavitelia komunity - regiónu, v ktorom dané zdravotnícke zariadenie pracuje, apod.).

5. Riešenie koncepčných otázok. Znamená podieľanie sa EK na riešení otázok súvisiacich so samotným poslaním, ďalšou existenciou a smerovaním zdravotníckeho zariadenia (napr. plán ďalšieho rozvoja, priority investičnej činnosti, priority modernizácie, rozvoja určitých oddelení, reštrukturalizácia, ai.). Môže ísť aj o reflexiu špeciálnych etických otázok, súvisiacich s aplikáciou špecifických morálnych noriem správcu alebo vlastníka daného zdravotníckeho zariadenia (napr. určitej cirkvi alebo náboženskej spoločnosti) v situácii neustáleho pokroku samotnej medicíny a ošetrovateľstva – a potreby zavádzania nových diagnostických, liečebných a preventívnych metód, ktoré môžu predstavovať v rámci daného morálneho systému väčší alebo menší morálny problém alebo konflikt.

Záverom je potrebné zdôrazniť, že revitalizáciu a rozvoj činnosti EK v SR je potrebné vidieť v kontexte vytvárania predpokladov pre úspešný priebeh pripravovaných transformačných krokov zdravotníckeho systému, a to tak v oblasti samotnej zdravotnej starostlivosti (EK pre „klinickú etiku"), ako aj na poli klinického skúšania liečiv a biomedicínskeho výskumu. Tieto kroky majú prispieť aj k úspešnému začleneniu domácich pracovísk a inštitúcií do príslušných európskych a medzinárodných štruktúr, zvlášť na pôde Európskej únie a Rady Európy.

Doc. MUDr. Jozef Glasa, CSc.

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Abstract

Glasa, J.: K problému revitalizácie etických komisií v Slovenskej republike. [Contribution to the Problem of Revitalisation of Ethics Committees in the Slovak Republic.] Med. Eth. Bioet., 9, 2002, No. 3 - 4, p. 10 - 15. Ethics committees (ECs) begun to develop in the Slovak Republic (SR) after the political changes started in November 1989. First ECs of a modern type were established in SR as informal groups of enthusiasts composed of health professionals (physicians and nurses), theologians, psychologists, and workers in other humanities, being usually bound to

bigger hospitals (teaching, faculty, regional) or to other health care facilities, where, in the recent past, despite some risks or even persecution, some ethical traditions were kept alive, frequently in connection to the intellectual or religious dissent. In 1990, the Central Ethics Committee (CEC) was established at the Ministry of Health (MH) SR, which undertook various conceptual activities that contribute considerably to establishing of the basic institutional pre-requisites for the establishment and work of ECs in SR, as well as for founding and successful development of the disciplines of medical ethics and bioethics in the country. In 1993 - 2001, some stagnation occurred, which was cau-sed by insufficient legislative, political, professional and organisational support. Despite these shortcomings, the work of ECs, especially those established in the big hospitals and health and biomedical research institutes, continued to exist and develop, mainly due to the necessity of ethics review of the protocols of clinical trials of drugs, and the projects of biomedical research, which were strictly required by sponsoring pharmaceutical companies, as well as domestic and international grant research agencies. After restoration of the regular work of CEC in June 2002, it is necessary in SR to build on the previously established and developed institutional, professional and personnel foundations, and to make all necessary steps for the revitalisation of the ECs' work, as a system, both concerning their indispensable role in ethical review of clinical trials of drugs (according to the requirements of Good Clinical Practice) and the projects of biomedical research, but also for the perspective of their more active work in the health care facilities and health care institutes in SR (ECs for clinical ethics). ***Key words***: ethics committees, history, development, revitalisation, Slovak Republic, clinical trials of drugs, biomedical research, clinical ethics.

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DOKUMENTY / DOCUMENTS

INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS [1]

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)

CIOMS, Geneva, 2002

Preamble

The term „research" refers to a class of activity designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context „research" includes both medical and behavioural studies pertaining to human health. Usually „research" is modified by the adjective „biomedical" to indicate its relation to health.

Progress in medical care and disease prevention depends upon an understanding of physiological and pathological processes or epidemiological findings, and requires at some time research involving human subjects.

The collection, analysis and interpretation of information obtained from research involving human beings contribute significantly to the improvement of human health.

Research involving human subjects includes:

– studies of a physiological, biochemical or pathological process, or of the response to a specific intervention - whether physical, chemical or psychological - in healthy subjects or patients;

– controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation;

– studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures; and

– studies concerning human health-related behaviour in a variety of circumstances and environments.

Research involving human subjects may employ either observation or physical, chemical or psychological intervention; it may also either generate records or make use of existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information. The use of such records and the protection of the confidentiality of data obtained from those records are discussed in *International Guidelines for Ethical Review of Epidemiological Studies (CIOMS, 1991).*

The research may be concerned with the social environment, manipulating environmental factors in a way that could affect incidentally-exposed individuals. It is defined in broad terms in order to embrace field studies of pathogenic organisms and toxic chemicals under investigation for health-related purposes.

Biomedical research with human subjects is to be distinguished from the practice of medicine, public health and other forms of health care, which is designed to contribute directly to the health of individuals or communities. Prospective subjects may find it confusing when research and practice are to be conducted simultaneously, as when research is designed to obtain new information about the efficacy of a drug or other therapeutic, diagnostic or preventive modality.

As stated in Paragraph 32 of the Declaration of Helsinki, „In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed."

Professionals whose roles combine investigation and treatment have a special obligation to protect the rights and welfare of the patient-subjects. An investigator who agrees to act as physician-investigator undertakes some or all of the legal and ethical responsibilities of the subject's primary-care physician. In such a case, if the subject withdraws from the research owing to complications related to the research or in the exercise of the right to withdraw without loss of benefit, the physician has an obligation to continue to provide medical care, or to see that the subject receives the necessary care in the healthcare system, or to offer assistance in finding another physician.

Research with human subjects should be carried out only by, or strictly supervised by, suitably qualified and experienced investigators and in accordance with a protocol that clearly states: the aim of the research; the rea-

[1] Editorial Note: We reprint here, with the kind permission of CIOMS, the excerpts of the 2002 CIOMS Guidelines, namely the Preamble, and the Guidelines 1 - 21. Ommitted here, because of the space constraints, were the chapters: Background, Introduction, International Instruments and Guidelines, General Ethical Principles, the Commentaries to the Guidelines 1 - 21, and the Appendices 1 – 3 (the 2000 version of the WMA Helsinki Declaration was already published in our journal: Med. Eth. Bioet., 7, 2000, No. 3 - 4, p. 13 - 14). The deleted portions of the original text were replaced by the following sign: (...). **As the Commentaries are essential for the proper understanding and application of the Guidelines, we strongly recommend the reader to read the full text of the Guidelines.** It may be found at the CIOMS website, or purchased as a separate publication directly from CIOMS, c/o WHO, Avenue Appia, 1211 Geneva 27, Switzerland, or from the booksellers through the network of WHO sales agents.

sons for proposing that it involve human subjects; the nature and degree of any known risks to the subjects; the sources from which it is proposed to recruit subjects; and the means proposed for ensuring that subjects' consent will be adequately informed and voluntary. The protocol should be scientifically and ethically appraised by one or more suitably constituted review bodies, independent of the investigators.

New vaccines and medicinal drugs, before being approved for general use, must be tested on human subjects in clinical trials; such trials constitute a substantial part of all research involving human subjects.

The Guidelines

Guideline 1: Ethical justification and scientific validity of biomedical research involving human beings

The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out. Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature.

(...)

Guideline 2: Ethical review committees

All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees. The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review. The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.

(...)

Guideline 3: Ethical review of externally sponsored research

An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country. The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards.

(...)

Guideline 4: Individual informed consent

For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.

(...)

Guideline 5: Obtaining informed consent: Essential information for prospective research subjects

Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand:

1. that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary;
2. that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled;
3. the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;
4. for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;
5. the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;
6. whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;
7. that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;
8. that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);
9. any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;
10. the direct benefits, if any, expected to result to subjects from participating in the research
11. the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;
12. whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them;
13. any currently available alternative interventions or courses of treatment;
14. the provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified;
15. the limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;
16. policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests
17. to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject;
18. the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;

19. the possible research uses, direct or secondary, of the subject`s medical records and of biological specimens taken in the course of clinical care (See also Guidelines 4 and 18 Commentaries);

20. whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed (See Guideline 4 Commentary);

21. whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;

22. whether the investigator is serving only as an investigator or as both investigator and the subject`s physician;

23. the extent of the investigator's responsibility to provide medical services to the participant;

24. that treatment will be provided free of charge for specified types of research-related injury or for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;

25. in what way, and by what organization, the subject or the subject`s family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);

26. whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed;

27. that an ethical review committee has approved or cleared the research protocol.

(...)

Guideline 6: Obtaining informed consent: Obligations of sponsors and investigators

Sponsors and investigators have a duty to:

- refrain from unjustified deception, undue influence, or intimidation;
- seek consent only after ascertaining that the prospective subject has adequate understanding of the relevant facts and of the consequences of participation and has had sufficient opportunity to consider whether to participate;
- as a general rule, obtain from each prospective subject a signed form as evidence of informed consent - investigators should justify any exceptions to this general rule and obtain the approval of the ethical review committee (See Guideline 4 Commentary, *Documentation of consent*);
- renew the informed consent of each subject if there are significant changes in the conditions or procedures of the research or if new information becomes available that could affect the willingness of subjects to continue to participate; and,
- renew the informed consent of each subject in long-term studies at predetermined intervals, even if there are no changes in the design or objectives of the research.

(...)

Guideline 7: Inducement to participate

Subjects may be reimbursed for lost earnings, travel costs and other expenses incurred in taking part in a study; they may also receive free medical services. Subjects, particularly those who receive no direct benefit from research, may also be paid or otherwise compensated for inconvenience and time spent. The payments should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment („undue inducement"). All payments, reimbursements and medical services provided to research subjects must have been approved by an ethical review committee.

(...)

Guideline 8: Benefits and risks of study participation

For all biomedical research involving human subjects, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized.

Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual subject must be justified by the expectation that they will be at least as advantageous to the individual subject, in the light of foreseeable risks and benefits, as any available alternative. Risks of such 'beneficial' interventions or procedures must be justified in relation to expected benefits to the individual subject.

Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual must be justified in relation to the expected benefits to society (generalizable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

(...)

Guideline 9: Special limitations on risk when research involves individuals who are not capable of giving informed consent

When there is ethical and scientific justification to conduct research with individuals incapable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them.

(...)

Guideline 10: Research in populations and communities with limited resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

(...)

Guideline 11: Choice of control in clinical trials

As a general rule, research subjects in the control group of a trial of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention. In some circumstances it may be ethically acceptable to use an alternative comparator, such as placebo or „no treatment". Placebo may be used:

- when there is no established effective intervention;
- when withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms;
- when use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

(...)

Guideline 12: Equitable distribution of burdens and benefits in the selection of groups of subjects in research
Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. The exclusion of groups or communities that might benefit from study participation must be justified.

(...)

Guideline 13: Research involving vulnerable persons
Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

(...)

Guideline 14: Research involving children
Before undertaking research involving children, the investigator must ensure that:

- the research might not equally well be carried out with adults;
- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal representative of each child has given permission;
- the agreement (assent) of each child has been obtained to the extent of the child`s capabilities; and,
- a child`s refusal to participate or continue in the research will be respected.

(...)

Guideline 15: Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent
Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired;
- the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;
- the consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in research is always respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objection; and,
- in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.

(...)

Guideline 16: Women as research subjects
Investigators, sponsors or ethical review committees should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enrol in a clinical study. In this discussion, if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the sponsors/investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possibly hazardous research women who might become pregnant.

(...)

Guideline 17: Pregnant women as research participants.
Pregnant women should be presumed to be eligible for participation in biomedical research. Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility.

Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her fetus, or to the health needs of pregnant women in general, and, when appropriate, if it is supported by reliable evidence from animal experiments, particularly as to risks of teratogenicity and mutagenicity .

(...)

Guideline 18: Safeguarding confidentiality
The investigator must establish secure safeguards of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

(...)

Guideline 19: Right of injured subjects to treatment and compensation
Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

(...)

Guideline 20: Strengthening capacity for ethical and scientific review and biomedical research
Many countries lack the capacity to assess or ensure the scientific quality or ethical acceptability of biomedical research proposed or carried out in their jurisdictions. In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research.

Capacity-building may include, but is not limited to, the following activities:

- establishing and strengthening independent and competent ethical review processes/committees
- strengthening research capacity
- developing technologies appropriate to health-care and biomedical research
- training of research and health-care staff
- educating the community from which research subjects will be drawn.

(...)

Guideline 21: Ethical obligation of external sponsors to provide health-care services
External sponsors are ethically obliged to ensure the availability of:

- health-care services that are essential to the safe conduct of the research;
- treatment for subjects who suffer injury as a consequence of research interventions; and,

● services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned.

(...)

Appendix 1: Items to be included in a protocol (or associated documents) for biomedical research involving human subjects. **(...)**

Appendix 2: World Medical Association Declaration of Helsinki **(...)**

Appendix 3: The Phases of Clinical Trials of Vaccines and Drugs **(...)**

LIFE SCIENCES AND BIOTECHNOLOGY - A STRATEGY FOR EUROPE

European Parliament resolution on the Commission communication on Life sciences and biotechnology - A Strategy for Europe

COM(2002) 27 - C5-0260/2002 - 2002 /2123 (COS)

The European Parliament,

– having regard to the Commission communication (COM(2002) 27 - C5-0260/2002 [1]),

– having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [2],

– having regard to the Commission's report to the European Parliament and the Council on the development and implications of patent law in the field of biotechnology and genetic engineering (COM(2002) 545),

– having regard to its resolution of 15 March 2001 on the Future of the Biotechnology Industry [3],

– having regard to the European Charter of Fundamental Rights proclaimed at the European Council of 7 December 2000,

– having regard to the European Convention on Human Rights and Biomedicine of the Council of Europe, signed on 4 April 1997,

– having regard to its first reading positions on the proposal for a European Parliament and Council regulation on genetically modified food and feed [4] and on the proposal for a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and traceability of food and feed derived from genetically modified organisms [5],

– having regard to Rule 47(1) of the Rules of Procedure,

– having regard to the report of the Committee on Industry, External Trade, Research and Energy and the opinion of the Committee on Agriculture and Rural Development (A5-0359/2002),

A. whereas the Lisbon European Council set the European Union the new strategic goal of becoming the most competitive and dynamic knowledge-based economy in the world,

B. whereas biotechnology contributes to healthcare, helps to protect the environment and can be used in industrial production processes, while respecting the preventive and precautionary principles,

C. whereas the European Union is not merely an economic area, but is also an area of shared fundamental values based on respect for human dignity,

D. whereas awareness of biotechnology and the principles of genetics is not widely known,

E. whereas in spite of increasing efforts in the biotech sector in recent years, the EU is lagging behind its global competitors, which can be demonstrated by insufficient levels of R&D expenditure, particularly from the private sector, the geographical migration of researchers outside the EU (brain-drain) and of companies, mainly to the US, the difficulty of access to investment and venture capital and cumbersome patenting legislation and bureaucracy,

F. whereas the European Union has only limited competencies in the field of education,

G. whereas, although genetics specialists and professional organisations make efforts to promote quality assessment, genetic testing services are provided under widely varying conditions and regulatory frameworks in the individual Member States,

H. whereas there exists no EU legislation to guarantee a minimum standard of genetic testing and analysis services in conformity with other provisions,

1. Welcomes the Commission's Action Plan on Life sciences and Biotechnology and its vision for a long-term, competitive and responsible European model for biotechnology with all its benefits and opportunities for our society, while respecting the cultural diversity of each Member State;

2. Welcomes the Commission's willingness to explore areas where common views on fundamental guidelines are possible, to promote an inter-institutional dialogue, and to ensure that ethical implications are taken into account at the earliest possible stage of EU-supported research;

3. Calls for primary responsibility for coordinating the biotechnology strategy to be conferred on one Commissioner in particular and on a directorate-general created to that end so as to ensure greater consistency in Community activities;

4. Considers it important to inform the public that biotechnology offers opportunities in various fields: from health to agriculture, from industry to alternative energy resources; opposes the view that, in medicine, genetic technology and biotechnology are primarily associated with opportunities, whereas in agriculture they are primarily associated with risks; is much more inclined to believe that in both areas there are major opportunities which should be taken advantage of, but also significant risks which need to be reduced by means of appropriate legislation;

5. Calls on the Commission to launch a 'B-Europe' policy which lays down the specific political agenda for the next few years in the field of biotechnology;

6. Stresses that further basic statistical information is also required on the industry's structure and development in Europe;

7. Recalls that better statistics, e.g. on epidemiological data or on ongoing research projects, etc. will help to better focus R&D projects on the real needs of citizens;

Knowledge, education and the workforce

8. Calls on the governments of the Member States, as the European Union has only limited competencies in the field of education, to improve basic education in schools, higher education and education for adults in the field of biology with a particular focus on genomics and microbiology, not only to improve the knowledge of the workforce but also to improve the knowledge base on which consumers can take their decisions;

9. Calls on the Commission to hasten its review of Regulation (EEC) No 1408/71 and to draft a proposal for a harmonised procedure to transfer pension rights also for supplementary pensions between different Member States to provide an incentive for the mobility of the workforce;

10. Calls on the Member States to increase the proportion of women in science and research and development by supporting educational programmes and by changing working conditions and improving the availability and the quality of childcare;

Public information and debate

11. Observes the need to enhance and broaden public debate, the access to objective information and the level of scientific knowledge; emphasises the need for consumers to have the opportunity to address questions to scientists and to receive answers from them;

12. Calls for the public authorities and industry to pursue a transparent information policy based on scientific data; reminds the media of the major role which they play in this field and calls on them to cover the issue impartially and fairly;

13. Calls for an increased influence in the nomination of members of the European Group on Ethics in support of the Commission's proposal to strengthen Parliament's role in exploring and providing information on European ethical guidelines and stresses that the work of this group must be transparent and that consumers should be involved at an early stage;

14. Calls on the Commission to submit before the end of 2003 a legislative proposal specifying the mandate, working methods and the procedure of nomination of members of the European Group on Ethics;

15. Recommends forming a group of parlamentarians from the relevant committees to begin the cooperation with the Commission proposed in Action 16; stresses that the actions in the field of ethics proposed by the Commission should not undermine the European Parliament 's codecision rights in the relevant fields; insists that the proposed ethical guidelines should not undermine the competence of the Member States; proposes, therefore, that only minimum ethical standards which must be applied by all Member States should be adopted and that Member States should have the possibility of going further under national law;

International cooperation

16. States that biotechnology alone will not help to overcome hunger in the world and that other methods, for example a better distribution of available food, are currently more important, but underlines that given the ever increasing world population it might also be necessary to use genetically modified crops to produce enough food;

17. Recalls that the European Union is the largest development aid partner world-wide, and calls on the Commission and Member States to promote international guidelines on the role of biotechnology in cooperation in respect of the improvement of health, nutrition and environment, respecting human dignity in developing countries;

18. Considers that Community rules concerning the welfare and protection of consumers in the field of the life sciences and biotechnology should also be promoted at international level but without creating barriers to commerce and trade since many aspects are related to the world's trading system, which is governed by WTO agreements;

19. Emphasises that developing countries themselves must decide if and to what extent they want to use GMOs; considers that, should a developing country want to use biotechnology, the EU and Member States should provide support so that it can strengthen its own capacities;

20. Considers that biotechnology can contribute towards finding genuine solutions to environmental problems, sustainable development and food sufficiency, which would help to combat chronic hunger and to improve human health; considers, therefore, that this technology should be promoted with caution and its applications supported, taking full account of environmental and health safeguards;

21. Calls on the Commission and the Member States to promote the Johannesburg process for sustainable development and include technology transfer as one of the preconditions for sustainable development in the developing countries, underlines that biotechnology if applied prudently can contribute to sustainable development because it helps to save energy and raw materials and can lead to less pollution;

22. Supports the Commission's idea to play a leading role in developing international guidelines but regrets that this action is focused mainly on the food sector; points out that the establishment of international guidelines is also necessary regarding the protection of human dignity in the field of biotechnology;

23. Repeats its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development and urges the Commission and the Member States to work towards this end;

Legislation and enforcement of existing legislation

24. Emphasises the urgency to complete a harmonised, knowledge-based, predictable and ethical legal framework for biotechnology companies and farmers, which aims to secure consumer safety and competitiveness and to prevent both a 'brain-drain' in this field and a future dependency on the import of biotech products;

25. Calls on the Member States to implement existing legislation (e.g. Directive 2001/20/EC on clinical trials and Directive 98/44/EC on the legal protection of biologi-cal inventions) in a way that promotes the necessary research activities in Europe and at the same time preserves citizens' interests; urges, therefore, the Commission to clarify the wording of Article 5(2) of Directive 98/44/EC by way of an amendment to the Directive to exclude the total or partial sequence of a gene isolated from the human body from patentability;

26. Calls for the introduction of a European patent which meets the requirements of researchers and innovators in both public research institutes and industry;

Consumer protection

27. Considers that users of biotechnological developments should bear no risk of liability under the relevant European Union legislation;

28. Recalls the need for information based on reliable scientific assessments and studies to enable consumers to make their choice on a sound basis, emphasises that new technologies often have been met with doubt and that some of these doubts are not really rational and that the precautionary principle should be applied in a rational manner so as to provide consumer and environmental protection and not serve as a barrier to political decision-making and technological innovation;

29. Stresses that the use of genetically modified products and genetic engineering in production must be accompanied by research, particularly into the long-term effects;

30. Stresses the need to ensure that consumers receive reliable information about GMOs and products, food and animal feed produced from GMOs so that they can choose a product on the basis of prior information and can acquire confidence in GMO products and technology;

31. Supports the view that, when new products and production methods are introduced, the potential risks to human health and the environment should be minimised and that, therefore, transparent, knowledge-based risk assessment and risk management procedures must be used, taking account of the precautionary principle;

32. Notes that the cautious attitude of consumers towards GMOs and their products recorded in various European surveys (Eurobarometer, December 2001, ITPS Report, etc.) is in large measure attributable to insufficient provision of information about GMO technology;

considers it essential, therefore, that consumers receive reliable and full information;

33. Considers that market mechanisms operate effectively when the European policy of compulsory labelling of GMOs and their products is based on Community rules, the implementation of which can be monitored by means of scientific and analytical methods which do not allow fraud, the misleading of consumers or distortion of competition;

Research and development, industry, employment and SMEs

34. Calls on the Commission to promote public and private networking within the 6th Framework Programme and elsewhere amongst European, national and regional biotech research units, clusters and companies;

35. Urges Member States and the Commission to reconsider public policies that encourage or even oblige academic scientists to collaborate with industry in order to secure adequate funding for research since such policies may mean that doubt is cast on the independence of scientists employed by academic institutions;

36. Calls on the European Union to continue research in particular with regard to the development of foodstuffs that are beneficial for consumers, whereby the definition of consumer benefit should always include the nutritional and toxicological consequences of a product;

37. Calls on the European Union to continue research into the improvement of risk assessment, taking into consideration the latest scientific findings;

38. Takes the view that policy, together with the industry and research, must produce better information as to risks for consumers, the environment and animals and launch a carefully formulated accompanying programme for growing genetically modified plants;

39. Asks the Member States to implement the abovementioned Directive 98/44/EC and to recognise that the decision of the European Patents Office on the so-called Edinburgh Patent in July 2002 shows that ethical concerns are respected by the European Patents Office; regrets on the other hand that the earlier mistake on this patent by the Patents Office was discovered by Greenpeace (and not by the Patents Office itself); asks the European Patents Office to review its working methods, so that such mistakes will not be repeated and, refers to its resolution of 30 March 2000 [6] on the Decision of the Patents Office on the cloning of human beings;

40. Encourages the initiative of the Commission to identify with appropriate European experts how to overcome the issue of insufficient funding regarding biotech start-ups; asks the European Investment Bank to favourably consider recommendations resulting from that initiative;

41. Stresses the importance of giving SME easier access to innovation, training and risk capital in line with the spirit of the European Charter for Small Enterprises;

42. Encourages the Commission, Member States, the European Investment Bank and the Committee of the Regions to actively support setting-up bio-clusters, and where appropriate to support them with finance skills and other means, and encourage networking of bio-clusters throughout Europe to exchange experiences and establish best practices; calls for the development of bio-clusters and other models for technological transfer to be promoted in the European Union and in the applicant countries in order to stimulate investment.

Environment, agriculture and food

43. Calls on the Commission and the Member States to support research concerning uses of biotechnology offering clear social or environmental benefits, including the use of genetically modified micro-organisms in water purification and soil restoration, replacing dangerous chemicals currently in use, and developing sustainable and environmentally friendly energy sources (including biogas, hydrogen and ethanol);

44. Asks the Commission to support the potential of biotechnology regarding sustainable development and to support the development and selection of adequate assessment techniques allowing a quantitative measurement of sustainability, including all three pillars: environmental, economical and social;

45. Calls on the Commission and the Member States to review legislation on fuels, in particular Directive 98/70/EC on the quality of fuels, so as to allow biological energy sources to be economically explored and products to be placed on the market in the short term, e.g. blending ethanol with traditional engine fuels, in particular because current limitations are not economically or scientifically justified as they favour polluting fossil fuels and undermine significant environmental improvement through reduction of CO2;

46. Strongly supports the view that the existing de-facto moratorium on GM foods in force since 1998 should cease in order to promote innovation; the current situation has particularly harmed SMEs, which are the main originators of innovation;

47. Supports the establishment of legal thresholds for the adventitious presence of GM foods and feeds which enable consumer choice, are set at practically appropriate levels and are based on scientific assessment, provided these products have been established as safe by EU standards;

48. Calls for the adoption of practicable thresholds and the immediate implementation of Directive 2001/18/EC on the deliberate release of GMOs into the environment within the framework of an overall strategy for green genetic engineering in which products containing genetically modified material or produced therefrom must be clearly and unambiguously labelled and traceability ensured in order to give consumers the greatest possible transparency and full freedom of choice;

49. Strongly supports the reduction in the use of pesticides and herbicides through biotechnology if it is achieved without risk to the environment or human health;

50. Expects that greater consumer confidence in the regulatory process is achievable through centralised scientific review procedures performed by the European Food Safety Authority; therefore asks the Commission to make a proposal in this direction;

Health and reproductive medicine

51. Calls on the Commission to draft a regulation for the introduction of a standard for genetic tests, since these services lie outside the scope of Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and Directive 98/79/EC on in-vitro diagnostic medical devices, which applies only to products to be marketed;

52. States that genetic testing and analysis must be conducted under clear rules within the frame of competent, independent and personal counselling which must cover medical, ethical, social, psychological and legal aspects;

53. Solemnly reaffirms that the life and dignity of all human beings, whatever their stage of development and state of health, must be respected and is opposed to any form of research or use of life sciences and biotechnology that runs counter to this fundamental principle;

54. Notes that genetic testing analysis and diagnosis data must remain confidential and should be used only for the benefit of the person requiring such tests, with the exception of tests undertaken for clearly defined scientific or criminal investigation purposes, therefore such tests should be inadmissible for social or recruitment

purposes, and should not jeopardise personal privacy and dignity;

55. Calls on the Commission to take the necessary steps for an EU-wide regulation on DNA-testing, choosing, if possible, a legal basis (e.g. Article 152 (health) or Article 153 (consumer protection)) which leaves Member States free to introduce more stringent protection measures and asks its competent Committee, subject to prior authorisation by the Conference of Presidents, to consider drafting an own-initiative report on the legal aspects of DNA testing;

56. Considers it particularly important to ensure that no woman is compelled to have prenatal diagnosis carried out and that any decision not to resort to such diagnosis is respected and supported;

57. Takes the view that determination of sex in connection with prenatal diagnosis should be permitted only - if at all - if there is a risk of serious gender specific hereditary diseases;

58. Instructs its President to forward this resolution to the Council and the Commission and the parliaments of the Member States.

[1] OJ C 55, 2.3.2002, p. 3.[2] OJ L 213, 30.7.1998, p. 13.[3] OJ C 343, 5.12.2001, p. 292.[4] P5_TA(2002)0354.[5] P5_TA(2002)0353.[6] OJ C 378, 29.12.2000, p. 95.

INTERNATIONAL CONFERENCE ON BIOETHICS IN CENTRAL AND EASTERN EUROPE

Vilnius, Lithuania, 11-12 November 2002

FINAL STATEMENT

At the close of International Conference on Bioethics in Central and Eastern Europe held on 11 and 12 November 2002 in Vilnius, Lithuania we, the participants coming from Albania, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Republic, Estonia, Former Yugoslav Republic of Macedonia, Georgia, Latvia, Lithuania, Moldova, Poland, Romania, Russian Federation, Slovakia, Slovenia and Ukraine, adopt this Final Statement:

Recognizing that bioethics today plays an important role in the protection of human rights and fundamental freedoms,

Aware of the need to promote informed, pluralistic public bioethics debate, taking into account the various schools of thought, value systems, historical and cultural backgrounds, and philosophical and religious convictions that make up our various societies,

Also aware of the need to ensure the imperative of freedom of research, with full respect for human dignity, Recalling the Universal Declaration on the Human Genome and Human Rights, adopted in 1997 by the General Conference of UNESCO and endorsed by the United Nations General Assembly in 1998,

Recalling also the Convention for Human Rights and Biomedicine with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and opened for signature on 4 April 1997:

1. Reiterate our common position that human reproductive cloning shall not be permitted and invite our Governments to take appropriate measures, including legislative or regulatory action in order to prohibit any attempts to clone human being.

2. Reiterate further the need to ensure that the results of research in biology and genetics are used exclusively for peaceful purposes.

3. Emphasise the necessity to follow ethical principles in the research and use of the biomedicine and biotechnology, taking into account the principle of just and equitable access to health care.

4. Underline the importance of ensuring the informed consent and the protection of privacy in obtaining and using genetic information, and to support the international efforts aimed at developing an international declaration on human genetic data.

5. Express our support for the provision of article 4 of the Universal Declaration on the Human Genome and Human Rights, that „the human genome in its natural state shall not give rise to financial gains".

6. Stress the urgent need for education in bioethics in Central and Eastern European countries.

7. Stress also the need for disseminating information on bioethics throughout the countries of Central and Eastern Europe and strongly encourage the initiatives aimed at designing the national, regional and international bioethics information networks.

8. Encourage the Member States of the Council of Europe not yet party to the European Convention on Human Rights and Biomedicine to sign and ratify this Convention and sign and ratify its Additional Protocol on Prohibiting Human Cloning.

9. Welcome UNESCO's efforts to explore the possibility of developing a universal legal instrument on bioethics.

In conclusion, we, the participants in the Conference:

(i) Call on our Governments to proceed in accordance with this Final statement;

(ii) Undertake the responsibility of promoting the human rights and ethical consideration in science, biomedicine and biotechnology;

(iii) Invite Lithuania and UNESCO to bring this final statement to the attention of Member states of UNESCO, and to disseminate it as widely as possible.

Vilnius, November 12, 2002

THE NATURE AND DIGNITY OF THE HUMAN PERSON

Final Communiqué of the VIII General Assembly of the Pontificial Academy for Life, 25. - 27. II. 2002 [1]

From February 25th to February 27th the VIII General Assembly of the Pontifical Academy for Life took place in the Old Synod Hall of Vatican City. According to the usual practice, the members of the Academy, from various scientific disciplines, and from around the world were convoked to discuss their experience of giving witness to life as a service to the Church and to all men. With regards to the purpose of the Academy, which is specifically: the study, information and formation on the principal problems of biomedicine and of law, relative to the promotion and defense of life, above all in the direct relation that they have with Christian morality and the directives of the Church's Magisterium, this years assembly was dedicated to *The Nature and Dignity of the Human Person as the basis for the Right to Life: The Challenge of the Contemporary Cultural Context.*

1. No one can mistake the fact that in the contemporary cultural context there exist currents of thought that more or less explicitly negate the existence of human nature or the capacity to know it. As a consequence, they do not admit that the dignity of the person has an unconditional and immutable value, especially at the beginning and end of human life, which require more care and pro-

tection. In fact, as the Holy Father recalled in his address to the participants of the Assembly „*For many contemporary thinkers, the concepts of "nature" and of "natural law" appear to apply only to the physical and biological world, or, as an expression of order in the cosmos, in scientific research or in the field of ecology. Unfortunately, in such a view, it becomes difficult to use natural law to mean human nature in a metaphysical sense and to use natural law for the moral order*" (John Paul II, *Address to Participants of the VIIIth General Assembly of the PAV*, n.2).

Faced with these cultural paradigms, the Academy for Life understood the need to commit itself to maintaining continuity with the essential components of the lengthy tradition of the Catholic Church, as well as classical philosophical thought and to expressing them in new ways, and with a different vocabulary if necessary, so as to foster dialogue with the modern world, as desired by the Second Vatican Council.

Moreover, this theme is currently of fundamental relevance to an examination of the link between the creation of laws and codes at various levels of government and the human values on which they must be based.

To this end, the General Assembly followed an itinerary organized around three lines: the anthropological question; natural moral law considered in terms of its existence and our capacity to know it; and, finally, the problem of rights, with particular emphasis on the right to life.

2. In terms of anthropology, and recalling the teachings of *Gaudium et Spes* (n. 14), the assembly wanted to reaffirm a unitary vision of man, „*corpore et anima unus*", in refutation of all dualism or reductionism, whether of a spiritual or materialist kind. Authentic respect for each human being has its foundations in this corporo-spiritual identity, of which corporeality is an authentic and constitutive dimension of the person through which he manifests and expresses himself (cf. *Donum Vitae*, 3), as is the spiritual dimension, through which man is open to God, finding in Him the ultimate foundation of his dignity.

A problem may arise concerning the recognition of the existence of a universal human nature from which we derive the natural moral law. With regards to this, the presentations discussed the ways in which, in contemporary culture, certain schools of thought relying solely on the historico-evolutionary dimension of man, end up by negating the existence of a universal human nature. Nevertheless, this nature, understood as a „rational nature" seemed to the members of the Academy - in line with the teachings of the Church - to be an undeniable paradigm for clearly understanding the natural moral law. In fact, what else could form the basis of the dignity of the human person, if not that which specifically characterizes him, which is to say his nature?

The Holy Father himself wished to repeat to the members of the Academy that „*The human person with his reason, is capable of recognizing this profound and objective dignity of his own being, and the ethical requirements that derive from it. In other words, man can discern in himself the value and the moral requirements of his own dignity. It is a discernment that entails a discovery open to further refinement following the coordinates of the "historicity" so much a part of human knowing*" (John Paul II *Address to Participants*, n. 3).

3. Based on this anthropological vision, the reflections of the members were centred on the question of the natural moral law; which, „is nothing other than the light of understanding infused in us by God, whereby we understand what must be done and what must be avoided. God gave this light and this law to man at creation." (*Veritatis Splendor*, 12 and 40). Therefore, the existence of such a law is a direct consequence of the existence of human nature.

In particular, recalling the doctrine of St. Thomas Aquinas concerning the natural moral law, we wanted to underline the fact that each man has the natural capacity to know with certainty the fundamental dictates (first principles) of that law, which spring up in his heart, calling him always to do good and avoid evil (*Gaudium et Spes*, 16). To human nature also belongs the capacity to know the derived moral norms (such as the moral norms concerning the defence of human life) even though in certain instances teir derivation seems to be difficult, because of the inevitable personal and cultural limitations that constitute the history of each person.

In this respect, the moral virtues, understood as acquired habits towards a specific good, constitute a tremendous help, either towards the acquisition of knowledge of that law, or, once such knowledge is acquired, towards actions in accordance with it. At the same time, there exists the contrary, which are moral vices, and which represent prior obstacles either towards the acquisition of that knowledge, or, once acquired, towards the capacity to act in accordance with it.

4. The requirements which derive from the natural moral law, and which human history clearly demonstrate, call for both their recognition and protection by law, within society. In this way, we may speak of „natural right", and its subsequent codification in law. The foundation of this right is not mere human consent; rather, it is founded on human nature, and the dignity of the person.

It is for this reason that, historically, until the end of the eighteenth century, we find that the fundamental rights of man were considered as inviolable and non-negotiable, and therefore they were safe from the arbitrary decisions of society, or from the will of the majority.

After that time, on the contrary, in our times, we are witnesses to a progressive change, marked by exaggerated claims to the 'right' of personal freedom, which carries with it many forms of attack against life at its earliest and final stages, „which present *new characteristics with respect to the past and which raise questions of extraordinary seriousness.* It is not only that in generalized opinion these attacks tend no longer to be considered as "crimes" paradoxically they assume the nature of "rights" (*Evangelium Vitae*, 11). A certain sector of public opinion, beginning from the above presupposition, maintains that the State must not only cease to punish such actions, but must also guarantee their free exercise, even going so far as to sanction them.

Faced with this transformation, referring to the fundamental rights of man, „*the Catholic Church claims for every human being the right to life as the primary right. She does it in the name of the truth about man and as a protection of his freedom, that cannot be sustained without respect for the right to life. The Church affirms the right to life of every innocent human being at every moment of his existence. The distinction sometimes implied in international documents between "human being" and "human person" so as to limit the right to life and to physical integrity to persons already born is an artificial distinction without any scientific or philosophical foundation: every human being, from the moment of his conception until the moment of his natural death, possesses an inviolable right to life and merits all the respect owed to the human person* (cf. *Donum vitae*, n. 1)" (John Paul II *Address to Participants* n. 6).

For this reason, the assembly of Academicians calls upon the legislators of all countries, to elaborate contemporary juridical norms based upon an authentic truth about man, above all in regards to the primary right to life.

5. In conclusion, this final communiqué wishes to make its own the desire of the Holy Father who encou-

raged the Assemble to continue its "*reflection on the natural moral law and natural rights with the hope that from your discussions will come a new source of zeal for establishing the true good of the human being and of a just and peaceful social order. It is always by returning to the deep roots of human dignity and of the true good of man, and by building on the foundation of what exists as everlasting and essential in man, that a fruitful dialogue can take place with men of every culture in order to build a society inspired by the values of justice and brotherhood*" (John Paul II *Address to Participants* n.7).

[1] The original Italian version was published in L'OSSERVATORE ROMANO, March 6th, 2002, p. 6.

ASSISI DECALOGUE FOR PEACE[1]

1. We commit ourselves to proclaiming our firm conviction that violence and terrorism are incompatible with the authentic Spirit of religion, and, as we condemn every recourse to violence and war in the name of God or religion, we commit ourselves to doing everything possible to eliminate the root causes of terrorism.

2. We commit ourselves to educating people to mutual respect and esteem, in order to help bring about a peaceful and fraternal coexistence between people of different ethnic groups, cultures, and religions.

3. We commit ourselves to fostering the culture of dialogue, so that there will be an increase of understanding and mutual trust between individuals and among peoples, for these are the premises of authentic peace.

4. We commit ourselves to defending the right of everyone to live a decent life in accordance with their own cultural identity, and to form freely a family of their own.

5. We commit ourselves to frank and patient dialogue, refusing to consider our differences as an insurmountable barrier, but recognizing instead that to encounter the diversity of others can become an opportunity for greater reciprocal understanding.

6. We commit ourselves to forgiving one another for past and present errors and prejudices, and to supporting one another in a common effort both to overcome selfishness and arrogance, hatred and violence, and to learn from the past that peace without justice is no true peace.

7. We commit ourselves to taking the side of the poor and the helpless, to speaking out for those who have no voice and to working effectively to change these situations, out of the conviction that no one can be happy alone.

8. We commit ourselves to taking up the cry of those who refuse to be resigned to violence and evil, and we desire to make every effort possible to offer the men and women of our time real hope for justice and peace.

9. We commit ourselves to encouraging all efforts to promote friendship between peoples, for we are convinced that, in the absence of solidarity and understanding between peoples, technological progress exposes the word to a growing risk of destruction and death.

10. We commit ourselves to urging the leaders of nations to make every effort to create and consolidate, on the national and international levels, a world of solidarity and peace based on justice.

[1] Adopted at the prayer meeting of the leaders of many religious confessions held in Assisi (Italy) on January 24, 2002. Present text is the official English version. It was taken from the website: www.zenit.org, text identifier: ZE02030405.

ETICKÝ KÓDEX LEKÁRA A ZUBNÉHO LEKÁRA[1]

Všeobecné povinnosti lekára a zubného lekára

(1) Stavovskou povinnosťou lekára a zubného lekára je profesionálna starostlivosť o zdravie jednotlivca a spoločnosti v súlade so zásadami ľudskosti, v duchu úcty k ľudskému životu od jeho počiatku až do konca so všetkými ohľadmi na dôstojnosť ľudského jedinca.

(2) Povinnosťou lekára a zubného lekára je zachovávať život, chrániť a obnovovať zdravie, mierniť utrpenie bez ohľadu na národnosť, rasu, vierovyznanie, politickú príslušnosť, spoločenské postavenie, morálnu či rozumovú úroveň a povesť pacienta a bez ohľadu na osobné pocity lekára.

(3) Lekár a zubný lekár pri výkone povolania postupujú v súlade so všeobecne záväznými právnymi predpismi.

(4) Povinnosťou lekára a zubného lekára je byť za všetkých okolností vo svojich profesionálnych rozhodnutiach nezávislý a zodpovedný.

(5) Lekár a zubný lekár napomáhajú pacientom uplatňovať právo slobodného výberu lekára.

Lekár a zubný lekár a výkon ich povolaní

(1) Lekár a zubný lekár v rámci svojej odbornej spôsobilosti a kompetencie vykonávajú preventívne výkony, diagnostické výkony a liečebné výkony spôsobom zodpovedajúcim súčasným poznatkom lekárskej vedy.

(2) Lekár a zubný lekár plnia svoje povinnosti aj v situáciách verejného ohrozenia a pri katastrofách prírodnej alebo inej povahy.

(3) Od lekára a zubného lekára nemožno vyžadovať taký lekársky výkon alebo spoluúčasť na ňom, ktorý odporuje ich svedomiu, okrem prípadov na ochranu života, zdravia alebo práv iných.

(4) Lekár a zubný lekár nesmú predpisovať lieky, od ktorých vzniká závislosť, alebo také lieky, ktoré majú účinky dopingu, na iné ako liečebné účely.

(5) Lekár a zubný lekár u nevyliečiteľne chorých a zomierajúcich miernia bolesť, rešpektujú ľudskú dôstojnosť a zmierňujú utrpenie. Eutanázia a asistované suicídium sú neprípustné.

(6) Lekár a zubný lekár, ktorí vykonávajú povolanie, sú povinní dbať o svoj odborný rast a sústavne sa vzdelávať.

(7) Lekár a zubný lekár sú povinní pri výkone povolania primerane chrániť zdravotnú dokumentáciu pred neoprávnenou zmenou, zničením alebo zneužitím.

(8) Lekár a zubný lekár nesmú sami alebo po dohovore s inými ordinovať neúčelné diagnostické, liečebné ani iné výkony.

(9) Pri predpisovaní a odporúčaní liekov a zdravotníckych pomôcok sa lekár a zubný lekár nesmú riadiť komerčnými hľadiskami, ale výlučne poznatkami lekárskej vedy, svojím svedomím a potrebou pacienta.

(10) Lekár a zubný lekár sa môžu zúčastňovať na prezentácii medicínskych tém na verejnosti, v tlači, rozhlase a televízii a na diskusii k nim.

(11) Lekár a zubný lekár nemôžu používať nedôstojné praktiky smerujúce k rozšíreniu počtu pacientov. Je zakázané takéto aktivity iniciovať prostredníctvom druhých osôb. Reklama a inzercia súkromnej praxe, zdravotníckych zariadení a používaných diagnostických a liečebných metód sú povolené. Reklama musí byť pravdivá, striedma, výsostne informujúca a nesmie mať znaky nekalej súťaže. Text reklamy a jej zverejnenie nesmú znížiť vážnosť povolania lekára a povolania zubného lekára.

(12) Lekár a zubný lekár si majú byť vedomí svojej občianskej úlohy a svojho vplyvu na okolie.

Lekár, zubný lekár a pacient

(1) Lekár a zubný lekár si plnia voči každému pacientovi svoje profesionálne povinnosti.

(2) Lekár a zubný lekár sa k pacientovi správajú korektne, s pochopením a trpezlivosťou a neznížia sa k hrubému alebo nemravnému konaniu. Lekár a zubný lekár rešpektujú pacienta ako rovnocenného partnera so všetkými občianskymi právami i povinnosťami vrátane zodpovednosti za svoje zdravie.

(3) Lekár a zubný lekár nesmú napomáhať porušovanie cti a dôstojnosti človeka alebo sa na ňom zúčastňovať. Každý lekár a zubný lekár je povinný oznámiť príslušným orgánom podozrenie z hrubého alebo krutého zaobchádzania a týrania pacienta, a to najmä maloletej osoby a osoby zbavenej spôsobilosti na právne úkony.

(4) Lekár a zubný lekár sú povinní zrozumiteľným spôsobom poučiť pacienta alebo jeho zákonného zástupcu o charaktere ochorenia, zamýšľaných diagnostických a liečebných postupoch vrátane rizík, o uvažovanej prognóze a o ďalších dôležitých okolnostiach, ktoré môžu nastať v priebehu diagnostiky a liečby.

(5) Lekár a zubný lekár nijakým spôsobom nesmú zneužiť dôveru a závislosť pacienta.

Vzťahy medzi lekárom a zubným lekárom

(1) Základom vzťahov medzi lekárom a zubným lekárom je vzájomne čestné, slušné a spoločensky korektné správanie spolu s kritickou náročnosťou, rešpektovaním kompetencií a priznaním práva na odlišný názor.

(2) Lekár a zubný lekár kolegiálne spolupracujú s lekármi, ktorí súčasne alebo následne vyšetrujú alebo liečia toho istého pacienta.

(3) Lekár a zubný lekár sú povinní požiadať ďalšieho lekára o konzílium vždy, keď si to vyžadujú okolnosti a pacient s tým súhlasí. Lekár a zubný lekár majú právo navrhnúť osobu konzultanta. Závery konziliárneho vyšetrenia majú byť dokumentované písomne a je povinnosťou informovať o nich pacienta s osobitným dôrazom v prípadoch, keď sa názory lekárov a zubných lekárov rôznia.

Lekár, zubný lekár a ostatní pracovníci v zdravotníctve

(1) Lekár a zubný lekár nesmú poskytovať zdravotnú starostlivosť za prítomnosti osoby, ktorá nie je lekárom alebo zubným lekárom a nepatrí k zdravotníckemu personálu. Výnimkou z uvedených zásad je osoba, ktorá lekárovi a zubnému lekárovi umožňuje poskytnúť prvú pomoc, alebo taká osoba, ktorá sa u lekára vzdeláva alebo pracuje, a ďalšia osoba, s ktorej prítomnosťou pacient súhlasí.

(2) Lekár alebo zubný lekár nesmú podporovať osoby vykonávajúce činnosť, ktorú môže vykonávať len zdravotnícky pracovník.

[1] Príloha k zákonu č. 219/2002 Z. z., in: Zbierka zákonov č. 219/2002, Čiastka 93, s. 2184 - 2185.

KONFERENCIE / CONFERENCES

ETHICS IN SCIENCE AND RESEARCH: SITUATION AND PERSPECTIVES IN THE CANDIDATE COUNTRIES TO THE EUROPEAN UNION

International Bioethics Conference, Bratislava, March 17 - 19, 2002

On March 17 - 19, 2002, an international conference under the same title took place in Bratislava, the capital of the Slovak Republic (SR). The meeting was co-organised by the Directorate General for Research (DGR), Directorate Science and Society (DSS) (Unit Ethics in Research and Science) of the European Commission (EC), Brussels, and the Institute of Medical Ethics and Bioethics (IMEB) Fdn., Bratislava, under the auspices of both the Slovak minister of health Mr. Roman Kováč and minister of education Mr. Milan Ftáčnik. The conference was supported also by the Central and East European Association of Bioethics (CEEAB), the secretariat thereof should be opened in Bratislava, together with the new „Bioethics Information and Documentation Centre", soon after the meeting.

The **participants** of the conference were delegates of 13 candidate countries to EU (representing national coordinators for research, national ethics committees and other national structures of relevant expertise and scope of activity), as well as international speakers and experts, invited to the meeting by EC (altogether more than 70 people, 22 European countries were represented). The meeting was attended also by the high ranking representatives of the local scientific community (universities, Slovak Academy of Sciences, leading research institutions, etc.) and had a strong working character, dealing with sets of new, original facts, and assessing perspectives the candidate countries face in their integration and harmonisation efforts to EU in the field of research and science.

The **program** of the conference comprised several monothematic sessions and panel discussions, as well as a special event open to the public, which was devoted to the problem of responsibility, transparency, and media role(s) in relation to the unprecedented scientific progress underway in the contemporary developed countries, and importance of public information and debate in promotion of better understanding, and perhaps also better societal control of science and application of its breaking results in practice and societies' life and future(s).

The **major topics** of the meeting were as follows: the problem of the conflict of interest in science and research; data protection and data-banking with genetic content (incl. concrete country-specific case analyses of the Estonian, Latvian, Icelandic and UK projects experiences); elements of institutional infrastructure building in Europe for ethics in research (incl. national ethics committees, roles of the ministries of education, science and research, ministries of health, local and regional research ethics committees, and also the relevant international activities, such as the Council of Europe's (CE's) CDBI (Steering Committee on Bioethics), COMETH (Conference of the Representatives of the National Ethics Committees) and DEBRA Programme; the EC's „Action Plan Science and Society", and many others); requirements of the EC's 6th Framework

Programme (6FP) and the national legal situations; exploring new strategies for ethics in science and research in Europe and beyond (including EURETHNET Project of EC, international networking, collaboration of ethics committees on the national and international basis, etc.); the specific possibilities and concrete projects for collaboration between the Central and East European (CEE) countries.

Among the many **highlights** of the meeting, the most important probably were (1) the presentation of the results of the EC-sponsored enquiry on the ethical and legal situation in science and research in the candidate countries to EU; (2) the debate of the country-specific case studies on the problem of gene-banking; the outline of (3) the EC's „Action Plan Science and Society"; and of (4) the future activities of CEEAB and IMEB Fdn. co-sponsored „Bioethics Information and Documentation Centre", to be devoted specifically to the bioethics collaboration and networking in CEE countries.

A more comprehensive **information** on the conference proceedings (to be published in a special volume by EC) and follow-up could be found at the conference web-site, which should be maintained alive by DGR - DSS of EC to foster, document and promote further developments and collaboration in this most important field.

Jozef Glasa

ETIKA HUMÁNNEJ GENETIKY – PROBLÉMY (POST)GENÓMOVÉHO VEKU

Medzinárodná konferencia bioetiky, Bratislava, 23. - 24. 10. 2002

V dňoch 23. - 24. októbra sa v Bratislave konala už druhá významná medzinárodná bioetická konferencia v roku 2002 pod názvom - *(angl.) International Bioethics Conference - Ethics of Human Genetics: Challenges of the (Post)Genomic Era.*

Usporiadateľmi konferencie boli: Riaditeľstvo pre právne záležitosti Rady Európy (RE, Štrasburg; konferencia sa konala v rámci Programu DEBRA) a Ministerstvo zdravotníctva Slovenskej republiky (MZ SR) (v spolupráci Centrálnej etickej komisie a Odboru zahraničných vzťahov). Spoluusporiadateľmi boli Generálne riaditeľstvo - Veda a spoločnosť Európskej komisie (GR - VS EK; Brusel), Detská fakultná nemocnica s poliklinikou Lekárskej fakulty UK v Bratislave, Slovenská zdravotnícka univerzita v Bratislave, Kancelária Svetovej zdravotníckej organizácie (SZO) v SR a Nadácia Ústav medicínskej etiky a bioetiky v Bratislave. Slávnostného otvorenia konferencie, ktorá sa konala pod záštitou ministra zdravotníctva SR MUDr. Rudolfa Zajaca, sa zúčastnili poprední zástupcovia usporiadajúcich organizácii, ako aj predsedníčka zdravotníckeho výboru Národnej rady SR poslankyňa MUDr. Anna Záborská. Súčasťou podujatia bolo aj prvé diskusné sústredenie predsedov a členov etických komisií v SR, ktoré zorganizovala obnovená Centrálna etická komisia MZ SR.

Program konferencie mal predovšetkým pracovný charakter. Dôraz sa kládol na etickú analýzu najnovších poznatkov a trendov v rýchlo sa rozvíjajúcej oblasti humánnej genetiky a jej súčasných i perspektívnych aplikácií v medicíne a zdravotníctve. Z celej šírky danej problematiky bolo pochopiteľne na konferencii možné prebrať len malú časť. Pri zostavovaní odborného programu preto prednosť dostali problémy s bezprostredným dopadom na medicínsku prax a tiež problémy, ktoré by sa mali v dohľadnej dobe stať predmetom nových legislatívnych úprav v SR. Pre celý priebeh konferencie, vrátane plenárnych diskusií, bolo zabezpečené kvalitné simultánne tlmočenie. Súčasťou spoločenského programu konferencie bola návšteva predstavenia baletu P. I. Čajkovského „Labutie jazero" v historickej budove Slovenského národného divadla.

Odborný program sa sústredil do niekoľkých monotematických blokov. V úvodnej časti pozvaní prednášatelia predstavili viaceré **medzinárodné aktivity v oblasti bioetiky**, ktoré sa úspešne rozvíjajú v európskom meradle. *P. Zilgalvis* (RE, Štrasburg) referoval o aktivitách RE v oblasti humánnej genetiky, ktorá sa v súčasnosti sústreďuje v práci Pracovnej skupiny pre humánnu genetiku (*angl. Working Party on Human Genetics*) Riadiaceho výboru pre bioetiku (*angl. Steering Committee on Bioethics* - CDBI), pripravujúcej Dodatkový protokol o humánnej genetike k Dohovoru o ľudských právach a biomedicíne (tzv. Dohovor z Ovieda, 1997). Práce na protokole v súčasnosti smerujú k ukončeniu jeho prvej časti - aplikácie genetiky v medicíne a zdravotníctve, menej rozpracovaná je nateraz druhá časť protokolu - aplikácie genetiky v oblasti zdravotného poisťovníctva a zamestnávania (skríning pracovníkov s geneticky podmieneným zdravotným rizikom). Cieľom protokolu je zabezpečiť ochranu ľudských práv, integrity a identity každého človeka pri aplikácií genetiky v uvedených situáciách. *A. Bitušíková* (GR - VS EK, Brusel) hovorila o aktuálnych etických problémoch dotýkajúcich sa oblasti humánnej genetiky, ktoré EK riešila v súvislosti s prípravou 6 rámcového programu (*angl. 6th Framework Program*) pre oblasť biomedicínskeho výskumu. S ohľadom na kandidátske krajiny Európskej únie (EÚ) priniesla v referáte zaujímavé výsledky dotazníkového prieskumu uskutočneného GR - VS EK v týchto krajinách v rokoch 2001 - 2002, ktoré sa týkali etiky a legislatívy pre oblasť humánnej genetiky v týchto krajinách. *J. Glasa* referoval o aktivitách a perspektívach činnosti Stredo- a východoeurópskej asociácie bioetiky (*angl. Central and Eastern European Association of Bioethics* - CEEAB), najmä v súvislosti s plánovaným otvorením kancelárie CEEAB a dokumentačno-informačného centra v rámci programu EURETHNET (EK) v Bratislave. Informácie doplnili *R. Komel* (Ljubljana) - hovoril o legislatívnych aspektoch vývoja v oblasti humánnej genetiky a verejnej diskusii o týchto problémoch v Slovinsku, *B. Belicza* (Zágreb) - venovala pozornosť výuke študentov a zdravotníckych pracovníkov so zameraním na etické problémy humánnej genetiky z hľadiska skúseností v Chorvátsku (prednáška v písomnej forme). *M. Lukáčová* (Bratislava) podala prehľad o doterajšom vývoji a súčasnom stave lekárskej genetiky v SR.

Výnimočné svojou informačnou hodnotou, kvalitou prednesu i prezentovanej dokumentácie boli dve vyžiadané ***state-of-the-art* prednášky**, ktoré priniesli prehľad aktuálneho vývoja i najnovšie poznatky v danej oblasti. Išlo o prednášku *J. Rogers* (The Welcome Trust Sanger Institute, Cambridge, Veľká Británia (VB); predstaviteľka významného centra medzinárodného projektu výskumu ľudského genómu) na tému „*Projekt výskumu ľudského genómu - výsledky, aplikácie a budúce perspektívy*" a prednášku *M. - L. Labat* (Maisons - Alfort, Francúzsko; objaviteľka tzv. adultnej kmeňovej bunky) na tému „*Ľudské kmeňové bunky - biológia a etika*".

V sekcii venovanej **legislatívnym a etickým problémom humánnej genetiky** vystúpili ako pozvaní prednášatelia významné osobnosti na poli medzinárodného práva: *A. McCall-Smith* (Edinburg, VB) hovoril o probléme ochrany „genetického súkromia" a zamedzení

diskriminácie z dôvodu genetickej výbavy daného človeka; *J. Sandor* (Budapešť) referovala o problematike ochrany genetických údajov a o doterajších a perspektívnych problémoch v tejto oblasti z právneho hľadiska; *A. Nomper* (Tallin, Estónsko) hovoril o legislatívnych aspektoch projektu výskumu ľudského genómu v Estónsku (ide o jeden z troch v súčasnosti rozvíjaných projektov výskumu ľudského genómu na populačnej úrovni: podstatou je zbieranie a uchovávanie vzoriek biologického materiálu, najmä krvných vzoriek, na genetickú analýzu, pričom snahou je zachytiť čo najväčšiu časť danej populácie; podobný projekt už prebieha na Islande, kde však legislatívne i praktické riešenia vyvolali vlnu domácej i medzinárodnej kritiky; ďalší projekt sa pripravuje v niektorých vybraných oblastiach VB - a venuje mimoriadnu pozornosť zvládnutiu etickej a legislatívnej problematiky, ako aj primeranému informovaniu verejnosti).

Panelová diskusia na tému ***Etické komisie - ich úlohy a zodpovednosť v*** SR bola súčasne prvým diskusným sústredením členov etických komisií v SR po obnovení práce Centrálnej etickej komisie (CEK) MZ SR. V úvode diskusie *J. Glasa* (predseda CEK) informoval o súčasných legislatívnych iniciatívach v tejto oblasti. Ide najmä o podporu urýchleného vydania dvoch vykonávacích vyhlášok MZ SR - Vyhlášky o klinickom skúšaní liečiv a o správnej klinickej praxi a Vyhlášky o etických komisiách. Prvá vyhláška je už po opakovanom medzirezortnom pripomienkovom konaní, druhá je pripravená v paragrafovom znení. Obe vyhlášky bude možné vydať až po plánovanej novelizácií príslušných zákonných noriem (zákona o lieku; zákona o zdravotníckych zariadeniach alebo zákona o zdravotníckej starostlivosti). *V. Fedelešová* (predsedníčka Etickej komisie vo FDNsP v Bratislave na Kramároch) a *V. Spustová* (predsedníčka Etickej komisie ÚPKM v Bratislave) hovorili o praktických aspektoch práce etických komisií v podmienkach fakultnej nemocnice a veľkého výskumného ústavu. Prítomní v bohatej diskusii poukázali na viaceré konkrétne problémy práce etických komisií v SR, ktoré si vyžadujú urýchlené a systémové riešenie. Medzi najdôležitejšie otázky zaradili: doriešenie legislatívnej bázy činnosti etických komisií; ujasnenie kompetencií a zodpovednosti, a to aj vo vzťahu k orgánom profesijných organizácií; riešenie otázky hmotnej a nehmotnej motivácie práce členov komisií, najmä otázky prípadnej honorácie vyžiadaných expertíz, vrátane odborného posúdenia predkladaných projektov z etického hľadiska; vzájomnú komunikáciu a informovanosť etických komisií (privítali možnosť celoštátnych diskusných sústredení organizovaných najmenej raz ročne, najlepšie v nadväznosti na odbornú konferenciu alebo postgraduálny kurz bioetiky); nutnosť „vstupného" a kontinuálneho vzdelávania členov etických komisií, informovanosti o aktuálnych trendoch a nových problémoch v oblasti bioetiky; aktívnejšiu úlohu CEK, ktorá by mala mať koordinačnú, konzultačnú a informačnú funkciu vo vzťahu k lokálnym a regionálnym (krajským) etickým komisiám na celom území SR; dostupnosť vzdelávacích a informačných materiálov pre prácu etických komisií v slovenskom jazyku (plánované *vydanie príručky* pre etické komisie, zostavenej J. Glasom; lepšia dostupnosť časopisu *Medicínska etika & Bioetika* (zasielanie jednotlivým zdravotníckym zariadeniam, dostupnosť v PDF formáte na internete).

V úvode bloku venovaného problematike **genetickej prenatálnej diagnostiky** vystúpila *A. Dorries* (Hannover, Nemecko; členka CDBI; pediater - genetik a bioetik) s prednáškou na tému *Genetická prenatálna diagnostika - Dilema lekára a rodičov*, v ktorej citlivým a fundovaným spôsobom poukázala na zložité metodické, etické a psychologické problémy, ktoré lekár - genetik rieši pri genetickom poradenstve v spolupráci s konkrétnymi rodičmi. *K. Šipr* (Brno) poukázal na problém prenatálnej genetickej diagnostiky vo vzťahu k autonómii a rozhodovaniu konkrétneho rodičovského páru (prednáška v písomnej forme). *M. Šustrová* (Bratislava) hovorila o situácií a živote rodičov, rodiny a detí narodených s fyzickým alebo mentálnym handikapom, pričom poukázala na existujúce aktivity v SR, i na potrebu nových iniciatív v tejto oblasti, vrátane lepšej systémovej spolupráce zdravotníckeho, sociálneho a mimovládneho sektoru. V bohatej diskusii prítomní poukázali na rôznorodosť etických postojov v súčasnej pluralitnej spoločnosti i na potrebu otvorenejšieho, komplexného a pravdivého informovania rodičov i širšej verejnosti. Rozvoj vedeckých poznatkov - i v oblasti špeciálnej edukácie a rehabilitácie, umožňuje čoraz väčšiemu počtu detí narodených so závažným handikapom prežiť ľudsky hodnotný a šťastný život. Nevyhnutnosťou je však vytvorenie primeraného sociálneho, zdravotného i legislatívneho a kultúrneho zázemia.

V záverečnej sekcii konferencie poukázali prednášatelia na niektoré **nové vývojové trendy** a aplikačné oblasti humánnej genetiky. *D. Sacchini* (Centro di Bioetica, Rím) analyzoval etickú problematiku genetického skríningu. Poukázal na možné prínosy a niektoré nebezpečenstvá, spojené s nekontrolovanou aplikáciou genetických skríningových metód (napr. ich narastajúcej komerčnej dostupnosti, avšak bez zabezpečenia náležitého odborného poradenstva). *J. Glasa* (Bratislava) referoval o vývoji a etických problémoch v oblasti farmakogenetiky a farmakogenomiky. *A. Miyah* (Glasgow, VB) sa venoval etickej problematike genetických manipulácií na zvýšenie úspešnosti v oblasti športu (*angl. Genetic Enhancement in Sport?*; prednáška v písomnej forme). *P. H. Kieniewicz* (Lublin, Poľsko) ponúkol zamyslenie nad skúmaním a prekonávaním doterajších metodologických, „technologických" a etických hraníc v oblasti humánnej genetiky a niektorými nebezpečenstvami, ktoré by tento vývoj mohol priniesť pre vývoj ľudskej spoločnosti. Prednášky *G. Magilla* (St. Louis, USA) a *R. W. Evansa* (Castro Valley, CA, USA) o problematike výskumu ľudských kmeňových buniek a prednáška *A. Carvalho* (Porto, Portugalsko) o vývoji etických postojov k problematike humánnej genetiky, klonovania a ľudských kmeňových buniek v obraze mienkotvornej dennej tlače v Portugalsku, boli poskytnuté v písomnej podobe.

Záverom možno konštatovať, že konferencia priniesla cenný prehľad aktuálnych poznatkov o kľúčových odborných a etických problémoch v oblasti humánnej genetiky, zvlášť v súvislosti s ich perspektívnou aplikáciou v klinickej medicíne a programoch verejného zdravotníctva. Pozitívom je plánované urýchlené vydanie knižnej publikácie - zborníka, ktoré sa uskutočňuje pod záštitou Rady Európy (v tlači už začiatkom roka 2003). Najnovšie poznatky prezentované na konferencii budú teda už v krátkom čase k dispozícii aj pre širšiu odbornú verejnosť.

Jozef Glasa

DEPARTMENT OF MEDICAL EDUCATION OF THE SLOVAK POSTGRADUATE ACADEMY OF MEDICINE: 25 YEARS OF LEADERSHIP IN MEDICAL EDUCATION METHODOLOGY

Katedra medicínskej pedagogiky Slovenskej postgraduálnej akadémie medicíny: 25 rokov činnosti v metodológii medicínskeho vzdelávania

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Abstract

The establishment of the Department of Medical Education (DME; in 1977) of then the Institute for Postgraduate Education of Physicians and Pharmacists (IPP) in Bratislava, Slovakia; was aimed to help the new pedagogical staff of various IPP departments to manage the adaption phase of becoming the postgraduate education and training professionals in their respective disciplines, as well as to obtain or develop the necessary pedagogical knowledge and skills, which would help them to attain the level of required educational mastership. It also should help to promote and deliver continuous training and methodology development in medical education to the more senior pedagogical staff of IPP. 25 years of various DME activities is documented by a survey of its national and international publications and topical lectures. These deal with various methodological issues in the field of medical education, as well as conceptually support, or evaluate different DME's activities, which altogether serve as a basis for postgraduate education and training of doctors and teachers engaged in the health care service. A close cooperation and coordinated approach of biomedical ethics and pedagogy in the field of medicine was considered a necessary aspect of DME's work. It obtained a new impetus after the Institute of Medical Ethics and Bioethics was founded at IPP (in 1992) and mutual collaboration between the two departments was started.

Key words: Department of Medical Education - Bratislava, 25 years of activity, literature survey.

On 1-st November 1977, at the meeting of the Scientific Board of the Institute for Postgraduate Education of Physicians and Pharmacists (IPP) in Bratislava (present Slovak Postgraduate Academy of Medicine - SPAM), the concept of the Cabinet of Methodology and Medical Education, which later on (by 1-st January 1985) became the Department of Medical Education (DME), was discussed. Under this name, DME has been operating till nowadays, and it has been incorporated, among other departments, into the School of Public Health (SPH) in Bratislava. The initiative of establishing such institutions came directly from the World Health Organisation (WHO). The first such training centre, working under the auspices of WHO, was established at the College of Medicine, University of Illinois, Chicago (USA). DME was the first department of its type in Slovakia, although at the same time, there were two similar departments in Prague. One of them was headed by doc. MUDr. Jozef Vyšohlíd, DrSc., the second by prof. MUDr. Aleš Šatánek, DrSc.

The staff of DME has developed, and implemented in its practical educational and training activities, an original system of preparation of young assistant professors of IPP for their teaching work in their respective medical disciplines. The information on various aspects of this educational methodology was published nation - wide, and also abroad **(1-14).** The graduates of this system of educational preparation for teachers in medicine include present-day professors, associate professors, faculty deans and deputy deans, ministers, department heads, and also several full or associate university professors being active abroad.

A particular emphasis was put on continuous implementation of the newest developments in educational strategy and up-to-date didactical methods in updating and developing the system, while being at practical use and scrutiny in everyday's work of DME. This long-term perspective enables to follow the changes concerning particular educational methods and assimilate them into the teaching programmes, so the requirements of modern medical education methodology are continuously met **(15-23).** A proper orientation in the work of various international organisations in the field of medicine and health care, their history, activities, structure and tasks, is vitally important for new postgraduate teachers in the field of medicine. The problem has been dealt with in a number of publications by DME staff **(24-35)**.

The DME staff has been training also the employees of the so-called training districts (at present certified districts), who work as trainers. Having been requested they arranged short-term courses and seminars for other departments or educational institutions. The qualification structure of the department is formed by one professor and two doctors (one of them is a clinician-geriatrist, the other is an epidemiologist). There are two assistant professors (one of them is a doctor of pharmaceutics, the other is a master of andragogy-culturology).

The department participates in continual education. The head of the department prof. MUDr. L. Badalík, DrSc. is a president of the Society for Health Service Workers Education which organizes regular seminars on education in medicine. The department is involved also in the postgraduate education activities.

Its staff are officers and members of the state boards for conferring PhD. (philosophiae doctor) degrees, and they serve as tutors/mentors, and reviewers of PhD. dissertations as well.

Conclusion

During 25 years of its activity, the Department of Medical Education of IPP (later on SPAM) has developed and implemented in practice the original system of assistant professors' preparation for the educational work in various medical disciplines. The system has been tested and successfully presented in Slovakia and also abroad. For example, 90 new assistant professors have passed training preparation for medical education at SPAM alone. The department has been operating as an advisory point for the staff of other educational institutions, especially, when something new has been introduced or developed. An already long-term and fruitful relationship and cooperation exists between DME and those working in the field of medical ethics and bioethics as teachers, scientific workers, managers or volunteers.

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Dňa 1. 11. 1977 bol na zasadnutí Vedeckej rady Inšti-tútu pre ďalšie vzdelávanie lekárov a farmaceutov (ILF; dnešná Slovenská postgraduálna akadémia medicíny - SPAM) prerokovaný návrh koncepcie Kabinetu metodiky a medicínskej pedagogiky, ktorý sa neskoršie (od 1.1. 1985) stal Katedrou medicínskej pedagogiky (KMP). Pod týmto názvom KMP existuje dodnes, pričom je organizačne začlenená ako samostatná katedra Školy verejného zdravotníctva.

Iniciatíva na zakladanie útvarov tohoto typu vyšla zo SZO, pričom prvé školiace stredisko SZO bolo vytvorené na College for Medicine, University of Illinois, Chicago, USA. KMP bola na Slovensku svojho druhu prvá, i keď v Čechách v tom čase už pôsobili dve obdobné katedry v Prahe. Jednu z nich viedol doc.MUDr. Jozef Vyšohlíd, DrSc., druhú prof. MUDr. Aleš Šatánek, DrSc..

Pracovníci KMP vypracovali a odskúšali systém prípravy asistentov ILF na pedagogickú činnosť v medicíne, ktorý bol mnohonásobne odprednášaný doma i v zahraničí **(1-14)**. Medzi absolventmi tohoto systému pedagogickej prípravy učiteľov medicíny sú dnešní profesori, docenti, dekani, ministri, prodekani, vedúci katedier, prípadne úspešní vysokoškolskí učitelia pôsobiaci v zahraničí.

Okrem vypracovania systému prípravy kládli pracovníci katedry veľký dôraz na výchovu edukačnej stratégie a jednotlivých didaktických metód. Dlhodobý pohľad umožňuje porovnávať, ako sa mení paleta jednotlivých metód a prispôsobovať výučbu aktuálnym požiadavkám **(15-23)**. Pre nového pedagóga v oblasti zdravotníctva je veľmi dôležitá aj dobrá orientácia v práci medzinárodných organizácií pôsobiacich v oblasti medicíny a zdravotníctva, ich histórii, činnosti, štruktúre a cieľoch. Túto problematiku pracovníci katedry spracovali vo viacerých publikáciách **(24-35)**.

Pracovníci katedry školili v medicínskej pedagogike aj pracovníkov tzv. školiacich obvodov (v súčasnosti akreditovaných obvodov), ktorí pôsobia ako školitelia. Na požiadanie usporiadali krátkodobé kurzy a semináre aj na iných fakultách prípadne iných vzdelávacích inštitúciách. Kvalifikačná štruktúra katedry pozostáva z jedného profesora a dvoch doktorov lekárskych vied (jeden z nich je klinik-geriater, druhý je epidemiológ). Na katedre pracujú dve odborné asistentky (jedna doktorka farmácie, druhá magistra andragogiky-kulturológie).

Katedra sa aktívne zúčastňuje na kontinuálnom vzdelávaní. Vedúci katedry prof. MUDr. L. Badalík. DrSc. je prezidentom Spoločnosti pre výchovu pracovníkov v zdravotníctve, ktorá poriada pravidelné semináre zamerané na oblasť pedagogiky v zdravotníctve.

Katedra sa podieľa aj na doktorandskom štúdiu, kde jej pracovníci pôsobia ako funkcionári a členovia komisií pre udeľovanie hodností PhD. (philosophiae doctor), z čoho vyplývajú aj ich funkcie školiteľské, prípadne oponentské.

Záver

Katedra medicínskej pedagogiky ILF (dnes SPAM) za 25 rokov svojej existencie vypracovala systém prípravy asistentov na pedagogickú činnosť, ktorý preverila v praxi a opakovane prezentovala na domácich fórach i v zahraničí. Len napríklad v rámci SPAM-u absolvovalo vstupné školiace miesta z medicínskej pedagogiky 90 nových asistentov. Katedra pôsobí poradensky tiež pre pracovníkov iných vzdelávacích inštitúcií predovšetkým tam, kde sa rodí niečo nové. Dlhoročný a dobrý je tiež vzťah a prikladná spolupráca KMP s tými, ktorí pracujú na poli medicínskej etiky a bioetiky, či už ako učitelia, vedeckí pracovníci, riadiaci pracovníci alebo nadšenci.

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Abstrakt

Takáčová, Z., Glasa, J.: Department of Medical Education of the Slovak Postgraduate Academy of Medicine: 25 Years of Leadership in Medical Education Methodology. [Katedra medicínskej pedagogiky Slovenskej postgraduálnej akadémie medicíny: 25 rokov činnosti v metodológii medicínskeho vzdelávania.] Med. Eth. Bioet., 9, 2002, No. 3 - 4, p. 28 - 30. Cieľom vytvorenia Katedry medicínskej pedagogiky (KMP) Inštitútu pre ďalšie vzdelávanie lekárov a farmaceutov (ILF) v Bratislave bolo pomôcť novým pedagogickým pracovníkom ILF zvládnuť adaptačnú fázu a získať pedagogické vedomosti, schopnosti a návyky, ktoré vyústia do potrebného pedagogického majstrovstva. Okrem toho pomôcť mladým pedagogickým pracovníkom prejsť plynulo do fázy kontinuálneho vzdelávania v medicínskej pedagogike, v rámci ktorej by si toto majstrovstvo udržiavali a ďalej ho rozvíjali. 25-ročnú činnosť KMP demonštrujú autori pomocou literárneho prehľadu obsahujúceho súbory doma i v zahraničí publikovaných a odprednášaných prác. Práce sú zamerané na jednotlivé problémy, ktoré sú z hľadiska činnosti katedry dominantné a predstavujú východiskový materiál pre ďalšie štúdium lekárov a pedagógov pôsobiacich v zdravotníctve. Tesná spolupráca a koordinovaný prístup etiky a pedagogiky sú práve v oblasti medicíny nevyhnutnosťou. ***Kľúčové slová:*** Katedra medicínskej pedagogiky, 25 rokov činnosti, literárny prehľad.

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O KNIHÁCH / BOOK REVIEWS

CIOMS: INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS [1]

This is to give the readers a brief information on the latest edition ot the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* prepared and published by CIOMS (The Council for International Organizations of Medical Sciences) in collaboration with WHO, while relying mostly on the information provided in the introductory chapters of the Guidelines themselves **[2]**.

This is the third in the series of international ethical guidelines for biomedical research involving human subjects issued by CIOMS since 1982. The 2002 text, which supersedes that of 1993, consists of a *statement of general ethical principles*, a *preamble* and *21 guidelines*, with an *introduction* and a brief account of *earlier declarations and guidelines.* Its scope and preparation reflect the transformation that has occurred in the field of research ethics in the almost quarter century. The Guidelines, with their stated concern for the application of the Declaration of Helsinki in developing countries, necessarily reflect the conditions and the needs of biomedical research in those countries, and the implications for multinational or transnational research in which they may be partners. They are designed to be of use, particularly to low-resource countries, in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects.

After 1993, **new ethical issues** arose for which the CIOMS Guidelines had no specific provision. They related mainly to *controlled clinical trials, with external sponsors and investigators, carried out in low-resource countries* and to the use of *comparators other than an established effective intervention*. The issue in question was the perceived need in those countries for low-cost, technologically appropriate, public-health solutions, and in particular for HIV/AIDS treatment drugs or vaccines that poorer countries could afford. Opposing sides were taken on this issue. One advocated, for low-resource countries, trials of interventions that, while they might be less effective than the treatment available in the better-off countries, would be less expensive. All research efforts for public solutions appropriate to developing countries should not be rejected as unethical, they claimed. The research context should be considered. Local decision-making should be the norm. Paternalism on the part of the richer countries towards poorer countries should be avoided. The challenge was to encourage research for local solutions to the burden of disease in much of the world, while providing clear guidance on protecting against exploitation of vulnerable communities and individuals. The other argued that such trials constituted, or risked constituting, exploitation of poor countries by rich countries and were inherently unethical. Economic factors should not influence ethical considerations. It was within the capacity of rich countries or the pharmaceutical industry to make established effective treatment available for comparator purposes. Certain low-resource countries had already made available from their own resources established effective treatment for their HIV/AIDS patients. This conflict complicated the revision and updating of the 1993 Guidelines. Ultimately, it became clear that the conflicting views could not be reconciled, though the proponents of the first view claimed that the new guidelines had built in effective safeguards against exploitation. The commentary to the Guideline 11, *Choice of control in clinical trials*, recognizes the unresolved, or unresolvable, conflict.

An issue, mainly for the low-income countries and perhaps less pertinent now than in the past, has been the *extent to which ethical principles are considered universal or as culturally relative* - the *universalist* versus the *pluralist view*. The challenge to international research ethics is to apply universal ethical principles to biomedical research in a multicultural world with a multiplicity of health-care systems and considerable variation in standards of health care. The Guidelines take the position that research involving human subjects must not violate any universally applicable ethical standards, but acknowledge that, in superficial aspects, the application of the ethical principles, e.g., in relation to individual autonomy and informed consent, needs to take account of cultural values, while respecting absolutely the ethical standards.

Related to this issue is that of the *human rights of research subjects*, as well as of *health professionals as researchers* in a variety of sociocultural contexts, and the contribution that international human rights instruments can make in the application of the general principles of ethics to research involving human subjects. The issue concerns largely, though not exclusively, two principles: respect for autonomy and protection of dependent or vulnerable persons and populations. In the preparation of the Guidelines the potential contribution in these respects of human rights instruments and norms was discussed, and the Guideline drafters have represented the views of commentators on safeguarding the corresponding rights of subjects.

Certain **areas of research** are **not represented** by specific guidelines. One such is *human genetics*. It is, however, considered in Guideline 18 Commentary under *Issues of confidentiality in genetics research*. The ethics of genetics research was the subject of a commissioned paper and commentary.

Another unrepresented area is research with *embryo* and *fetal research*, and *fetal tissue research*. An attempt to craft a guideline on the topic proved unfeasible. At issue was the moral status of embryos and fetuses and the degree to which risks to the life or well-being of these are ethically permissible. In relation to the use of comparators in controls, commentators have raised the the question of *standard of care* to be *provided to a control group*. They emphasize that standard of care refers to more than the comparator drug or other intervention, and that research subjects in the poorer countries do not usually enjoy the same standard of all-round care enjoyed by subjects in richer countries. This issue is not addressed specifically in the Guidelines.

In one respect the Guidelines **depart from the terminology of the Declaration of Helsinki**. '*Best current intervention*' is the term most commonly used to describe the active comparator that is ethically preferred in controlled clinical trials. For many indications, however, there is more than one established 'current' intervention and expert clinicians do not agree on which is superior. In other circumstances in which there are several established 'current' interventions, some expert clinicians recognize one as superior to the rest; some commonly prescribe another because the superior intervention may be locally unavailable, for example, or prohibitively expensive or unsuited to the capability of particular patients to adhere to a complex and rigorous regimen. '*Established effective intervention*' is the term used in Guideline 11 to refer to all such interventions, including the best and the various alternatives to the best. In some cases an ethical review committee may determine that it is ethically acceptable to use an established effective intervention as a comparator, even in cases where such an intervention is not considered the best current intervention.

I agree with the concluding statement of the introductory chapter of the Guidelines, which reminds the readers that „the mere formulation of ethical guidelines for biomedical research involving human subjects will hardly resolve all the moral doubts that can arise in association with much research, but the Guidelines can at least draw the attention of sponsors, investigators and ethical review committees to the need to consider carefully the ethical implications of research protocols and the conduct of research, and thus conduce to high scientific and ethical standards of biomedical research."

I strongly believe that **the careful study of the Guidelines is a must** not only for all the professional parties involved in the biomedical research involving human subjects, in particular for the sponsors, investigators and members of the ethics review committees; but also for the professionals concerned with the development or updating of their national legislation (laws and regulations) in this area. I hope, we shall be able to welcome soon also translations of the Guidelines into various languages of the countries of the Central and Eastern Europe, including their translation into Slovak. The full text of the Guidelines may be found at the CIOMS website, or purchased as a separate publication directly from CIOMS, c/o WHO, Avenue Appia, 1211 Geneva 27, Switzerland, or from the booksellers through the network of WHO sales agents.

[1] CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS, Geneva, 2002, pb, 112 pgs, price 20 CHF. [2] Ibid., p. 7 - 13.

Jozef Glasa

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Medicínska etika & bioetika - Medical Ethics & Bioethics, založený ako časopis Ústavu medicínskej etiky a bioetiky v Bratislave, spoločného pracoviska Lekárskej fakulty Univerzity Komenského a Inštitútu pre ďalšie vzdelávanie zdravotníckych pracovníkov v Bratislave. Je určený pracovníkom etických komisií v Slovenskej republike, ako aj najširšej medicínskej a zdravotníckej verejnosti. Má tiež za cieľ napomáhať medzinárodnú výmenu informácií na poli medicínskej etiky a bioetiky. Prináša informácie o aktuálnych podujatiach a udalostiach v oblasti medicínskej etiky a bioetiky, pôvodné práce, prehľady, reprinty legislatívnych materiálov a smerníc pre oblasť bioetiky, listy redakcii a recenzie. Príspevky a materiály uverejňuje v slovenskom alebo anglickom jazyku. Vybrané materiály vychádzajú dvojjazyčne. Vedecké práce publikované v časopise musia zodpovedať obvyklým medzinárodným kritériám (pozri Pokyny prispievateľom - ME&B 2/94, s. 10).

Medicínska etika & bioetika - Medical Ethics & Bioethics, founded as the journal of the Institute of Medical Ethics & Bioethics (Bratislava), a joint facility of the Medical Faculty of the Comenius University and the Postgraduate Medical Institute in Bratislava (Slovak Republic). 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. Choosen materials are published in both languages. Scientific papers published in ME&B must respect the usual international standards (see Instructions for authors - ME&B 2/94, p. 10)

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