Ethically speaking

A newsletter providing information on the activities of the National Ethics Committees compiled by the Secretariat of the European Group on Ethics in Science and New Technologies to the European Commission

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Ethically speaking

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Ethically speaking, the European Union’s newsletter on bioethics, which reports on the activities of the 27 national ethics committees of the EU Member States and the European Group on Ethics in Science and New Technologies (EGE), is opening its pages to contributions from non-European national ethics committees. This initiative follows the first International Dialogue on Bioethics meeting held by the European Commission in Brussels on 19 February 2009 at the EGE’s request.

The International Dialogue on Bioethics, aimed to facilitate information sharing and open dialogue between European and non-European National Ethics Councils (NECs), was chaired by the President of the EGE, Prof. Göran Hermerén, and the Chair of the National Ethics Council of the EU Member State currently holding the Council Presidency and representing the EU-27 NEC Forum, Prof. Josef Kuře. The EU’s Commissioner for education, training, culture and youth, Mr Ján Figel’, stressed that the EU is a global player in a global economy and emphasised the need to launch international debates on incorporating fundamental rights in global governance of science and technology. The Chair of the European Parliament’s Scientific Technology Options Assessment Commission, Mr Philippe Busquin, highlighted the relevance of ethics to the global governance of science and technology and the role of the European and national parliaments passing national measures on bioethics in the EU. They both stressed the need to hold an international debate on ethics in science and technology.

The European Commission has already started embedding ethics in its policy on research, food production, ICT, pharmaceuticals, biotechnology, nanotechnology and many other policy areas. But the EU’s stance on the global debate on science and technology is to promote and respect pluralism and mutual understanding.

The European Commission is convinced that a unitary approach to bioethics would neglect the complexity of the different values involved and thus, as in Europe, where socio-cultural and religious diversity are a feature of the debate on bioethics, internationally there is a need to facilitate information sharing and debates as a precondition for proper reflection on ethics in science and technology. The strategy the Commission therefore wants to support and implement is to strike a balance between ethical and socio-cultural diversity, both at EU level and globally in other regions of the world, and respect for internationally recognised fundamental values. EU policy respects subsidiarity and promotes shared values and human rights protection at EU and non-EU level. But this entails open debate, mutual respect and tolerance; three themes on which the EU is focusing efforts, action and initiatives.

1 The event was attended by members of the EGE, the Chairs of 15 non-EU NECs, the Chairs of the EU-27 NECs and representatives of international organisations. The non-European countries represented were Argentina, Australia, Brazil, Canada, China, Egypt, India, Indonesia, Japan, Mexico, the Philippines, Russia, South Africa, the USA, and a cluster of African countries represented by PABIN (the Pan-African Bioethics Initiative, an African ethics network), together with COPAB (the Pan-African Bioethics Congress). The EU NECs were all represented with the exception of Bulgaria and Cyprus, which were unable to attend due to other commitments. In all, representatives of the National Ethics Councils of 40 countries, UNESCO, WHO, the EP (STOA) and the Commission attended the meeting. The video of the Conference is available at http://ec.europa.eu/european_group_ethics/index_en.htm.
The Lisbon Treaty reinforces the EU’s role in the international policy arena, a policy strategy already embodied in the Commission’s 2008 Work Programme. Research, global trade, agriculture, security, humanitarian aid, energy and climate change are examples of policy sectors where the EU is playing a key role at global level. In the 2009 Work Programme, the Commission is developing ideas to help guide the EU towards the right balance between an enhanced economic and political relationship with its neighbourhood as a whole, on the one hand, and the need to tailor relationships to different regions and different partners, on the other.

Opening *Ethically speaking* up to the NECs of non-European countries is just the first step in the Commission’s intention to facilitate international debate on ethics in science and bioethics. Holding annual International Dialogue on Bioethics meetings, with systematic participation by the EU-27 NEC Forum representatives and relevant international organisations, and setting up a web portal for members of this initiative are examples of the complex effort the European Commission intends to make to promote global debates on ethics in science and technology.

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Contributions from members of the EGE
Conditions for the Proper Working of National and International Ethics Committees

Göran Hermerén, EGE President

National ethics committees (NECs) – and similar bodies – differ in terms of their size, composition, working methods and mandates, as a study by Michael Fuchs (Nationale Ethikräte, Nationaler Ethikrat, Berlin, 2005; also available in English) has shown. Obviously, the impact of ethics committees on public debate and legislation depends not only on the people serving on those committees, their knowledge, wisdom, commitment, and willingness to work and invest time and thought in the problems – but also on the secretariat they have supporting their work.

However, having served on regional, national and international ethics committees over a long period of time, I have come to realize that these committees have a number of general features in common which are important in terms of their ability to function properly. Functioning properly means describing the problems/issues concisely and clearly, providing relevant scientific, legal and social information in an unbiased and fair way, and proposing recommendations supported by sound arguments, while at the same time maintaining credibility, being open about dissent and differences of views in the committee, and avoiding being manipulated or used for political ends.

Of course, the challenges of ethics committees on a variety of levels are not the same: problems can be more complex on an international level, because the praxis, the historical, religious and political background, and the legal regulations are more diverse. For example, it is well known that there are considerable legal differences between EU Member States in biomedicine, ethics of science and new technologies, in relation to issues such as medical tourism, stem cell research, assisted suicide, euthanasia, IVF, abortion, animal welfare, biosecurity and biotechnology. On a regional or national level, the cultural background – and certainly the legal regulation – is more homogeneous.

Many of the features of ethics committees to be discussed here are independent of the level, mandate and function of the ethics committee. However, I want to concentrate here on national and international ethics committees, which is what I have in mind when the expression "ethics committee" is used without a qualifying adjective. Needless to say, the list below makes no claim to completeness, and the emphasis placed on some of the factors may vary according to the type of ethics committee. Hopefully, those who have long experience of work in such committees will recognize the features listed below. These features have been identified in a three-step procedure.

The first step is obviously to clarify the goals of the ethics committees. Why have they been established? The reasons, the focus of the work and the links to parliaments, ministries and other State bodies are not the same, as Michael Fuchs showed in his study. Emerging and converging new technologies raise difficult and complex ethical issues, and in an open society the debates and the decision-making processes need to be prepared and alternative scenarios identified and described.
What were the NECs intended to achieve? The goals of national and international ethics committees include identifying important ethical issues, facilitating the ethical debates in their countries by providing relevant background material and advancing sound (tenable and relevant) reasons for recommendations on what to do and what to avoid in difficult and complex issues. NECs base their conclusions on certain value judgments, combined with relevant information of other kinds – i.e. not just scientific information, important though it is, but also information about people’s attitudes, existing regulations, societal trends, economic conditions and consequences, and so forth.

The second step consists in identifying the obstacles that prevent these goals from being achieved. What are the dangers and the pitfalls? It would be dangerous, for instance, if important aspects of the problem were missed or disregarded, or if the ethics committees spent time on yesterday’s problems, instead of on those raised by the current scientific developments confronting contemporary society. Clearly, public mistrust is likely to be yet another problem. The obstacles could be organizational, legal or psychological issues, … or the lack of knowledge, public participation or economic resources.

These dangers and obstacles have to be tackled in different ways. The third step consists in suggesting ways of dealing with (i.e. circumventing, minimizing or eliminating) these obstacles. The list below should be viewed from that perspective. The features discussed could help us to deal with some of these obstacles and dangers.

**Transparency** or openness is important for public trust. This feature has several dimensions: transparency about composition, methods of selecting members and chairpersons and the terms of reference of the committee. Who decides what the committee discusses, its working methods and the rules of procedure of the group, including the possibility to express and record dissent, and so forth…

**Time** for deliberation is essential. If high-quality recommendations are the goal, the problems have to be analysed, the state of the art in the relevant sciences described, the legal background clarified, and the relevant value premises identified. Robust decisions require that both value premises and other premises be scrutinized. This takes time. If there are dissenting views within the group, it is essential to allow time to clarify the reasons for the dissent. Is it related to terminology, or is it a disagreement over facts or values? Is it genuine or only apparent?

**Tolerance** for different views and mutual respect are two other important features of ethics committees. Dogmatism and fundamentalism make the work of an ethics committee very difficult, regardless of its level and type. There are different sorts of competences, just as there are different kinds of intelligence, and these have to be respected. Complex and difficult decisions need to be elucidated from several points of view. Nobody has a monopoly on truth or on the best ways of dealing with problems. These decisions need to be exposed to scrutiny from different starting points – this is the best way to make sure that they will not be short-lived or become quickly outdated.

**Explicitness** is an ideal to strive for, including for ethics committees. It is related to, but not identical with, openness or transparency. This does not simply mean that the value premises should be stated explicitly – the same equally applies to statements about what scientists can do today or in the near future. The knowledge basis has to be explicit and unambiguous, and this also holds true for information about the legal and social background, where relevant. It is very important that uncertainties, knowledge gaps and value instability are not covered up or swept under the carpet.

What do we know? What is uncertain? What do we not know? These questions are always important. As to the value premises chosen as points of departure, we should – by analogy – try to be explicit about their possible instability, varying interpretation and uncertainty, if any. However, explicitness also has
other dimensions. Ideally, the reader should be able to follow the reasoning step by step, from premises agreed on and/or explicitly stated to concise and clear recommendations.

‘Integrity’ has many meanings. It goes back to a Latin word that is often translated by ‘wholeness’. In discussions of ‘scientific integrity’ – a topic that has surfaced forcefully during the last decade – it refers to the idea that scientific work should be carried out according to its own logic and methodological rules. Personal interests and prestige, religious persuasions, and economic and political interests should not be allowed to interfere with this process, particularly when it comes to testing hypotheses, interpreting and drawing conclusions from the results of the research – or deciding whether or not the results should be published. Similar concerns about integrity are relevant when it comes to the work of ethics committees.

Ethics committees can be misused or manipulated. They can be employed as megaphones by political parties in power or to provide legitimacy for decisions that politicians have already taken – or for postponing decisions they do not want to take. It is dangerous for the credibility of the ethics committees if this is the case. It is also dangerous if the general public believes this to be the case, even if that belief is mistaken. The best way to prevent this seems to be to ensure that ethics committees are independent of the political power.

This independence covers many dimensions, and the concept is also a vague one. It can be graduated in the sense that the committee can be independent to a greater or lesser extent. It ranges from economic independence (the committee is able to decide for itself about how to use its funds) to independence in terms of deciding which topics to work on, choosing between alternative working methods and rules of procedure, deciding which experts to invite, and in particular – this goes without saying – adopting its conclusions. If political or religious powers tell the ethics committees what to recommend, then the credibility of these committees would be seriously undermined if they were to follow such signals.

The interdisciplinary nature of such committees is another important feature. This is essential in order to avoid a one-sided perspective or the risk of overlooking important aspects of the problem. Interdisciplinary composition of the committee is essential to ensuring that relevant background information and perspectives are not missed. Different scientific, legal and cultural backgrounds are vital in this context, including as a way to avoid the predominance of particular scientific views in the work of the committee. The experiences of several professions, genders and age groups are vital too. Obviously, if the size of the committee is to be manageable, not all disciplines and experiences can be represented. However, the committee’s remit should be wide enough for it to be able to recognize when it needs to invite additional experts.

Interaction with the general public is also important for the simple reason that, in a democracy, people’s views count. There are two aspects that need to be separated: input and insight. The first is about providing information and inspiration to drive the work of the committee, and the second concerns obtaining information about, and insight into, its work. Different models and methods – such as sending out preliminary texts for comments, web consultations and round-tables, have been tried, with varying degrees of success. Public participation is essential in a democratic society.

In conclusion, it should be stated that this list of features is a description of an ideal, based on personal experience over several decades. Of course, it is possible to hold different views on the precise interpretation and implementation of these features, and these remarks should be regarded as no more than a rough outline/sketch. However, in the discussion of the future of NECs and international ethics committees, the focus should be not only on the contents of their reports and their recommendations, but also on their working conditions and methods.
Ecological Footprints

**Diána Bánáti**

The area of the Earth’s surface needed to sustain an individual differs from country to country, from region to region. In the USA, 9.5 hectares are needed to provide food, energy and other inputs for living, compared with 5.4 in the UK. In contrast, hardly more than half a hectare (0.53 ha) is needed in Bangladesh (WWF, 2006). People thus leave unequal footprints around the world. The global average is 2.28 hectares. The production of food, clothes, cars, technical equipment and other things requires fresh water, natural resources and energy. The energy we consume and the goods we buy confront us directly with many of the most pressing issues in the world: from the potentially catastrophic impacts of climate change to the oceans’ dwindling fish stocks; from the long-term sustainability of our farming systems to the benefits gained by highly industrialised countries from foreign trade. We live in a globalised, increasingly integrated world, and the implications of our agriculture and industrial practices and our lifestyles have more influence than we might think.

The widely used concept of a carbon footprint grew out of a longer established, broader idea, the ecological footprint. This measures our consumption in terms of the area of the Earth’s surface needed to support our individual existence. This area — measured in hectares of average productivity — includes the space needed for growing crops, grazing animals, harvesting timber, catching fish, accommodating infrastructure and absorbing carbon dioxide emissions (Clark, 2006). Most of it is land used by agriculture for the production of agricultural raw materials of plant and animal origin.

The exact quantity of feed required to produce a kilogram of meat or fish varies according to species and farming method, and there are also great differences between the figures from different sources. Approximately 1.5-2.0 kilos of feed are required to produce 1 kilo of farmed fish, rising to 2.1-3.0 kg for poultry meat, 4.0-5.5 kg for pork and 10 kg for beef meat. The production of feed crops and the farming of animals use up an astonishing amount of water. The amount required to produce certain meats is often very high. Five hundred litres of water are needed to produce 1 kilo of potatoes, 900 l for 1 kg of wheat, 1400 litres for maize and 1910 l for rice, compared with 3500 l for 1 kg of chicken and 15 000 or, based on other sources, 100 000 litres of water for 1 kg of beef. The average amount of water required to supply a single individual with meat is 1150 litres per day (Rakonczai, 2008).

There are different approaches to reducing ecological footprints, either aiming to reduce our direct impact on the environment through more efficient use of electricity, gas, petrol and other resources or considering environmental matters when deciding which products and services to buy. One way to reduce the carbon footprint of an individual is simply to try and buy less, or buy and consume differently.

The rapid growth in the world’s population (13 %), global income (36 %) and meat consumption (beef 14 %, pork 11 % and chicken 45 %) in the last decade (EuropaBio) are major drivers behind the increased demand for raw materials. The growth of emerging economies, such as China, Brazil and India, is radically changing food requirements with a corresponding impact on sustainable agriculture, as consumers demand more meat and processed food. Chinese consumers now eat 50 kg of meat per year, compared with just 20 kg in 1985.
Global meat consumption has rocketed by around 500% since 1950. The world today contains around twice as many chickens as humans, plus 1 billion pigs, roughly 1.3 billion cows and 1.8 billion sheep and goats. According to estimates, if the consumption of animal products continues to grow at the current rate, by 2050, livestock will consume as much food as the entire human population did in 1970.

According to a recent FAO study, the high consumption of meat products affects primary agricultural production, the use of land and water, and environmental pollution. In this context, educating consumers on public health (healthy dietary habits), food quality and agricultural sustainability (e.g. imports of non-seasonal food, food waste, etc.) would be beneficial and make a major contribution to food security and sustainability (EGE, 2008). In its recent opinion, the European Group on Ethics (EGE) therefore underlined the specific responsibilities consumers have for orienting the market.

Another way to reduce our carbon footprint is to try to buy less and consume differently in order to avoid wasting high amounts of food. An astonishing 20% of the food that we buy is wasted, either as leftovers or because it is no longer fresh (Clark, 2006). One-fifth of America’s food ends up in the bin — enough to feed the people who starve each year around the world twice over (USDA). This waste results in considerable costs and emissions of methane. Each tonne of biodegradable waste produces between 300 and 500 cubic metres of landfill gas. One of its ingredients, methane, is a greenhouse gas more than twenty times as potent as CO₂.

Food waste is a major issue in modern times from several points of view. First of all, from an ethical standpoint, as better management and distribution of food resources could benefit the least privileged in society. Secondly, from an economic standpoint, as food waste implies a considerable loss of money. And thirdly, from an environmental perspective, as the decomposition of organic material is a major contributor to the greenhouse gas (GHG) emissions causing global warming (WRAP, 2008). Food waste is a phenomenon that involves not only mechanisms from food production to distribution and consumption, together with the legal obligations set out in EU food law, but also, in particular, consumer attitudes.

A considerable amount of food waste is generated for a variety of reasons: because of miscalculation of needs, because portions are often bigger than consumers’ appetites and because a higher standard of living means that consumers tend to pay less attention to saving. A huge amount of food is thrown away every day. For example, according to the US Department of Agriculture (USDA), 5% of the USA’s yearly food waste equals one day’s food for 4 million people.

The responsibility lies not only with food producers, food business operators or policy-makers but also with individuals and their choices in food consumption. For example, following diets rich in meat products and purchasing non-seasonal foods certainly have an impact on global warming. In its recent opinion on the ‘Ethics of modern developments in agriculture technologies’ (EGE, 2008), the European Group on Ethics called on Member States to take specific action to increase public participation in designing policy for the primary production of food of plant origin. This debate should be linked to information campaigns on the consequences of dietary habits for food sustainability (consumption of meat in particular), including (1) preventing waste of food products, (2) promoting healthy lifestyles and (3) raising public awareness of agricultural methods and technologies.

Consumers in industrialised, highly developed countries have much bigger footprints and thus greater responsibility than those elsewhere. The total area of the Earth’s surface needed to support our individual existence, our ecological footprint, very much depends on the foods we buy, consume and waste, so we ourselves can influence the footprint we leave behind on Earth.
References:


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Is Human Reproductive Cloning a Problem?*

Francesco D. Busnelli

Human reproductive cloning has been intensively debated among bioethicists and policy makers, but the recent publication of a report by the United Nations University Institute of Advanced Studies\(^2\) has re-opened the debate about the regulatory framework to be adopted internationally on this contentious use of human biotechnology.

Human cloning has been categorically condemned (if not prohibited) in several international documents: the Resolution of the World Health Organisation (14 May 1997), the UNESCO \textit{Universal Declaration on the Human Genome and Human Rights} (3 December 1997, Article 11), and the \textit{United Nations Declaration on Human Cloning} (8 March 2005). The UNU-IAS report, however, highlighted the need to provide the international community with a clear and explicit, legally binding, policy framework regulating the use of this technology. The issue is to what extent the regulatory frameworks so far adopted have used the notion of human dignity to regulate reproductive human cloning.

It is crucial to identify the basis for the strict ban advocated in all of the abovementioned international documents. They seem to reflect a widespread feeling of repugnance among people on both sides of the Atlantic. It has been reported\(^3\) that even Dolly’s creator confessed that he would find it offensive to clone human beings. However, as has been rightly stated, ‘repulsion is not an argument’ and ‘things considered to be repugnant yesterday are today accepted without any problems’\(^4\). These kinds of reaction seem to be based on impulse or emotion.

The apparent consensus turns out to be rather superficial since the ethical foundations of the common ban are wholly different in Europe and in America and reflect completely distinct legal (or, rather, constitutional) principles. The Report of the American National Bioethics Commission (NBAC) concerning the Cloning Prohibition Act (9 June 1997) solemnly affirms that cloning a human being is ‘morally unacceptable’. However, it adds ‘at the present time’, stressing that these techniques are not yet perfect from the standpoint of ‘safe usage’. Therefore, the ethical basis for the ban is ‘the issue of safety’; and the legal procedure to enforce it is that of a moratorium. From an ethical standpoint, the ‘if’ of reproductive cloning is not at issue. Rather, the critical question is what conditions have to be met for cloning to be allowed. In other words, the discussion is about \textit{how} and \textit{when} to do it. In the European documents, the moral unacceptability of reproductive cloning is given a radically different basis. The Additional Protocol to the European Convention on Biomedicine (12 January 1998) affirms that cloning must be prohibited because it leads to ‘instrumentalisation of human beings’. Article 3 (‘Right to the integrity of the person’) of the European Charter of Fundamental Rights (2000) calls for ‘the prohibition of the reproduc-

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\(^{4}\) L. R. Kass, op. cit., 687.
tive cloning of human beings'. The European Parliament adopted a resolution on cloning (7 October 2000), asking each Member State to enact ‘binding legislation prohibiting all research into any kind of human cloning within its territory and providing for criminal penalties for any breach’. The EGE (Opinion No 9 of 28 May 1997) stressed that ‘any attempt to produce a genetically identical human individual by nuclear substitution from a human adult or child cell (“reproductive cloning”) should be prohibited’. In Europe, therefore, the ethical basis for the unconditional (‘no derogation [...] shall be made’) prohibition on cloning is to protect ‘human dignity’. Indeed, the prohibition directly concerns the ‘if’ of reproductive cloning.

From a legal point of view the difference between the two ethical conceptions is reflected in the constitutional principles and foundations of the legal systems involved.

A legal system that is built on the fundamental idea of individual liberty and freedom, not as a social value (freedom to) but as a ‘condition of ethical and moral conceptions’ (freedom from) readily acknowledges the principle of reproductive freedom in order to allow for the procreation of ‘children of choice’. Such a legal system bases the protection of the unborn child on the objective aims of society. In such a legal system it is, as a matter of principle, impossible to condemn reproductive cloning. Therefore, the position of the scholar who thinks it should be regarded ‘as an exercise of procreative liberty and granted the special respect usually accorded to procreative choice’, is clear. There would not be anything wrong — this is the example given — with the possibility of ‘a situation in which the parents want another child and are so delighted with the existing one that they simply want to create a twin of her, rather than take a chance on the genetic lottery’. Less consistent, but nevertheless significant, is the position of the legal philosopher who, having said that reproductive cloning must lead to an expansion and not to a restriction of liberty, demonstrates concern for a possible ‘explosion of claims for reproductive freedom’: claims based on ‘rampant individualism heedless of the interests of society’. Quite embarrassing is the statement of the researcher, according to whom the liberal approach, ‘quintessentially American’, turns out to be ‘regrettably inadequate as an approach to human procreation’. He submits that the liberal approach is deprived of all the ‘anthropological, social and ontological elements that accompany the formation of a new life’.

By contrast, reproductive cloning does not seem appealing to a legal system that is based on the principal idea of protecting the dignity of all human beings (it extends this protection to the unborn child, giving him/her ‘adequate protection in respect of the applications of biology and medicine’), that does not acknowledge ‘reproductive liberty’ as a subjective right, that does not acknowledge abortion as an unquestionable right, and that is not directed towards suppressing the ‘genetic lottery’, but continues

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11 L. R. Kass, op. cit., 688 et seq.
12 Convention on Biomedicine, Article 1. See also Recital No 4 of the Additional Protocol, where the extension of its application to ‘all human beings’ is underlined.
13 Recital No 2 of the Additional Protocol.
14 Draft explanatory Report to the Additional Protocol.
15 A perfect example is a decision by the German Constitutional Court. After having stressed that ‘a solution that guarantees either the life of the unborn or the right of the mother to abort is not possible’, the court introduced the principle of ‘intol-
to consider the ‘mystery’ of procreation as a value to be preserved and defended from the ‘fanatics of artifice’ \(^{16}\). The legal philosopher’s reflection on this issue is persuasive: if it has to be acknowledged that every human life has the right to be a surprise in itself, it seems evident that a cloned being has first of all been deprived of his/her liberty and can only prosper under the protection of ignorance; therefore, nobody — not even a parent — has the right to deprive a future human being of his freedom \(^{17}\). Clearly, the lawyer does not hesitate in affirming that the ‘choice’ of the baby to be procreated is a ‘stretch of authority’. The fundamental right to free and responsible procreation cannot become one subject’s absolute abuse of power over another, reduced ‘to the rank of a product and a programmed object’ \(^{18}\). The warning of the researcher, who fears the advent of what he calls ‘normative procreation’ characterised by a new eugenics ‘mou, démocratique, consensuelle’, is meaningful and consequently urges the preservation of ‘the values of a lay humanism, not necessarily faithful to the traditional religions, but also not supinely attracted to the new techno-science mythologies’ \(^{19}\).

For all of these reasons, human reproductive cloning is a problem. Strictly speaking, it is not a problem in itself, but an issue that reveals the wide gap between ethical conceptions and constitutional principles which divide Western law. In other words: it might be correct to admit that ‘as far as cloning is concerned, the issue itself is relatively trivial’ \(^{20}\). But surely the discordance and the inevitable conflict between ethics and constitutional principles, pitilessly laid bare by the issue of cloning, is not so trivial and occurs, paradoxically, in not only an economic, but also a legal, context that is influenced by globalisation. The path to a shared ethic is still long and strewn with obstacles, and it is not known where it will lead: American Failures, European Challenges (as stated by Mary Ann Glendon)? Or American Challenges, European Failures? Or, finally, perhaps another option than the above two opposite systems?

The lawyer is not a prophet. Nevertheless, he has the duty to compare the systems and to point out the principles that are useful in creating a constructive dialogue, and to move forward along a road that is necessarily based on a ‘minimalist’ ethic. At least two principles can be pointed to at the moment: the principle of precaution; and the principle of the best interest of the child.

The principle of precaution essentially concerns the role of scientific research in those areas located at the new frontiers of ‘human rights and the dignity of the human being with regard to the applications of biology and medicine’ \(^{21}\). Disturbing, yet at the same time encouraging, pages have been written on the ethics of scientific research: ‘research does not self-guarantee its own moral property. However, the intrinsic ethical characteristic of research lies just in this: a researcher presupposes that the world in front of her/him has a meaning and he/she has a duty to uphold this meaning in the continuous construction of new things’ \(^{22}\). Dealing with the relationship between ethics and the law, it is now clear that ‘the principle that scientists are not responsible for the consequences of their own actions is no longer acceptable’ \(^{23}\). Nevertheless, the liability of researchers, when put in legal terms, cannot be confined to the legal framework

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\(^{20}\) R. C. L. Moffat, op. cit., 605.

\(^{21}\) This is the full title of the European Convention on Biomedicine.


of Roman Law: diligentia, peritia, prudentia (diligence, skill, caution). Scientific projects make it necessary to switch from a prevention approach (useful for managing known risks) to one of precaution (that also covers unknown risks). In other words, we must ‘manage scientific uncertainty; and management of uncertainty is a requirement of the principle of precaution’

Precaution aims ‘à privilégier l’hypothèse du pire, lorsqu’on peut redouter un dommage irréversible même à long terme’. However, this does not mean a shift from fault liability to strict liability; it means ‘the adoption of fault liability to contexts of uncertainty’. Without any doubt this position poses a possible limit on scientific initiatives. As stated in the French Rapport au Premier Ministre (2000): ‘in the hands of a legislator or a judge’ the principle of precaution ‘can be the best as well as the worst of solutions: the best when it succeeds in offering solutions that really improve people’s safety; the worst when it acts as a stumbling block that prevents any flexibility, discouraging new initiatives and progress’.

The principle of the best interest of the child should correct the unlimited freedom that, according to a libertarian view, could legitimately extend to licentiousness, giving freedom itself a ‘non-desirable reputation’. We can give the example of the English Human Fertilisation and Embryology Act 1990, according to which nothing is prohibited a priori, but everything is subject to selective scrutiny, preventing healthcare providers from offering ‘a woman […] treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth’ (Section 13(5)). The suggested use of the criterion of the best interest of the child would reduce the distance between ‘libertarian’ and ‘prohibitionist’ models, since both would contain the preventive control of lawfulness, to be performed by the competent agents according to a case-by-case approach for the former and by the rule makers for the latter.

Through all of these concepts some sort of super-principle shines that might be described as the ‘responsibility principle’. This is the still relevant lesson of Hans Jonas, who invokes ‘a new kind of humility — a humility that, unlike any previous one, is not due to the narrowness but to the excess of our capabilities, that is the prominence of our ability to act on our ability to forecast, to evaluate and to judge’.

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25 Jacques Chirac, President of the French Republic, in his opening address to the fourth session of the UNESCO International Committee of Bioethics (CIB) (3 October 1996).
28 R. C. L. Moffat, op. cit., 603.
29 H. Jonas, op. cit., 60 et seq.
EU national and regional ethics committees
The Austrian Bioethics Commission

Austria

Recent opinions, studies and events

Background
Acting on instructions issued by the Federal Chancellor on 29 June 2001, the Austrian Bioethics Commission first convened on 2 July 2001. Consisting of up to 25 experts from the fields of medicine, genetics, sociology, law, philosophy and theology, the Commission provides a forum for interdisciplinary debate on human medicine and human biology. Its members are appointed by the Federal Chancellor for a term of two years. Meetings are held monthly between October and July in Vienna. The current Commission strikes a better gender balance: 10 of the 25 members are female.

The Austrian Bioethics Commission is an independent body which puts great emphasis on publicising its work in order to stimulate public discussion on ethical questions.

This short report outlines its latest opinions, studies and events.

Latest opinions
Since the beginning of its current term, in October 2007, the Austrian Bioethics Commission has published an opinion on Cord Blood Banking and Recommendations with Gender Reference for Ethics Committees and Clinical Studies.

Cord Blood Banking
The opinion on Cord Blood Banking\textsuperscript{30}, issued on 19 May 2008, provides descriptions of ways of collecting and using stem cells from umbilical cord blood and of the advantages of cord blood stem cells for allogeneic transplants plus an overview of umbilical cord blood banks. These are followed by a summary of the relevant legal aspects and a critical ethical evaluation. The Bioethics Commission recommended that, in the context of allogeneic transplants, greater support should be given to public and private non-commercial cord blood banks which contribute to public welfare. It also recommended that potential donors should be informed of the possibility to donate cord blood for allogeneic transplantation and research purposes. The Commission did not recommend storage of cord blood stem cells for autologous transplantation at present.

Recommendations with Gender Reference for Ethics Committees and Clinical Studies
In its Recommendations with Gender Reference for Ethics Committees and Clinical Studies\textsuperscript{31} the Austrian Bioethics Commission addresses the issues of gender balance in the composition of ethics com-

mittees and of participation by women of childbearing potential in clinical trials. With regard to the composition of ethics committees, the Bioethics Commission recommended that action should be taken to ensure an even balance of the sexes in the composition of ethics committees with regard to all legally required representatives on an ethics committee. Furthermore, the Bioethics Commission recommended including a clause in the rules of procedure of ethics committees placing an obligation on members to undergo initial and continuous training on law, ethics and the principles of clinical research. As regards participation in biomedical research, the Bioethics Commission recommended that action be taken to guarantee inclusion of men and women of all ages in accordance with acknowledged scientific principles and that exclusion of women with childbearing potential should be accepted in exceptional cases only.

**Opinions in the pipeline**

In addition to the above-mentioned opinions, the Commission is putting the finishing touches to its opinion on research on embryonic stem cells.

It is currently working on an opinion and recommendations on assistive technologies, which are expected to be published during the summer.

**Recent studies**

The Commission also sub-contracted two studies on:

- stem cell research and protection of the embryo; and
- assistive technologies.

The report on stem cell research provides a comparative overview of practice and progress on research in this area in Belgium, Germany, Italy and the United Kingdom. It addresses scientific, legal, political, ethical and sociological questions regarding use of stem cells in scientific research.

The report on assistive technologies presents a study on the literature on ethical issues relating to research, design and use of assistive technologies in order to help older people lead independent lives.

**Recent events**

As part of its mandate to shape the public debate on bioethics in Austria, the Bioethics Commission has organised a series of scientific conferences, discussions and educational events:

- The international conference on ageing research, in October 2007, kicked off the fourth term of the Austrian Bioethics Commission.
- An international conference on ethical and legal aspects of stem cell research, held in January 2008 with the cooperation of the Institute of Ethics and Law in Medicine of the University of Vienna, attracted a large audience to discuss the current legislation and relevant ethical issues.
- In May 2008, the Bioethics Commission co-organised a national conference on research ethics.

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34 Conference documentation available in German at: http://www.bundeskanzleramt.at/DocView.axd?CobId=26554.

The international conference on “Bioethics and Women”, held in Vienna in June 2008, marked the start of the Commission’s work on the Recommendations with Gender Reference for Ethics Committees and Clinical Studies.

In response to the needs expressed by secondary school teachers teaching bioethics, the Bioethics Commission organised a two-day educational event for teachers, in October 2008, which marked the start of permanent cooperation between the Bioethics Commission and secondary schools.

The third Austrian-Slovakian Symposium on Bioethics, held in Trencianske Teplics (Slovak Republic) in October 2008, focused on the topic of living wills.

As part of the popular science event in Austria known as the “Long Night of Research”, the Bioethics Commission held a debate on patient autonomy and living wills.

Further information

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The Cyprus National Bioethics Committee

Cyprus

The Committee

The Cyprus National Bioethics Committee (CNBC) was established in 2001 by Law No 150(I)/2001. Its mandate is to monitor constantly, survey, systematically analyse and evaluate issues and problems associated with scientific research, advances in and applications of biotechnology, biology, medicine, genetics and pharmaceutics, along with human intervention in biological processes and the human genotype, and to investigate their moral, deontological, social, humanistic and legal dimensions.

The CNBC is an independent body subject to no administrative supervision by any ministry, agency, department or service and has the powers conferred on it by the current Law and any future legislation.

The CNBC has 13 members, including the chairperson. The members represent different professions and disciplines and are appointed by the Council of Ministers of the Republic of Cyprus for a four-year term. The Law stipulates that at least four members must come from the humanities and social sciences, four from medical and biological sciences and four members must be from any other science or profession or be distinguished for their contribution in any area of activity.

The CNBC adopted, with very few changes, the World Health Organization “Operational guidelines for ethics committees that review biomedical research” as the basis of the guidelines for ethics committees reviewing biomedical research involving human subjects in Cyprus, which were enacted on 31 March 2005 (Κ.Δ.Π. 175/2005).

In accordance with these guidelines and with the authority conferred on it by Law No 150(I)/2001, the Committee set up three Bioethics Review Committees to review protocols relating to:

- biomedical research on human beings and their biological substances;
- clinical trials on medicinal products for human use; and
- research on medical devices applied to human beings.

The role of the Bioethics Review Committees is to:

1. contribute to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants;
2. provide independent, competent and timely review of the ethical aspects of proposed studies;
3. review research proposals before the research begins.

The CNBC monitors, directs, coordinates and reviews the work performed by the Bioethics Review Committees, whose members are appointed for a period of two years.

Current work and forthcoming opinions

- Human biobanks
- Informed consent in emergency situations
- Revision of the guidelines for ethics committees reviewing biomedical research involving human subjects in Cyprus
Previous opinions

- Opinion on palliative care for terminally ill and dying patients (1.7.2008)
- Opinion on genetically modified organisms (3.4.2008)
- Opinion on prenuptial testing for thalassaemia before a civil wedding (24.3.2008)
- Opinion on predictive health information in the conclusion of health and life insurance contracts (22.1.2008)
- Opinion on medically assisted human procreation (5.3.2007)
- Opinion on PGD and sex selection of in-vitro procreated embryos (1.11.2006)
- Opinion on human organ donor registries (19.7.2006)
- Opinion on cord blood banking (27.4.2004)
- Opinion on use of preimplantation genetic diagnosis (20.10.2003)

Further information

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The German Ethics Council

Germany

Mandate, recent and upcoming topics and conferences

Mandate

In line with the Ethics Council Act of 16 July 2007, the German Ethics Council pursues the questions of ethics, society, science, medicine and law and the likely consequences for the individual and society connected with research and development, in particular in the field of the life sciences and their application to humanity.

Its duties include but are not limited to informing the public and encouraging discussion in society, engaging the various social groups; preparing opinions and recommendations for political and legislative action; cooperating with national ethics councils and comparable institutions of other countries and of international organisations.

The German Ethics Council prepares its opinions on the basis of its own work programme. The German Bundestag or the Federal Government can request it to issue statements on specific issues.

The Council is independent in its work and bound only by the mandate conferred on it by the Ethics Council Act. The members of the Council carry out their duties in person and independently.

The Council is composed of twenty-six members, specialising in scientific, medical, theological, ethical, social, economic and legal issues. Its members include academics from the above disciplines, and in addition persons of repute who are particularly familiar with ethical questions in the life sciences.

The Council comprises representatives of a variety of ethical approaches and a pluralist spectrum of opinion. Council members are appointed by the President of the Bundestag, half being nominated by the Bundestag and half by the Federal Government, for a four-year term. They may be re-appointed once. Council members may not belong either to a legislative body of the Federal Republic or of a Federal State or to the Federal Government or a Federal State Government.

The General Secretariat of the German Ethics Council is located on the premises of the Berlin Brandenburg Academy of Sciences and Humanities. The Council and its General Secretariat are funded by the Federation.

Recent topics

In 2008 the Council explored the following topics:

- Anonymous birth/baby drop-offs
- Biobanks
- Research on human-animal chimeras and hybrids
- Resource allocation in public health
- Public health nutrition
- Nursing services for elderly and disabled persons
- Ethical positions on suicide.

Of these, the first four will be pursued in greater detail in 2009.
The Council plans to publish an Opinion on anonymous birth and baby drop-offs by the end of June 2009. After an initial discussion on 26 June 2008 the Council invited external experts to a public hearing on 23 October, at which they reported on their experiences in this field.

Biobanks will be the subject of a second Council Opinion. The Council’s reflections are prompted by the significant changes resulting from the dramatic expansion of biobanks and the growing links between them, which call for fresh ethical and legal consideration. The working group set up to address this issue will revisit the Council’s 2004 Opinion “Biobanks for Research” and update it to take account of recent developments.

In addition, the Council has established working groups on human-animal chimera and hybrid research and on resource allocation in healthcare, to structure and prepare for longer-term consideration of these matters.

**Recent conferences**

26/11/2008: Is the State responsible for ensuring adequate nutrition? (evening public meeting)
25/2/2009: Preventive medicine: legal and ethical aspects (evening public meeting)

**Upcoming conferences**

28/5/2009: The steerable man? Insights and interventions in our brain (all-day public symposium)
24/6/2009: Questions of personalised medicine (evening public meeting)

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**Further information**

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The Hellenic National Bioethics Commission

Greece

A. Current composition of the Commission

On 26 February 2009 the Prime Minister appointed the Chairman, Deputy Chairman and Members of the Hellenic National Bioethics Commission for a term of five years 2009-2014 (Decision 368 of 25.2.2009).

Chairman:
Ioannis Papadimitriou, Emeritus Professor of Surgery, Medical School, University of Athens

Deputy Chairman:
George Maniatis, Emeritus Professor of Biology, Medical School, University of Patras

Members:
Costas Krimbas, Member of the Academy of Athens, Professor Honoris causa of Genetics, Agricultural University of Athens and Emeritus Professor of History and Philosophy of Biology, University of Athens.
Evangelos Moutsopoulos, Member of the Academy of Athens, Emeritus Professor of Philosophy, University of Athens.
Athanasios Papachristou, Professor of Civil Law, Law School, University of Athens.
Theocharis Patargias, Emeritus Professor of Genetics, University of Athens.
Julia Iliopoulou-Stranga, Professor of Constitutional Law, Law School, University of Athens.
Constantinos Tsoukalas, Emeritus Professor of Sociology, University of Athens.
Christos Voulgaris, Emeritus Professor of Theology, University of Athens.

B. Most recently issued opinions

1. Opinion on the Management of Biodiversity

Until relatively recently the exploitation of natural and biological resources was governed by purely economic criteria. Today, the importance of biodiversity for human existence and our responsibility to protect it are becoming increasingly obvious. In this opinion the commission endorses the value of biodiversity, the manmade dangers that it faces and the main arguments in favour of protecting biodiversity internationally and in Greece. In conclusion it proposes broader as well as specific environmental policy measures aiming to place environmental ethics and in particular the protection of biodiversity at the epicentre of national politics, a top priority during strategic planning of human activity.

The opinion is currently available only in Greek but is in the process of translation and will soon also be available in English, online at the commission's website: www.bioethics.gr
2. Code of Ethics for Research Institutions of Biological Sciences

As a supplement to its opinion on Research Ethics the Commission has prepared and published a template Code of Research Ethics in Biological Sciences. This template Code aims to help research institutions nationwide to prepare and adopt their own institutional Code of Research Ethics, as recommended in the commission’s opinion. It is hoped that this template will be a useful tool for research institutions and will initiate fruitful dialogue in the academic community.

The template Code of Research Ethics is available online in Greek and in English at the commission’s website: www.bioethics.gr

C. Recent publication

The Commission has recently published a complete collection of the opinions and reports issued up to 2008, entitled ‘Reflections on Contemporary Issues — Opinions and Reports 2000-2008’. The publication is dedicated to the memory of the Commission’s first Chairman, the late Professor George Koumantos.

Copies of this publication have already been sent to relevant ethics councils in Europe, libraries of universities and other institutions involved with bioethics.

For more information on obtaining this publication please contact our Secretariat (secretariat@bioethics.gr). The contents are also available online at the commission’s website.

Further information

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Italy

The National Bioethics Committee was set up following Resolution No 6-00038 of 5 July 1988, in which the Chamber of Deputies, among other things, committed the Government to promoting an international comparison of the state of the art in biomedical research and genetic engineering that could serve as a valid point of reference for future choices in which scientific progress can be reconciled with respect for human freedom and dignity.

The Committee’s tasks

The National Bioethics Committee was established by a decree signed by the President of the Council of Ministers on 28 March 1990 entrusting it with the following tasks:

- to make, if necessary by exercising its faculty to access the required information in existing national operating centres, as well as by liaising with similar committees set up in other countries and international organisations operating in the sector, an outline summary of the programmes, objectives and results of research and experimentation in the field of the life sciences and human health;
- to express opinions and suggest solutions, including for the purpose of preparing legislative acts, to address the ethical and legal problems that may emerge as a result of progress in research and the emergence of possible new applications of clinical interest, taking into account the need to safeguard fundamental human rights and human dignity and the other values expressed in the Constitutional Charter and in the international instruments supported by Italy;
- to propose solutions for the functions of control over both the safeguarding of human and environmental safety in the production of biological material and the protection from all risk of patients treated with products of genetic engineering or by gene therapy;
- to promote the drawing-up of codes of conduct for practitioners working in the various sectors concerned and to encourage action to ensure that public opinion is properly informed.

Composition

President: Prof. Francesco Paolo Casavola

Honorary Presidents: Giovanni Berlinguer, Adriano Bompiani, Francesco D’Agostino, Rita Levi Montalcini, Adriano Ossicini

Vice-Presidents: Lorenzo D’Avack, Riccardo Di Segni, Luca Marini, Laura Palazzoni

Members: Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Roberto Colombo, Bruno Dallapiccola, Antonio Da Re, Maria Luisa Di Pietro, Emma Fattorini, Carlo Flamigni, Romano Forleo, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Aldo Isidori, Claudia Mancina, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Alberto Piazza, Vittorio Possenti, Rodolfo Proietti, Lucetta Scaraffia, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa

Opinions

- Pharmacological experimentation on women (28 November 2008)
- Conscious refusal and renunciation of health treatment in the patient-doctor relationship (24 October 2008)
• Premature infants (29 February 2008)
• The fate of embryos resulting from medically assisted procreation (MAP) and not complying with the conditions for implantation (6 October 2007)
• Conflict of interest in biomedical research and clinical practice (8 June 2006)
• Nanosciences and nanotechnologies (9 June 2006)
• Biobanks and research on human biological material. Opinion of the NBC on a Recommendation of the Council of Europe and on a Document of the National Committee for Biosecurity and Biotechnology (9 June 2006)
• Caudotomy and conchectomy (5 May 2006)
• Ethics, health and new information technologies (21 April 2006)
• From pharmacogenetics to pharmacogenomics (21 April 2006)
• Bioethics and rehabilitation (17 March 2006)
• Differentiated diet and interculturality (17 March 2006)
• Bioethics and the rights of the elderly (20 January 2006)
• Assistance to pregnant women and post-partum depression (16 December 2005)
• Adoption for birth of cryopreserved and residual embryos obtained by medically assisted procreation (MAP) (18 November 2005)
• Bioethical problems concerning the use of animals in activities linked to human health and well-being (21 October 2005)
• Nourishment and hydration of patients in persistent vegetative state (30 September 2005)
• Bioethical remarks on so-called “ootides” (15 July 2005)
• Bioethics in dentistry (24 June 2005)
• Opinion on “the cellular therapy of Huntington’s disease through the implantation of foetal neurons” (20 May 2005)
• Alternative medicine and the problem of informed consent (18 March 2005)
• The precautionary principle: bioethical, philosophical and legal profiles (18 June 2004)
• Advanced care statements (18 December 2003)
• Ritual slaughtering and animal suffering (19 September 2003)
• Research using human embryos and stem cells (11 April 2003)
• Tobacco use (21 March 2003)
• Opinion of the NBC on the draft protocol on human genetics (6 March 2002)
• Aims, risks and limits of medicine (14 December 2001)
• Ethical and legal considerations on the use of biotechnologies (30 November 2001)
• Bioethics and veterinary science (30 November 2001)
• Animal well-being and human health (30 November 2001)
• Guidelines for ethical committees in Italy (13 July 2001)
• Violent acts, the media and children (25 May 2001)
• Bioethical guidelines for equal access to healthcare (25 May 2001)
• Pain therapy: bioethical guidelines (30 March 2001)
• Psychiatry and mental health: bioethical guidelines (24 November 2000)
• Therapeutic use of stem cells (27 October 2000)
• Protection of the human embryo and foetus. Opinion of the NBC on the preliminary draft protocol of the Bioethics Committee of the Council of Europe (31 March 2000)
• NBC statement on the patentability of human embryonic cells (25 February 2000)
• NBC opinion on the European protocol on biomedical research (19 November 1999)
• Bioethical guidelines for genetic testing (19 November 1999)
• NBC opinion on the proposal for a moratorium on human xenotransplantation clinical trials (19 November 1999)
• Statement on children’s right to a non-polluted environment (24 September 1999)
● NBC opinion on the Council of Europe White Paper on the treatment of mentally-ill patients (24 September 1999)
● The bioethical issue of non-voluntary sterilisation (20 November 1998)
● Circumcision: bioethics outline (25 September 1998)
● Youth suicide as a bioethical problem (17 July 1998)
● Ethics, health care system and resources (17 July 1998)
● Pregnancy and childbirth from the bioethical standpoint (17 April 1998)
● Bioethical issues in a multiethnic society (16 January 1998)
● The bioethical problem of non-kinsman living donor kidney transplant (17 October 1997)
● Cloning (17 October 1997)
● Childhood and the environment (18 July 1997)
● Ethics committees in Italy: Recent issues (18 April 1997)
● Animal testing and health of living beings (17 April 1997)
● NBC opinions on the “Convention for the protection of human rights and biomedicine” (Council of Europe) and on the “Preliminary draft of the universal declaration on the human genome and human rights” (Unesco) (21 February 1997)
● Identity and status of the human embryo (22 June 1996)
● The anencephalic infant and organ donation (21 June 1996)
● Coming to life (15 December 1995)
● Ethical aspects of electroconvulsive therapy (22 September 1995)
● Vaccinations (22 September 1995)
● Bioethics and the environment (21 September 1995)
● End-of-life issues in bioethics (14 July 1995)
● Medically assisted fertilisation — Documents by the National Bioethics Committee (17 February 1995)
● Medically assisted procreation techniques. Synthesis and conclusions (17 June 1994)
● Human genome project (18 March 1994)
● Bioethics with childhood (22 January 1994)
● Organ transplantation in childhood (21 January 1994)
● Report on the patentability of living organisms (19 November 1993)
● Drug experimentation (17 November 1992)
● Prenatal diagnosis (18 July 1992)
● Information and consent related to medical acts (20 June 1992)
● Ethical committees (27 February 1992)
● Organ donation for transplantation purposes (7 October 1991)
● Bioethics and education in the health care system (7 September 1991)
● Opinion on the proposed resolution concerning assistance to terminally ill patients (6 September 1991)
● Document on the safety of biotechnology (28 May 1991)
● Issues related to the collection and treatment of human seminal plasma for diagnostic purposes (5 May 1991)
● Gene therapy (15 February 1991)
● Definition and detection of human death (15 February 1991)

Motions and statements

Motion on the UN Convention on the rights of persons with disabilities (27 June 2008)
Motion on the collection, storage and use of stem cells deriving from umbilical cord (13 July 2007)
Motion on the trade in oocytes (13 July 2007)
Motion on assistance to newborns and children affected by serious pathologies or handicaps and on paediatric euthanasia (28 January 2005)
Motion on the trade in organs for transplantation (18 June 2004)
Note on emergency contraception (28 May 2004)
Motion on unconventional medicines and practices (23 April 2004)
Statement on the penitentiary issue (17 January 2003)
Motion on human cloning for reproductive purposes (17 January 2003)
Motion on the compulsory treatment of subjects convicted of paedophilia crimes (17 January 2003)

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The Bioethics Committee of Spain

Spain

The Committee

The Bioethics Committee of Spain was created by the Law on Biomedical Research (Ley 14/2007, de Investigacion Biomedica). This law defines ‘The Committee’ as an independent, collegiate organ which has a consultative role. The law states that the main aim of the Committee is issuing reports, proposals and recommendations dealing with subjects related to the social and ethical implications of the Health Sciences. The Bioethics Committee of Spain was formally constituted on 22 October 2008.

Working methods of the Committee

The subjects studied by the Committee are selected either by the Committee itself or chosen by any public or private organisation. The Committee is structured in working parties composed of members of the Committee according to the issue to be treated. The working parties prepare reports and recommendations to be submitted to the plenary Committee for its approval. The discussion of the various subjects will be summarised in reports, studies, guides or letters depending on their purpose and length.

Composition and appointment of the members of the Committee

The Committee is composed by twelve members from the different areas involved in bioethics. In accordance with the above-mentioned law, the members of the Committee are appointed by the Ministry of Health (Ministerio de Sanidad y Consumo), following these rules:

- 6 members nominated by Regional Governments
- 6 members nominated by the State Government:
  - 3 from the Ministry of Health (Ministerio de Sanidad y Consumo)
  - 1 from Ministry of Justice (Justicia)
  - 1 from Ministry of Education (Eduacion y Ciencia)
  - 1 from Ministry of Industry (Industria, Turismo y Comercio)

Current members of the Spanish Bioethics Committee

Chair of the Committee: Victoria Camps Cervera
Vice Chair of the Committee: Carlos Alonso Bedate
Deputy Secretary: Javier Arias Diaz

Other members of the Committee:

Carmen Ayuso Garcia
Jordi Cami Morell
Maria Casado Gonzalez
Yolanda Gomez Sanchez
Cesar Loris Pablo
Cesar Nombela Cano
Jose Antonio Martin Pallin
Marcelo Palacios Alonso
Current projects
Subjects under consideration by the Committee:
- Conscientious objection in health-care matters
- Code of good practice in health-care and biomedical research
- Biometrics and identifying data protection
- Social benefits derived from biomedical research. Patenting and patients’ rights
- Placebos
- Research in surgical practice. Informed consent
- Chimeras and biological hybrids in biomedical research
- Umbilical cord banks

International Meetings
The Bioethics Committee of Spain will be introduced to the European Council CDBI on the occasion of the CDBI general assembly to be held in Madrid on 27-29 April 2009.

Under the Spanish Presidency of the European Union in the first half of 2010, the Bioethics Committee of Spain will be in charge of organising the National Bioethics Committees Forum (NEC Forum).

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The Swedish Council on Medical Ethics

Sweden

Current work

The Council recently started work on a new theme – “neuroethics”, i.e. ethical issues arising from new methods in neurosciences – to consider ethical challenges in neuroimaging, neuronanoscience, cognitive enhancement, etc. A national open seminar on the topic is being organised on 8 May 2009 to kick off the project. Neuroethical issues will be discussed with experts in neuroscience, history, philosophy and law.

The Council has also started work on new methods of prenatal diagnosis by means of analysis of foetal cells and DNA in maternal blood.

The Council recently adopted opinions on:
1. the ethics framework for priority-setting in health care;
2. human/animal combinations in research;
3. patient autonomy in end-of-life decision-making;
4. patent protection for biotechnological inventions.

Recent opinions

1. The “ethics platform” for priority-setting in health care (16.2.2009)

The Council on Medical Ethics gave the Government its opinion on a proposal from the National Centre for Priority-Setting in Health Care to change the ethics framework for priority-setting in this area.

The Centre proposed clearer formulation of the prevailing ethical principles and further investigation of the option of adding a responsibility/liability principle. Furthermore, it proposed changes to the clear hierarchy between ethical principles.

However, the Council rejected the proposal from the Centre and put forward several arguments against the proposed changes.

The “ethics platform” for priorities in health care was adopted by the Swedish parliament (Riksdagen) in 1997. It is based on the principles of human dignity, needs and solidarity, and cost-effectiveness.

These three principles are ranked, putting the principle of human dignity first, followed by the principle of needs and solidarity and then the principle of cost-effectiveness. Since needs and solidarity come before cost-effectiveness, severe diseases and substantial deterioration or inequality of life should take priority over the less severe, even though treating severe conditions could cost much more. Hence, the principle of cost-effectiveness cannot be used to deny care or offer lower-quality care, e.g. to the dying, severely and chronically ill, elderly, functionally disabled or others for whom delivering care would not be “profitable”.

The 1997 recommendations also identified several ethically unacceptable principles for priority-setting. Old age per se cannot be a ground for prioritisation, nor can premature, low birth-weight infants be subject to any form of general restrictions on care. Self-inflicted injuries should not lead to negative special treatment, since at the outset the individual might not have known the harmful consequences. It is not possible to distinguish between effects of lifestyle and inherited factors.
In the opinion of the Council, the recommendations and the ranking/clear hierarchy should remain. The Centre proposed that the principles should be given equal rank as prima facie principles, which would mean that in each situation the correct ranking would have to be established. The Council pointed out that a “platform” without a ranking would not offer appropriate guidance for decision-making on health care and that the fundamental values of the “platform” could be lost. It argued that an “ethics platform” without a ranking between the principles could lead to arbitrary decisions. The Council also rejected the proposal to include the principle of responsibility/liability.


The Council wrote to the Government to draw its attention to developments in biological research involving mixing human and animal material. The letter briefly described past and present use of animal/human mixes in research. It then turned to recent developments in stem cell research, where the lack of human ova has led certain countries to conduct trials where human somatic cell nuclei are inserted in rabbit or cow ova to produce embryonic stem cells.

The Council referred to a report by one of its members, Professor Elisabeth Rynning, to the European research network Chimbrids, in which she concludes that Swedish regulations are not sufficiently up to date to deal with these matters. The Council called on the Government to address the ethical and legal aspects of research with human/animal mixtures.


The Council sent a letter to the Government accompanied by a discussion paper drafted by one of its working groups.

The paper identified a number of situations at the end of life that require difficult and potentially controversial decisions on whether to:

1. withhold life-sustaining treatment;
2. withdraw life-sustaining treatment;
3. offer palliative treatment and palliative sedation;
4. offer assistance in the form of a physician prescribing lethal doses of drugs in the case of self-determined termination of life; and
5. offer active assistance by a physician in the case of self-determined termination of life.

The working group clearly advocated greater patient autonomy in end-of-life decision-making. Patients should, under certain conditions, be able to request and receive continuous palliative sedation even if death is not imminent. Patients with certain progressive degenerative incurable diseases inducing severe pain and possibly mental impairment should be able to ask their doctor for help and the doctor should be permitted to prescribe a lethal dose of a drug that the patients can take home and use if and when they choose to end their life.

The Council submitted this discussion paper to the Government and at the same time published it on its website. The intention was primarily to promote public debate about end-of-life decision-making. But the Council also discussed the paper itself and described the outcome of its own discussions (to date) in the letter to the Government. The Council endorsed the emphasis on patient autonomy in end-of-life decision-making.

The Council stated that it is important to dispel as soon as possible the existing uncertainties about the legal conditions for decisions in different situations at the final stage of life. For example, the extent to which patients’ influence over decisions at the final stage of life could be increased should be examined.
In particular, this means whether the patient could ask for palliative sedation. A majority within the Council also felt that consideration should be given to whether physicians should be allowed to prescribe medicine for self-determined termination of life in special cases.

The Council’s initiative has generated lively debate in Sweden about end-of-life issues, including physician-assisted suicide and active euthanasia.

A translation of the opinion and the discussion paper is available at: www.smer.se.

4. Response to the consultation on the final report by the Committee on patent protection of biotechnological inventions (SOU 2008:20) (9.10.2008)

The Council has been following the issue of patents based on human DNA sequences, taking a broad and critical approach, since the EC Directive was adopted and implemented in Swedish legislation. The fundamental position of the Council is that patents, particularly concerning human DNA sequences, cannot be discussed solely from the perspective of patent law. There are ethical consequences at both individual and societal level that call for particular consideration to be given to such patents.

The opinion can be summed up as follows:

- Patents are not ethically neutral and therefore ethics assessments should be part of the patenting procedure.
- The consequences for bio-patents of polygenetic systems need further review.
- Action should be taken to ensure, as far as possible, that donors in research are informed that the results may be patented. The guidelines and Law on ethics review of research with human subjects may need to be revised along these lines.
- In order to assess possible consequences for Swedish legislation, it is necessary closely to follow the EPO’s handling of human embryonic stem cell lines in particular and developments concerning new methods for producing such stem cells in general.
- It is too early to draw conclusions about the consequences of product protection for the health care sector. This item therefore needs further attention.
- The EC Directive on legal protection of biotechnological inventions ought not to have been adopted as it stands.
- Also, the Directive should not have been implemented in Swedish law the way it was.
- Sweden should push for revision of the Directive.

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Introduction

The Nuffield Council on Bioethics was established by the Nuffield Foundation in 1991 to identify, examine and report on the ethical questions raised by recent advances in biological and medical research. Since 1994, it has been funded jointly by The Nuffield Foundation, the Medical Research Council and The Wellcome Trust. The Council’s role is to respond to public concern about aspects of biomedicine and biotechnology; to provide independent advice to policy makers; and to stimulate debate in bioethics.

Working Party on personalised healthcare

This Working Party is considering the ethical issues raised by online healthcare, telemedicine and commercial medical profiling technologies such as DNA testing and body imaging. These technologies and services are increasingly individualised, but are often accessed without the involvement of the person’s General Practitioner.

The Working Party, chaired by Christopher Hood, Professor of Government at the University of Oxford, will be holding a public consultation from April to July 2009. A report setting out the Council’s findings will be published in spring 2010.

Volunteering, donation and payment in clinical practice and research

The Council has decided to set up a Working Party to consider the ethical issues raised by volunteering, donation and payment in clinical practice and research, including the ‘donation of the whole body’ through human subject research.

Working Party on dementia

The Council will publish its report Dementia: ethical issues in October 2009. The report will include recommendations for policy and practice in a number of areas, including:

- what is an ethical approach to dementia care?
- dilemmas in day-to-day care
- decision making
- including people with dementia in society
- recognising the needs of family carers
- ethical issues in dementia research

S and Marper v UK ruling

Two men from Sheffield, known as S (a minor) and Marper, won a victory after the European Court of Human Rights ruled that keeping their DNA on the national police DNA Database, when they had not been convicted of any crime, breached their human rights. The ruling endorses the Council’s recommendations against storing DNA profiles and samples of innocent people on the National DNA Database. The Council’s report The forensic use of bioinformation: ethical issues was referred to substantially throughout the judgment. This ruling has significant consequences for the Government which now has an obligation to bring its policies into line with the Court’s ruling.
**Forward Look activities 2009**

The Council’s Forward Look seminar takes place each spring and is an opportunity for members to examine possible future work topics. This year’s seminar, to take place on 29 and 30 April, will consider the following four topics:

- Drug trials and prescription in children
- Ethical and effective health interventions in a global context
- Biological approaches to biofuel production
- Synthetic biology

The Council will be hosting its annual public lecture on the evening of Wednesday 29 April, at the Royal Society in London. The lecture will be given by Dr Thomas H. Murray, President of The Hastings Center in the US, on the ethical issues raised by synthetic biology.

**New Council members**

Six new members joined the Council in January 2009:

- Professor Steve Brown FMedSci, Director, Medical Research Council Mammalian Genetics Unit, Harwell
- Professor Robin Gill, Michael Ramsey Chair of Modern Theology, University of Kent
- Professor Graeme Laurie FRSE, Professor of Medical Jurisprudence, University of Edinburgh
- Dr Tim Lewens, Senior Lecturer, Department of History and Philosophy of Science, University of Cambridge
- Professor Ottoline Leyser CBE FRS, Professor of Plant Developmental Genetics, University of York
- Professor Anneke Lucassen, Professor of Clinical Genetics and Honorary Consultant Clinical Geneticist, University of Southampton

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Non-EU national and regional ethics committees
Comité National d’Ethique en Recherche

Brésil

La Commission nationale d’éthique en recherche (CONEP) a été créée à partir de la résolution 196/96 du Conseil national de la santé du ministère de la santé.

La résolution a été élaborée par une commission de bioéthique (multidisciplinaire) et approuvée après une large consultation des sociétés scientifiques, des organes gouvernementaux et de diverses associations représentatives de la société.

Le texte de base de la résolution se fonde sur un corps doctrinaire et opérationnel comprenant des caractéristiques essentiellement bioéthiques. La résolution n’est pas un code de déontologie. Elle contient un corps doctrinaire, établissant des conditions pour l’évaluation bioéthique des projets de recherche et dispose d’un système informatisé efficace (système CONEP – CEP). Le système n’est pas corporatif, n’est lié à aucun conseil ou entité professionnel, et déploie l’ensemble de son action en totale autonomie et indépendance. Le système dépend uniquement du conseil national de la santé qui est, par la loi, un organisme de contrôle social.

Dans la foulée de la résolution 196/96, des résolutions spécifiques ont été élaborées pour:

- des nouveaux médicaments,
- des recherches associant des coopérations étrangères,
- la recherche sur la reproduction humaine,
- la recherche sur des populations locales,
- la recherche en génétique humaine,
- la mise en œuvre de banques de matériel biologique.

Après analyse par les comités institutionnels, le projet doit passer par la CONEP quand il dépend des résolutions spécifiques.

La Commission nationale d’éthique en recherche est de nature essentiellement bioéthique (moins de la moitié de ses membres appartient à la même profession); elle est composée de treize membres (professionnels de la santé, des sciences humaines, des sciences exactes, théologiens, représentants de porteurs de pathologie (sujets de recherche)) et de treize suppléants.

La Commission est chargée de normaliser et de coordonner toutes les recherches engageant des êtres humains dans n’importe quel domaine de recherche.

La Commission a un mandat de quatre ans, avec un renouvellement à l’issue de la deuxième année. Ses membres sont nommés par le conseil national de la santé, à partir de noms proposés par les divers comités de recherche de différentes institutions.

Comités de recherche institutionnels

Depuis 1996, aucun projet de recherche relatif aux êtres humains ne peut commencer sans être approuvé au préalable par un comité d’éthique en recherche (CEP).
Les institutions qui veulent réaliser des recherches sur des êtres humains doivent donc constituer un comité d’éthique en recherche. Ce comité a les mêmes caractéristiques que la Commission nationale d’éthique en recherche. Il doit être approuvé et autorisé par la CONEP pour pouvoir évaluer les projets de recherche sur des êtres humains de l’institution. Environ 90 % des projets relèvent de la responsabilité exclusive du comité; 10 % doivent obtenir l’approbation de la CONEP, cas prévus par les résolutions complémentaires et propres à la résolution 196/96.

Protection du sujet de recherche

Le sujet de recherche bénéficie de tout un système de protection: le consentement libre et éclairé, qui vise davantage à protéger le sujet de recherche lui-même plutôt que de dispenser le chercheur de sa responsabilité, l’entreprise payant la recherche ou l’institution où est réalisée la recherche. Le consentement est rédigé par le chercheur et signé simultanément par le sujet de recherche et par le chercheur une fois que celui-ci a donné toutes les explications et répondu à toutes les questions du sujet sur l’objet de la recherche (deux exemplaires originaux sont établis: un pour le sujet de recherche et l’autre pour le chercheur).

Quelques données quantitatives

Nombre de comités institutionnels: il y a 581 comités institutionnels autorisés dans tous les États de la République fédérative du Brésil. Environ 10 000 personnes de diverses disciplines, travaillant dans le domaine de la bioéthique, se réunissent au moins une fois par mois pour évaluer des projets de recherche, émettre un avis et développer des activités éducatives dans leurs institutions.

Nombre de projets évalués par la Commission nationale d’éthique en recherche: annuellement, plus ou moins 1 000 projets, soit environ 10 %; cela signifie qu’au Brésil, 10 000 projets de recherche sur des êtres humains sont menés, annuellement: projets d’études rétrospectives jusqu’à des projets de pointe comme les cellules-souches.

Nombre de sujets de recherche: environ 500 000 personnes par an sont protégées par le système CEP/CONEP.

La CONEP: environ 47 % des projets sont approuvés lors de la première analyse; 42 % nécessitent davantage d’explications et 11 % ne sont pas approuvés.

Thèmes: environ 65 % des projets évalués par la CONEP relèvent de la coopération étrangère (approbation obligatoire par la CONEP – résolution spécifique). Dans ces cas-là, l’information sur la réalisation du projet dans le pays d’origine et l’approbation par le comité d’origine est exigée, ainsi que l’identité du chercheur brésilien responsable.

Written and submitted by Christian de Paul de Barchifontaine, infirmier, maître en administration hospitalière et gestion de la santé, étudiant doctorant en soins de santé à l’université catholique portugaise (UCP), professeur de maîtrise en bioéthique du centre universitaire São Camilo, actuellement recteur du centre universitaire São Camilo – São Paulo, Brésil (cpb@saocamilo-sp.br) and William Saad Hossne, médecin, président de la Commission nationale d’éthique en recherche (CONEP) 1996-2007, actuellement coordinateur de la maîtrise en bioéthique du centre universitaire São Camilo – São Paulo – Brésil.
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The Bioethics Cell is located at the New Delhi Headquarters Office of the Indian Council of Medical Research (ICMR). The ICMR is an apex body in India for the formulation, coordination and promotion of biomedical research under the Department of Health Research within the Ministry of Health and Family Welfare. It was established in 1911 as the Indian Research Fund Association (IRFA) and in 1949 it was renamed the Indian Council of Medical Research, with a considerably expanded remit. It has 21 permanent theme-oriented research institutes/centres and 6 regional centres addressing regional health problems.

Activities of the Bioethics Cell

The Bioethics Cell coordinates all activities related to ethical issues in animal as well as human experimentation. It performs the following activities:

- Acts as the secretariat for: (a) the Central Ethics Committee on Human Research (CECHR), set up in 1996 and consisting of members from various disciplines, e.g. neurosurgery, pharmacology, paediatrics, law, genetics, molecular biology, biostatistics, epidemiology, basic sciences, immunology, social sciences, theology, as well as a women's rights campaigner, etc. The CECHR is a national ethics committee and a referral body for the Ministry of Health and Family Welfare and other Indian Government Ministries on all bioethics-related activities; and (b) the Institutional Ethics Committee for reviewing projects generated by ICMR Headquarters scientists.
- Formulates Policy Statements, Ethical Guidelines and Guidance Documents.
- Conducts education/training in bioethics.
- Gives advice on issues related to bioethics and the functioning of institutional ethics committees.
- Maintains a database for bioethics resources.
- Coordinates international collaboration on bioethics.
- Organises workshops/seminars/symposia related to bioethics.
- Conducts research in the area of bioethics.
- Maintains the bioethics page http://www.icmr.nic.in/bioethics/bioethics%20cell/index.htm on the ICMR website (www.icmr.nic.in), which gives comprehensive information on topics related to ethics in animal experimentation (including articles on the use of animals in biomedical research, guidelines on the humane use of animals in experimentation, legislation and rules) as well as experimentation involving human subjects (guidelines, downloadable forms for institutional ethics committees, reports of workshops on bioethics, bioethics journals, bioethics education in India, news and events, etc). This webpage also carries useful information for visitors on the ICMR's recent initiatives in the area of bioethics as well as some important resources and links.

Documents issued

- Revised version of ‘Ethical Guidelines for Biomedical Research on Human Participants’ (2006).
• Guidelines on Stem Cell Research & Therapy, in collaboration with the Department of Biotechnology (2007).
• Draft Guidelines on Safety assessment of foods derived from GM crops.
• Draft Ethical Guidelines for Biobanking in India.
• Model Standard Operating Procedures for IECs in India.
• Standard Operating Procedure for Ethics Committees, prepared under an ICMR-FERCAP joint initiative.
• WHO-sponsored textbook on ‘Contemporary Issues in Biomedical and Health Research’, intended as resource material for teaching bioethics in India.

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The National Commission of Bioethics

Mexico

Main Goals and Challenges of the National Commission of Bioethics in Mexico

The history of the National Commission of Bioethics is not very recent. It was first established in 1992 as a group of academics who wanted to discuss issues related to bioethics. In 2000 a presidential agreement declared it a permanent body. Finally, since 2005, it has been recognised by a presidential decree as an independent body. It is a decentralised body independent of the Ministry of Health, which means it has technical and operational autonomy. The budget still comes from the Ministry of Health and the chair and members of the Council are appointed by the Ministry. There are six members that change every two years and one chair appointed for four years. Nevertheless, the structure of the commission is based on permanent members who are responsible for the operation of the commission and for putting in place the policies and programs approved by the Council. They access the job via the civil service, so there is public advertisement of the jobs and an independent selection process, and they cannot be removed by political changes. Both at the level of the Council and the permanent members, importance is attached to multidisciplinary and plural approaches.

The mission of the commission is to build a bioethical culture in Mexico. Its mandate includes activities in public policy, building bioethical infrastructure and creating public awareness. It is the official body responsible for defining national policies on bioethics and for establishing public health policies related to bioethics, and is the national body to be consulted on specific bioethics issues.

Issuing reports is not its main task. In fact, reports are not issued as such. The aim is to formalise the ethical issues involved in bioethical issues that are of social concern. In this way, the commission aims to provide society with relevant, sound and objective information and with a diversity of well-founded ethical arguments on the subject at issue. The commission wants to promote and support reflection: people’s ability to deliberate in a respectful, informed, sound, multidisciplinary and pluralistic way.

The context in which the commission has to perform its job is in an extremely polarised population, both economically and culturally. Among the 100 million inhabitants lives one of the richest men in the world, and a very small number of families hold most of the wealth of society while the rest lives in poverty or extreme poverty with a very weak middle class. Access to health care is limited and the quality of public services is very poor. More than 50% of the population is not entitled to any kind of health insurance. More than 66 diseases have been identified as causing catastrophic expenses to families and institutions and there is not enough money for the State to cover them either.

Research is carried out in a scarce-resources population, mainly in public institutions. This is a very important issue because it has an impact on informed consent as well as on benefit sharing and the social relevance of the research conducted.

It is very difficult to speak of the Mexican population as if it were an homogenous group, but in general terms one can say that the majority is illiterate and has little access to and understanding of either basic or complex scientific information. Many are not used to exercising their citizenship, so it is a major challenge for the commission to accomplish its mission of creating a bioethical culture. That is also why issues of social and distributive justice are prominent in our perspective on bioethics.
The commission has diverse strategies to fulfil this aim. It has a website on which interesting information is posted for the general public and enables people to make contact in case of questions and needs. It is in the process of establishing a Centre of Bioethical Knowledge, CECOBE. So far CECOBE has a large collection of electronic journals and books, helps with free retrieval of papers and gives the research ethics committees and the clinical committees free access to the collections. There is a library of print books and journals with an interlibrary exchange service.

Other public-oriented activities are the production of ‘Debate Bioetico’ (Bioethical Debate) a publication on a particular issue such as the UN debate on cloning. The commission has organised two public forums, one on dying with dignity and the second on the impact of homophobia on health care. One of the outcomes of the forums has been a publication on each, containing all the talks. In preparation we have the publication of a seminar on Social Aspects of Bioethics.

The last strategy worth mentioning is the publication in a large-circulation national newspaper of objective ethical arguments on various issues that worry society; for example during the controversy over a new law on abortion, and to clarify the different meanings of terms related to euthanasia.

Despite all the above there are many gaps to be filled and many new strategies to be implemented and created. The Mexican population is big and heterogeneous in all respects, so the approach needs to be targeted at different groups (multicultural, multiethnic, illiterate, poor and the different age groups).

The second main goal of the commission is to build an infrastructure of bioethics. The commission has the mandate to promote the establishment of bioethics commissions in every federal state; to promote the establishment of research ethics committees and hospital bioethics (clinical) committees, at public and private health institutions, to support the training of the members, and to produce the guidelines for all types of commissions and committees. Mexico is composed by 32 federal states and the health system is decentralised, so the national commission coordinates and guides the process respecting their own needs and priorities but sets the criteria for them to operate on specific issues such as the establishment of research ethics and clinical committees. In 2005, nine federal states had bioethics commissions installed; today there are 20 of them.

To date, the commission has issued the National Guidelines for the integration and functioning of Research Ethics Committees, and similar guidelines for the Clinical Committees will be ready soon. Permanent working groups have been established, one for the research ethics committees and another for the clinical committees. The commission will start a national registry of both types of committees, and discussion forums will start soon for each working group on the commission’s website. A database with information on the protocols being reviewed by committees and their status and rationale for rejection will be shared by the research ethics committees. A training course for 105 members of ethical committees has just finished.

Again, the challenges faced in this regard are not easy. Some of them are: there are many research ethics committees, but there is no certainty as to how many, how do they operate, how they are constituted? There is also heterogeneity among them, because some, particularly those at the national institutes of health, are more experienced and work better than others. There is still a lot of confusion among the committees regarding their objectives. Some still believe they can both review research protocols and also review clinical cases and advice on clinical bioethical dilemmas. At the clinical committees’ level, there is confusion regarding their objectives, and some still consider they can deal with issues of institutional resource allocation and labour problems among health-care personnel, and there is a serious lack of training in methodology on how to approach cases and analyse the ethical issues. Another common problem among research ethics committees and clinical committees, and in the federal state commissions, is having the director of the institution or the minister of health in the role of chairperson.
That is why establishing communication networks, issuing national guidelines, and working on legal initiatives to clearly establish the differences and the aims of each committee are key strategies followed by the commission.

Written and submitted by Dafna Feinholz Klip, PhD, Executive Director

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Establishing the African Advisory Ethics Council (2AEC)

On 28 May 2008 in Yaoundé, at the Cameroon Parliament building, a milestone was reached after two decades of struggle by the Cameroon Bioethics Society (CBS) and other African and international actors in pursuit of the ideals of bioethics in Africa: the holding of the first Pan African Bioethics Congress — COPAB.

The Pan African Bioethics Congress, which saw the active participation of the African Union Commission, the Pan African Parliament and the United Nations Economic Commission for Africa, aims to establish an integrated ethics sphere in Africa, with the African Advisory Ethics Council playing a key role. Organisation of the Congress was, without doubt, the culmination of a long process of maturation.

COPAB is an African forum for consultation, dialogue and guidance on social issues related to ethics, bioethics, human rights and the development of Africa, operating under the auspices of the African Union. COPAB was proposed as part of the implementation of Resolution AHG/Res.254 (XXXII) adopted by the OAU Bioethics Summit at the 32nd Summit of the OAU in Yaoundé in July 1996. The institution of reference of COPAB is the African Union.

COPAB’s ambition is to be an organisation of African civil society supported by governments, international and pan-African organisations, recognised as a public utility institution, and serving as an advisory body on ethics and bioethics for African States, the African Union and international cooperation. It aims to bring together in a pan-African and international forum delegates of the African States, African parliaments, African universities, African research institutes, organisations of African civil society, including faith-based organisations, African organisations on ethics and bioethics. The concern of this forum is inter-African dialogue, and international dialogue within the international community, on the whole field of bioethics, i.e. the defence and protection of life linked with human rights and development in Africa.

The cornerstone of COPAB, the African Advisory Ethics Council (2AEC), will result from the pooling of all the forces of the African nation, organised through national and continental coordination to help Africa further the principles of respect for the sacredness of life and human rights, through the promotion and protection of human life in Africa, and to guarantee the sustainable development of Africa. The twenty members of the African Advisory Ethics Council (2AEC) must therefore be appointed from COPAB.

The role of 2AEC is to issue opinions and conduct studies in various areas of the field of bioethics. To do so it must rely on the Scientific Commission of COPAB. This Commission includes experts and delegates from institutions working on major ethical issues of research and ethical dilemmas and brought together as much as possible within African platforms, for example:

- African platform on the ethics of clinical trials and evaluation of guidelines for health research
- African platform on Good Clinical Practice
- African platform on health and human rights in prison
- African platform on research on GMOs, toxic waste and climate change
- African platform on genital mutilation, female genital mutilation in particular
- African platform on biosafety standards
- African platform on the values of the start and end of life.
COPAB has the task of building, in the crucial area of bioethics, the circular dynamics of the African palaver, where each member is represented, and each member is at once essential and autonomous and linked to all by the community consensus developed by all and for all.

COPAB has the task of ensuring the implementation and sustainability of the Integrated Ethics Sphere of the African continent, especially proposing and implementing an African Convention on Bioethics.

**Composition of the General Assembly of COPAB**

1. Delegates of technical institutions, i.e. the Scientific Commission of COPAB (delegation/ country + continental coordination)
   - Research institutions (53)
   - National advisory ethics councils and ethics associations (53)

2. Delegates of the pan-African institutions
   - African Union Commission
   - Pan African Parliament
   - United Nations Economic Commission for Africa
   - African Commission on Human Rights

3. Delegates of African States
   - Government (53)
   - Parliament (53)

4. Delegates of African civil society
   - FBOs (delegation/country + continental coordination)
   - Professionals in the health sector, the Bar, education (delegation/country + continental coordination).

This organisation is the expression of the African palaver. Bioethics, with its universe of research and debate, is a new opportunity in Africa for affirming the structure of the African personality and its contribution to universal culture.

It is of the utmost importance that the African continent is organised effectively to ensure its full expression with all its diversity and complexity in these issues of life, survival and perpetuation of the human species.

African voices in bioethics should therefore leave the beaten path or transcend the lessons received from non-African cultures, and communicate to the world the values experienced since the birth of humanity and the earliest civilisations, which have survived the test of time and all sorts of calamities, through the creativity of generations in the African continent, to maintain the culture of the sacredness of life that is the hallmark of the African world.

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The Russian Committee for Bioethics

Russia

Some areas of activity

The Russian Committee for Bioethics (RCB) was established in April 2006 under the Russian Federation’s National Commission for Unesco.

The RCB brings together more than 30 specialists (physicians, biologists, philosophers and lawyers) from the Russian Academy of Sciences, the Russian Academy of Medical Sciences and Russian universities. The Committee is headed by Prof. Rem Petrov (biologist and medical scientist); there are also four Vice-Chairmen: Prof. Yury Lopykhin (medical scientist), Prof. Yury Sergeev (lawyer), Prof. Konstantin Skryabin (biologist) and Prof. Boris Yudin (philosopher).

The RCB is an independent inter-agency public expert advisory body.

The key areas of the RCB’s activity are listed below:

- Formulation of the national position on current bioethical issues;
- Assessment of international documents and projects in the field of bioethics, expert assistance in their ratification by the Russian Federation;
- Expert assessment of international and Russian legislation and promotion of legislative initiatives on bioethically relevant issues;
- Monitoring of the implementation of international and national ethical standards in biomedical research and practical healthcare services;
- Identification and analysis of new trends, study of international practice in bioethics and provision of information to the general public, ministries, political and administrative bodies and agencies on these issues.

After it was appointed the RCB:

- initiated activities on extending the validity of the Federal Law imposing a temporary ban on human cloning, dating from 2002 and expiring in June 2007;
- issued a statement regarding the desirability for Russia to accede to the Council of Europe’s Convention on Human Rights and Biomedicine (with reservations regarding Article 20(2)(ii));
- proposed an expert assessment of the draft of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing;
- proposed an opinion with regard to euthanasia, which was expressed in the corresponding statement;
- prepared an opinion on the draft Federal Law on biomedical research;
- initiated, arranged and held the First Russian Congress on Bioethics (with international participation), which was entitled “Bioethics and Human Rights” (Kazan, Republic of Tatarstan, September 2008);
- carried out a discussion about the ethical and legal issues involved in the transplantation of human organs and tissues in Russia.

In particular, the need to prepare and issue an opinion on euthanasia stemmed from the fact that a deputy of the Council of the Federation (one of the two Russian federal legislative bodies) had tabled a bill legalising some forms of cessation of life-sustaining treatment. The proposal gave rise to heated discussions
in the mass media. In its opinion, which was issued in May 2007, the RBC acknowledged that “Russian law forbids euthanasia, and in general this rule corresponds to the position of the medical community”. Yet proposals to legalise euthanasia are put forward from time to time by certain physicians, lawyers and politicians. The recurrence of these proposals can be explained, at least partly, by the current demographic situation, which is characterised by ageing of the country’s population. This means that in many cases patients with incurable diseases, in particular cancer, do not have access to quality medical care. Other arguments put forward by the proponents of euthanasia refer to the right to die with dignity as a basic human right. Such a right can be interpreted as the right of a person to decide for themselves what to do with their own life, including the right to end it when its continuation becomes unbearable, as well as the need to help patients facing acute physical and psychological suffering. So the problem of euthanasia has its objective roots in the current situation in Russia and, according to public surveys, the majority of the Russian population is in favour of legalising it.

For its part, the RCB considers it necessary to warn against hasty action aimed at legalising euthanasia which could give rise to negative social, legal and moral consequences. At the same time, to ignore the problem seems intolerable, as does any attempt to settle the question behind the scenes within a narrow circle of experts. According to the RCB, any legal measures in the field could be adopted only if they are understood and accepted by Russian society.

The RCB suggests holding a wide public debate not just on the problem of euthanasia but on the whole range of serious problems faced by incurably ill patients and their relatives.

In the very near future the RCB will discuss problems to do with the ethical review of biomedical research in Russia.

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Established in November 2001 by executive order of the President, the President’s Council on Bioethics, the longest-running bioethics commission in American history, will end on 30 September 2009. President Barack Obama could: (1) extend the 18-member Council, leaving its mandate and membership intact; (2) extend the Council, leaving its mandate intact but appointing new members; (3) establish a new commission with a revised mandate and membership; (4) choose not to have a presidentially appointed bioethics commission. No such public body is required by law and every commission to date has been time-limited and a creature of the will of either the US Congress (which was the case with the National Commission of the mid- to late-1970s and its successor, the President’s Commission of the early 1980s) or the President (which was the case with the National Bioethics Advisory Commission, which worked from 1996 to 2001, and, of course, the current President’s Council).

With the end of its mandate looming on the horizon, the Council is now engaged in an intensive effort to complete work already underway, focusing, in the main, on two proposed reports — a white paper, tentatively entitled Health Care and the Common Good, and a comprehensive report entitled Organ Transplantation: An Ethical Inquiry. As the United States enters a new round of what promises to be a passionate debate about health care reform, the Council’s proposed white paper is offered as a contribution to the effort to clarify the ethical significance of health care. Against the claims that health care is or should be treated as a commodity (like any other commodity) or as a right, the proposed white paper argues that health care is a good critical to the common good. The proposed report on organ transplantation spans the different but interrelated processes of donating, procuring, allocating and transplanting human organs — less with the aim of making policy recommendations but more in the hope of illuminating the human and moral concerns behind the various ethical precepts governing transplant practice in the United States and elsewhere. The one exception is the question of markets in human organs: on this question, the Council does weigh in with a considered recommendation against any such further step towards commodification of the human body. Both reports should be published before the end of June.

At its March 2009 meeting, the Council heard and discussed presentations on the general theme of national bioethics commissions, paying special attention to alternative conceptions of their missions, functions, working philosophies and “impact measures.” These sessions were conceived as a means of looking back on the work of the President’s Council and of capitalising on that experience with a view to clarifying the options open to the public and policymakers for establishing such public bodies. Should such bodies be completely independent of — or closely related to — the national government’s policymaking apparatus? Should the outcomes of their deliberations be provided as opinions, recommendations, findings or background and input (i.e. for policy- and decision-making)? Should such bodies seek to develop consensus-based opinions, recommendations, etc. or should they limit themselves to explicating the range of ethical perspectives on a given bioethical question or issue? What issues or questions are likely to benefit from or require deliberation by a commission in the near future? These were the key questions explored by the Council at its latest meeting. The Council is likely to issue, as its final publication, a small anthology of contributed essays attempting to respond to the challenges posed by these and other questions.

This look back on the work of the Council and look forward to future bioethics commissions in the United States is a fitting way to bring to an end eight years of activity. Since its inception the Council
has sought to probe the human and moral significance of a wide range of issues and questions in contemporary bioethics — from cloning, embryonic stem cell research and assisted reproduction to aging, determination of death, newborn screening and the controversial relationship between enhancement and therapy. It has also sought to advance discussions in the United States about such foundational concepts as “human dignity,” which has immediate resonances in a European context but is somewhat alien to an American context, where autonomy is more familiar and more widely embraced.

Questions about such foundational concepts as “human dignity” and “autonomy” — along with “solidarity,” “social responsibility” and “justice” — inevitably lead to other questions about the viability of an authentically global bioethics. We are privileged, in the words of the Chinese proverb, “to live in interesting times”, when we are becoming more aware of and sensitive to cultural difference, at the same time as truly global problems and challenges are pushing us to move beyond difference to common approaches and solutions. Although rooted firmly in an American context, the President’s Council on Bioethics has attempted to focus on the universally human “core” of today’s dilemmas at the crossroads of science, medicine, biotechnology and ethics. The relative success or failure of that attempt will become clearer only with the passage of time.

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European Commission
Ethics Activities in the European Commission’s Framework Programme for Research

Ethics Research Funding

Via the Science in Society (SiS) Programme of the EC’s Seventh Framework Programme for Research (FP7), the European Commission provides significant funding for research on ethical frameworks for new technologies and for support and coordination activities of ethics committees. Under FP7, funding is consolidating the research capacity created under FP6, which was mainly in the field of bioethics. The scope of research activities has also expanded to include other fields of ethics inquiry, related to emerging technologies and cross-cutting issues such as privacy.

In 2007 general themes, such as the ethical aspects of security technologies, were launched to help bridge the gap between social concerns and topical areas in science and technology. The 2008 SiS Work Programme also focused on promoting pan-European and international awareness of the ethical aspects of security technologies. Furthermore, conceptual research has been funded on ethical frameworks for assessing and addressing ethical issues in science and technology. This research builds in part on the insights generated from FP6 projects and aims to improve tools and policy instruments for the governance of science and technology.

The 2009 SiS Work Programme will further support research on ethics in science and technology on current themes, especially in relation to emerging issues in the context of ethical reviews or (research in) science and technology, such as protecting the privacy of citizens and their personal data. There has been strong interest in the FP7 ethics calls and already over 20 ethics projects are being funded. For the latest information on funding opportunities, please consult: http://cordis.europa.eu/fp7/sis/

Support and Coordination Activities of Ethics Committees

The Commission also supports networking and capacity building activities between ethics committees across Europe and beyond, with the overall aim to consolidate and further strengthen the infrastructure for ethical review of (research in) science and technology. Examples of such activities are the European Network of Research Ethics Councils and the Forum of National Ethics Councils (NEC Forum). The European Network of Research Ethics Councils (EUREC) aims to stimulate networking between ‘local’ research ethics committees and develops training for the members of such committees.

The Forum of National Ethics Councils is an independent informal platform for exchange of information and meets twice a year, hosted by the National Ethics Council of the country that holds the current EU Presidency. The last meeting was 27-28 November 2008 in Paris, hosted by the French National Consultative Ethics Committee. In a joint session with the European Group on Ethics (EGE), the latest EGE opinion on food security and sustainability in agriculture was discussed. Furthermore, the theme of public versus expert perspectives on ethics was discussed. The next NEC Forum meetings are:

- 13th Forum: 4-5 June 2009 in Prague
- 14th Forum: 17-18 September 2009 in Stockholm

For more information on the NEC Forum, and for the Opinions of National Ethics Committees in Europe, please consult: http://ec.europa.eu/research/science-society
The EC Ethical Review

Accompanying the FP7 Decision in the ‘Statements by the Commission’ (Official Journal L 412/42 of 30.12.2006), and in reference to Article 6 of the FP Decision on ethical principles, the Commission ‘proposes to continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 6th Framework Programme’. This ethical framework is implemented through the Ethical Review process.

The Ethical Review of research proposals submitted under FP7 is a system that safeguards the protection of fundamental rights and respect for ethical principles. It consists of four steps (that become five in the case of research involving the use of human embryonic stem cells) and guarantees that no funding is allocated to research that does not comply with the relevant EU legislation and the ethical considerations specified in the Framework Programme. These five steps are:

- A Scientific Evaluation performed by a panel of independent experts. The scientific panel comments on the ethical issues raised.
- An Ethics Screening of proposals selected for funding that is performed by independent experts.
- An Ethical Review of those proposals that have been identified by the above two steps as raising ethical issues is performed by a panel of independent experts. The ethical requirements noted down by the ethics panel are included in the grant agreement signed by the Commission and the participating researchers.
- The coordinators of those proposals that raise ethical issues and have been selected for funding need to provide the Commission services with copies of the necessary approvals issued by the competent national authorities (i.e. local/regional research ethics committees). These approvals, when necessary, are requested by the participating researchers from these national authorities prior to the commencement of the research.
- In the case of research involving the use of human embryonic stems cells, the selected proposals undergo an additional assessment by a Regulatory Committee. Proposals that include research activities which destroy human embryos are ineligible for funding and are not submitted to the abovementioned Committee.

In following the above steps, the Commission considers that the established Ethical Review mechanism has been successful in implementing the relevant EC ethics legislation.

For more information on the EC ethical review, please consult: http://ec.europa.eu/research/science-society then click on ‘ethics’ and ‘Ethical review of research proposals’; the direct link is: http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=73

Code of Conduct for Nanotechnology

Nanosciences and nanotechnologies (N&N) are flourishing areas in science and technology. In the near future they could have major impacts in economic, social and environmental terms. At the same time — as specific technologies, products and services are being developed — there are legitimate worries, expressed mainly by civil society, about risks to health and the environment, and also for ethics and respect for fundamental rights.

The European Commission has set out a strategy (2004) and an Action Plan (2005) for integrated, safe and responsible nanosciences and nanotechnologies development and currently provides a large
part of the funding dedicated to N&N research in Europe. The EC has, therefore, a responsibility to ensure confidence in the safe development and harmonious integration of these technologies in European society.

For this reason, on 7 February 2008 the Commission adopted a Recommendation to the Member States on a Code of Conduct for responsible nanosciences and nanotechnology research, thus providing a basis for further initiatives in this field and contributing to proper coordination within the EU and internationally. The Code of Conduct provides guidance on N&N governance and basic orientations for application of the precautionary principle.

The principles and actions included in the Code of Conduct stem from a public consultation held in 2007, as well as from five years of reflection and practice at European level on the interface between science and society. From the first Science and Society Action Plan in 2002 to the Code of Conduct, stakeholders in this field have become increasingly aware of the vital importance of the interactions between ‘science’ and ‘society’.

The Commission continues to engage stakeholders and researchers with regard to the recommendation. For example, on 17-18 November 2008 it hosted a workshop on the implementation of the code with researchers from the natural (nano) sciences and the humanities.

**Joint EC-UNESCO Conference in May 2009**

Under the Science in Society Work Programme 2008, the EC will finance a EC-UNESCO conference for capacity building in bioethics (project name: JACOB). The conference focuses on bioethics capacity-building for National Bioethics Committees (NBCs) from the developing countries and countries in transition. The conference will have three major themes:

- Emerging bioethics issues: local perspectives from the newly established and experienced NBCs (series of presentations and discussions on bioethics topics relevant in different regions of the globe).
- Building an international network — devising a common vision for future collaboration and mutual capacity-building.
- Engaging in ethical discourse. Thematic discussion on the IBC report on Social Responsibility and Health, with a special focus on the role of NBCs in the promotion of this principle in their respective countries.

The main focus of the conference will be on the sharing of experiences from the NBCs from Africa and Latin America and the Caribbean region that are in most pressing need of capacity building, as well as the rich and multifaceted experience from the European national bioethics committees. The conference is planned to be held in Mexico City in the first week of May 2009, immediately following the Sixteenth Ordinary session of the International Bioethics Committee of UNESCO.

**Expert Group on Global Governance of Science**

The internationalisation of the European Union’s Framework Programme for Research and the accompanying challenges to address specific global aspects of the European Research Area, such as scientific misconduct, the possible emergence of ‘ethics-free’ zones and non-transparent forms of mandated science at the global level have led DG Research to establish an Expert Group on the Global Governance of Science, to which legal scholars, sociologists, philosophers and political scientists from Europe, the United States of America, China and South Africa have contributed. The expert group advocates a vision of global governance for the common good that invokes European principles of good governance and fundamental rights. The expert group has concluded its work and

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International organisations
Events

- 10th anniversary of the Convention on Human Rights and Biomedicine
  2009 will mark the 10th anniversary of the entry into force of the Convention on Human Rights and Biomedicine (Oviedo Convention). A conference focusing on the Oviedo Convention’s impact and relevance and the enduring nature of its principles will be held on 3 November 2009, within the framework of the Slovenian chairmanship of the Council of Europe’s Committee of Ministers.

- Research ethics in countries with an emerging or developing economy
  As part of its current chairmanship of the Committee of Ministers, Spain considered it important to initiate a ministerial conference (to take place in 2010) on research ethics in countries with an emerging or developing economy. Council of Europe member states and observers will be invited to draw up a charter of ethical principles for biomedical research conducted in third states, particularly in countries with an emerging or developing economy. The Council of Europe’s Steering Committee on Bioethics (CDBI) will contribute to the implementation of this initiative.

Normative activities

- New Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes
  A fourth Additional Protocol to the Oviedo Convention, which concerns Genetic Testing for Health Purposes, was opened for signature on 27 November 2008. The Protocol sets out principles relating inter alia to the quality of genetic services, prior information and consent and genetic counselling. It lays down general rules on the conduct of genetic tests, and, for the first time at international level, deals with directly accessible genetic tests for which a commercial offer could develop in future. It specifies the conditions in which tests may be carried out on persons not able to consent. Finally, it touches on genetic screening. The text of the Additional Protocol concerning Genetic Testing for Health Purposes can be consulted at: http://conventions.coe.int/Treaty/EN/Treaties/Html/TestGen.htm

- Predictivity, genetic testing and insurance: a new legal instrument being prepared
  The CDBI is continuing its work on predictivity and genetic testing in the field of insurance with a view to drafting a new legal instrument.

Other current activity

- Preparation of a Guide for research ethics committee members
  The CDBI is preparing a Guide for research ethics committee members to facilitate the implementation of the principles laid down in the European legal instruments that have been adopted. The draft guide, prepared by the Group of Specialists in Biomedical Research (CDBI-CO-GT2), was presented to the CDBI in December 2008. A revised version of the draft guide will be prepared and examined by the CDBI in December 2009, with a view to making it available for public consultation.

For more information on the above items, please consult our website:
http://www.coe.int/bioethics
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UNESCO Bioethics Core Curriculum (Ethics Education Programme)

After an intense drafting and consultation process involving independent and governmental experts from all regions of the world, the *Universal Declaration on Bioethics and Human Rights* (hereafter referred to as the Declaration) was adopted by 191 Member States on 19 October 2005 at the 33rd Session of the UNESCO General Conference. The bioethical principles enshrined by the Declaration form a global package to include and enhance bioethics in all Member States.

Since bioethics is not a subject that is taught in many universities around the world, and given UNESCO’s mandate to promote, disseminate and elaborate on the bioethical principles laid down in the Declaration, the Advisory Committee for the Teaching of Ethics was convened in 2005 as part of the Ethics Education Programme (EEP) to draft a bioethics core curriculum. The Advisory Committee consists of ethics teaching experts from the International Bioethics Committee (IBC) of UNESCO, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) of UNESCO, UNESCO Chair, the World Medical Association (WMA) and the Third World Academy of Sciences (TWAS).

Following almost four years of intense work, the UNESCO Bioethics Core Curriculum was officially launched on 30 October 2008. It is designed to act as an incentive to begin bioethics teaching where it is lacking, and to improve bioethics teaching in general. The UNESCO Bioethics Core Curriculum introduces the bioethical principles of the Declaration to university students and is structured along the lines of these principles. As such, the Core Curriculum does not impose a particular model or specific view of bioethics, but sets out the ethical principles that are shared by scientific experts, policy-makers and health professionals from various countries with different cultural, historical and religious backgrounds.

Although the primary target group of the Core Curriculum is medical students, it can also be used to teach bioethics to other categories of students in nursing, healthcare sciences, dentistry, public health, law, philosophy and social sciences. Where bioethics teaching is absent or weak at all levels of education, the Core Curriculum can be used as an initial introduction to bioethics for healthcare professionals, and as a tool to educate members of ethics committees. The Core Curriculum provides basic training on the fundamentals and major issues of present-day bioethics.

The Core Curriculum consists of two sections. Section 1 provides the core contents with objectives, the syllabus and a teacher manual for each unit of the curriculum, and presents a common framework that can be applied to different settings. Section 2 contains study materials for each unit of the curriculum, designed as suggestions and to be further tailored by teachers to different contexts and cultural settings. Whenever feasible, study materials suggested in Section 2 would be included in the Global Ethics Observatory (GEObs) Database on Resources in Ethics for public access (www.unesco.org/shs/ethics/geobs).

The first thing a teacher will notice about the syllabus of the Core Curriculum is its innovative and unconventional structure. Typically, ethics courses in medical schools are organised around specific medical dilemmas, such as beginning of life and end of life issues. The Core Curriculum, however, follows the bioethical principles of the Declaration, with each unit of the syllabus (except for the first two
units) exploring one of the principles. The rationale for this design is that Member States have achieved consensus on these bioethical principles, thus establishing an uncontroversial Core Curriculum to teach bioethics in all Member States.

However, the Core Curriculum should not be treated as an exhaustive curriculum in bioethics. It is recognised that it does not necessarily cover all aspects of bioethics. Traditional issues that have not been included could be incorporated as examples that are pertinent to one or several of the Declaration’s principles within the curriculum’s framework. Furthermore, the number of hours proposed for each unit should be considered as the minimum amount of time to be dedicated to the material. Teachers should ideally deem the proposed time allotment as insufficient, and strive to build more hours into their teaching. Although UNESCO has taken measures to ensure that the curriculum is sensitive to various social, cultural and economic contexts, it is emphasised that teachers using the curriculum must still exercise discretion on the methods employed to convey the content of the curriculum, selecting contextually relevant materials or sourcing other available materials. Therefore, the Core Curriculum is designed to be a minimum teaching programme in bioethics leaving scope to further innovate, expand and apply the teaching flexibly in different contexts. The aim is not to impose a particular model of teaching but rather to provide ideas and suggestions on how to approach bioethics teaching.

The next step in implementing the UNESCO Bioethics Core Curriculum is to test the prepared syllabus and study materials. During 2009/2010, the Core Curriculum will be tested at several university pilot sites around the world (in all five regions of UNESCO). Upon completion of this testing period, evaluation forms will be collected from teachers and students to enable the Advisory Committee to review and adjust the Core Curriculum as deemed necessary. Once the review phase is concluded, the Core Curriculum will then be made available for global deployment to Member States (expected in 2011).

Section 1 (Syllabus) of the UNESCO Bioethics Core Curriculum is now available in English and French, and will be available in Arabic, Russian and Spanish by mid 2009. Section 2 (Study Materials) will be finalised in early 2009 and will be available in English, Arabic, French, Russian and Spanish (the draft is now available in English).

The UNESCO Bioethics Core Curriculum can be requested from:

Ethics Education Programme (Bioethics Core Curriculum)
Division of Ethics of Science and Technology
Sector for Social and Human Sciences
UNESCO
1, rue Miollis
Paris 75732, France
Email: eep@unesco.org

Useful Internet Links:

Download UNESCO Bioethics Core Curriculum:

Division of Ethics of Science and Technology: www.unesco.org/shs/ethics
Ethics Education Programme (EEP): www.unesco.org/shs/ethics/eep
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Ethically speaking

A newsletter providing information on the activities of the National Ethics Committees compiled by the Secretariat of the European Group on Ethics in Science and New Technologies to the European Commission

August 2009