Ethically Speaking [No 6]

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Editorial

Appointment of the new EGE members under the revised Mandate for 2005-2009

On 19 October 2005 President Barroso signed the Decision appointing the 15 members of the European Group on Ethics in Science and New Technologies (EGE) under the EGE mandate for 2005 - 2009[1]. Six of the new members were reappointed from the previous mandate and nine of the new members were appointed for the first time. The EGE held its first meeting on 25 October 2005 and elected Göran Hermerén as the President and Paula Martinho da Silva as the Vice-President of the new Group.

The previous four-year mandate of the European Group on Ethics in Science and New Technologies expired in March 2005. The European Commission took this opportunity to review and revise the mandate of the EGE. The new mandate was published in the Official Journal of the European Union on 20 May 2005[2]. This confirmed the essential objectives of the EGE namely the provision of advice to the Commission on the ethics of science and new technologies. However, the mandate was changed to allow an increase in membership from the previous 12 to 15. This increase means that the new EGE has a wider range of competences and through its membership reflects the enlarged European Union.

The range of issues studied by the EGE during their previous mandate (from ICT implants in the human body to patents deriving from stem cell research) is described in the General Report for the 2000 – 2005 mandate, which was issued on 15 October 2005[3].

The EGE remains an independent, pluralist and multidisciplinary body providing important advice to the European Commission on the ethics in science and new technologies in connection with the preparation and implementation of Community legislation or policies. The 15 members are appointed for their expertise and personal qualities. They come from different countries and are high level experts in disciplines such as biology and genetics, informatics, law, philosophy and theology. Their names can be found on the EGE Website[4].

The initial Work Programme of the EGE under its new mandate

During the interregnum the EGE Secretariat had obtained the views of Commission Services with an operational interest in the work of the EGE on the priority subjects for ethical analysis by the EGE. It has then been decided, that the EGE will produce an Opinion on the ethical aspects of nanomedicine.

This decision follows from a Communication of the Commission to the Council, the European Parliament and the Economic and Social Committee entitled *Nanosciences and nanotechnologies: an action plan for Europe 2005 – 2009* (COM(2005) 243 final). Chapter 5.1.b) of this Communication provides that *'the Commission will ask the European Group on Ethics in Science and New Technologies to carry out an ethical analysis of nanomedicine. This will identify the primary ethical concerns and enable future ethical review of proposed N&N (nanosciences and nanotechnologies) R&D projects to be carried out appropriately.'*

[1] C(2005)754; OJ L 284, 27.10.2005, p. 6.
[2] C(2005)383; OJ L 383, 20.05.2005, p. 17.
[3] Available at http://europa.eu.int/comm/european_group_ethics/publications_en.htm
[4] http://europa.eu.int/comm/european_group_ethics/ege2005_en.htm

Consequently, the EGE members started work on this immediately following their appointment. A skeleton Opinion has been produced and over the next months a number of experts in the nanomedicine field have been consulted. The new mandate requires the EGE to hold a round table meeting for all full Opinions and the nanomedicine round table meeting took place in Brussels on 21 March 2006[5]. Following this, if all goes according to plan, the eventual Opinion should be finalised within 2006.

The Future

Following the departure of the previous Secretary of the EGE, Dr M. Rogers, I have been appointed as new Secretary of the EGE. It is not easy to maintain the standards of excellence of my predecessor, such a knowledgeable and nice colleague, but I will devote my efforts not only to keep the outstanding levels of the past successes but even to aim to achieve better results in the future.

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[5] http://europa.eu.int/comm/european_group_ethics/activities05_en.htm

European Union Presidency
News from AUSTRIA

the Austrian Bioethics Commission and the EU-Presidency 2006

by Robert Gmeiner, Head of the Secretariat of the Bioethics Commission[6]

As Austria assumed the Presidency of the Council of the European Union in January 2006 for the following six months, this provides a most welcomed opportunity to expose some spotlights on (bio)ethical approaches in Austria in general and within the Austrian Bioethics Commission in particular.

A sceptical attitude of a great part of the Austrian population

A Eurobarometer survey carried out in 2002 shows that Austrians, despite having a somewhat more positive outlook than in 1999, are still more concerned about biotechnology and genetic engineering than the average European. Evaluating the biotechnology and genetic-engineering items in this survey shows a clear distinction (as in 1999) between medical and agricultural applications. Genetically modified foods still fail to convince a majority of those polled, while medical applications, the cloning of human cells included, are more widely approved.

The latest Eurobarometer poll *Social values, science and technology* (June 2005) reveals a corresponding scepticism with regard to scientific and technical matters. A majority of the population in all Member Sates of the European Union – with the exception of Austria – is of the opinion that biotechnology and genetic engineering have a positive effect on society. While 77% of EU citizens believe that 'science and technology will improve the quality of life of future generations', the figure for Austria – with 62% – is the lowest on this scale. To give another example, seven out of ten Austrians polled think that 'the protection of the dignity of the unborn foetus is very important for our society in ten years time', while the average of the EU25 is 53%. And again: Medical applications, which are awarded more benefits too, have a higher approval-rate in the public than agricultural utilization.

Austria – 'a country of committees'

If one has a closer look on the different stages of the bioethical and biopolitical debate in Austria, a tendency to 'institutionalize bioethics' can be recognized. Besides the Bioethics Commission there are a number of further bodies, which deal with ethical questions in biomedicine and biotechnology.

The first ethics committees, dealing with research, especially dealing with questions of the protection of human beings involved in research activities, were established in 1980 at the three medical faculties (Vienna, Graz, Innsbruck) on the basis of the Helsinki Declaration. Further research ethics committees were introduced particularly in 1994 by the Hospitals Act and the Drug Law. Today up to 40 such entities responsible for ethical review and oversight of research involving human beings exist in Austria.

[6] This contribution was completed on 20 October 2005

In 1992 Austria experienced the one and, thus far, only creation of a parliamentary commission of enquiry to deal with legislation on genetic technology. No other biomedical and bioethical subject was ever again treated in this way in Austria. This is in contrast to the specialist commissions of enquiry set up by the German Bundestag (federal parliament).

An Advisory Board on Gene Technology was set up according to the Gene Technology Act in 1995.

The Bioethics Commission at the Federal Chancellery was established in summer 2001. This happened largely in line with parallel events in Germany (National Ethics Council) and Switzerland, but relatively late when seen in the European context (e.g. France, 1983, or Denmark, 1988). The main task of the Bioethics Commission is to advise the Federal Chancellor on the ethical aspects of all social, scientific and legal matters that arise in connection with the development of science in the field of human medicine and biology. In the words of the Federal Chancellor, the commission should serve as 'an early warning system'. The Bioethics Commission is a forum of experts only, composed of 19 members (15 men and 4 women) from a wide range of disciplines including medicine, molecular biology and genetics, jurisprudence, sociology, philosophy and theology. On 5 November 2003 the Federal Chancellor Schüssel reappointed the same nineteen members, who have served during the first mandate. The second two-year mandate of the Bioethics Commission completed in November 2005.

The composition of the Bioethics Commission provoked much criticism, above all from interest groups representing people with disabilities and patient advocacy groups. They decided therefore to create a committee on their own, in order to develop alternative positions parallel to the topics being dealt with by the Bioethics Commission and to influence the debate.

In the autumn of 2002, the Government of the Vienna Land set up a committee on biological and medical ethics 'to complement the work of the Bioethics Commission at the regional level'.

Summing up, one could say, that there is no lack of committees on (bio)ethics in Austria.

Bioethics Commission - the 'balance of activities'

From the beginning, the Bioethics Commission fulfilled its function of 'policy-advice' and issued opinions and recommendations on various subjects. In doing so it defined the key topics of past and future debates, clearly taking on an agenda-setting role in the Austrian biopolitical discussion.

- In its first recommendation (of February 2002), the Bioethics Commission unanimously called upon Austria´s accession to the Convention on Human Rights and Biomedicine of the Council of Europe.

- In March 2002 the Commission came to the unanimous conclusion that 'the domestic implementation of the European bio-patent directive is important also from an ethical point of view'.

- The Bioethics Commission issued its findings regarding the question of stem-cell research in the context of the sixth EU research framework programme (2002-2006) in May 2002. There was consensus among the members of the commission in that no financial support should be made available for research using embryos or therapeutic cloning. Eight of the

nineteen members of the Commission rejected all research on stem cells derived from human embryos for the reason that their extraction was ethically unacceptable. The majority group of eleven members were in favour of research work on existing lines of embryonic stem cells, given that the final decision in individual cases depended on whether strictly defined conditions had been met. There was consensus that priority should be placed on supporting research on adult stem cells.

- In an interim report of February 2003, the Commission unanimously rejected so-called 'reproductive' cloning (i.e. cloning designed to produce children), and asked for corresponding national and international prohibitions to be enacted.

- In March 2004, the Commission issued its opinion regarding a draft amendment to the Austrian Reproductive Medicine Law (FMedG). On that occasion a group of seven members welcomed the suggestion of a comprehensive ban on cloning (i.e. one covering both reproductive and therapeutic cloning). Nine members had the opinion that there were not sufficiently weighty reasons to justify the imposition of a statutory ban on so called therapeutic cloning.

- In July 2004, the Bioethics Commission issued a report on preimplantation (genetic) diagnosis (PGD), giving not only a comprehensive overview on the scientific, legal, ethical and social aspects of PGD, but also containing two different recommendations: one opinion in favour of a restricted approval of PGD, the other one in favour of maintaining the present legislation unchanged.

- During the first half of the year 2005 the Bioethics Commission was invited to discuss the aspects of advance directives (living wills).

- The Bioethics Commission has started discussions on biobanks. The aim is to deliver a report and recommendations on this subject in 2006.

- Additionally the Bioethics Commission and its members have (co)organized and have taken part in various conferences and symposia in order to promote and to contribute to the public debate.

Perspectives

When this Newsletter is published, it is to be expected, that the Federal Chancellor will have already convened and constituted the Bioethics Commission for its third term. The Commission will hopefully agree on a working programme. As concerns the function of advice, this catalogue should on the one hand aim to finish tasks the Commission has started already (e.g. the issue of biobanks). On the other hand it will be interesting to determine which other issues the Commission will emphasize, maybe not primarily having the 'beginning of life' in its focus. Simultaneously the Bioethics Commission and its members will further have to initiate and promote public debate.

The EU presidency will probably bring some additional tasks for the Bioethics Commission too. Only two areas – on different levels of activity - can be touched here.

Stem cell research

Research involving stem cells derived from human embryos and its funding by EU sources (particularly under the auspices of the sixth EU research framework programme) has attracted a certain amount of attention in Austria. The Austrian minister at that time responsible for this

area adopted a strong position regarding the observance of protection for human dignity and human life with respect to genome research and biotechnology at a very early stage (in December 2001). Furthermore, specific prohibition for funding certain types of research was demanded. In June 2002, Austria was the only EU Member Sate to vote against the adoption of the framework research programme: A programme establishing the basis for funding research with human embryonic stem cells was not acceptable for Austria. As a consequence of these discussions, comprehensive guidelines and bioethical principles have been implemented. A ban on funding certain areas of research (such as the cloning of humans for reproduction or the production of human embryos exclusively for research purposes) and a moratorium until 31 December 2003 on EU funding for research activities involving the use of human embryos and human-embryonic stem cells were resolved. After the termination of this moratorium, EU-funding for activities in the latter field is now permitted under certain conditions, subject to exhaustive studies and ethical reviews, on a case-by-case basis.

Domestic debate in Austria is characterized by the fact that no research with human embryonic stem cells has yet been carried out in Austria, and there are thus no research-funding applications pending. Significant research is however being carried out with stem cells from human adults. This suggests a substantial difference compared with the discussions in other countries. Austria's legislation prohibits the derivation of stem cells from embryos (for research purposes) and the research using human embryonic stem cells or lines of stem cells (it has to be mentioned, that this position is not uncontested), while import of existing stem cell lines is not forbidden by Austrian law. While the national political debate was limited, the issue of stem-cell research attracted (and still attracts) a comparatively high amount of media-coverage in Austria. In the public debate, it was again the Bioethics Commission and its opinion (see above), which was standing in the crossfire of criticism.

This discussion seems to be revived in the context of the current negotiations concerning the seventh EU framework research programme (FP7). Austria had already published a position paper in November 2004 that asks for the setting of high ethical standards and maintains the opinion that adult stem cell research should take priority over research with embryonic stem cells. The EC´s proposal for a decision on FP7 (from April 2005) has included only recitals and articles with regard to the respect of fundamental ethical principles (not mentioning the controversial issue explicitly). In the proposal concerning Specific Programme 'Cooperation' (from September 2005) the European Commission has detailed some fields of research, which will not be financed under FP7, but has also suggested that (the funding of) research involving the use of human embryos and human embryonic stem cells will be similar to the procedure which has been established since the beginning of 2004: Proposals, having passed the scientific evaluation and the ethical review, are to be decided in a regulatory committee, where the Member Sates have to examine the projects case-by-case. Discussions at the latest Competitiveness Council (11 October 2005) have shown resistance of some Member Sates (not only of Austria). As regards the approach of the European Commission they have emphasized the principle of subsidiarity (comparable with the position of the European Parliament in its resolution of 10 March 2005) and have advocated more restrictive rules.

Primary activities of the Bioethics Commission while Austria holds the EU-Presidency

- Forum of National Ethics Councils: The 7th Forum NEC will be held in Vienna on the evening of 9th March and all day on 10 March 2006.

- Conference on the 'European Biopatent Directive': As emphasized in its opinion of March 2002 the Bioethics Commission wants to stay in contact with the discussions and

advancements of the issues surrounding the patentability of biological material and especially its ethical questions. Therefore – in cooperation with the Austrian Patent Office and the European Law Academy Trier – a two-day conference is planned on this topic in Vienna on the 29-30 May 2006.

- Improving bilateral contacts in the European context: E.g. a second symposium on bioethical issues will be organized together with the Central Ethics Committee of the Ministry of Health in Slovakia.

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International Ethics Committees

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the Council of Europe

Draft Recommendation on Research on Human Biological Materials

At its 29th plenary meeting held in Strasbourg (France) on 17 – 21 October 2005, the Steering Committee on Bioethics (CDBI) approved the text of the draft Recommendation on Research on Human Biological Materials. The Recommendation applies to the full range of research activities in the health field that involve:

- the removal of human biological materials to be stored for research use; or
- the use of human biological materials initially removed for a purpose other than research storage.

Two chapters of the Recommendation are dedicated to collections of biological materials and to population biobanks. The draft Recommendation will now be sent to the Committee of Ministers for adoption.

Draft Additional Protocol on Genetic Testing

The Steering Committee continued its discussion on the preliminary draft Protocol on genetic testing. It examined in particular the provisions related to the scope, genetic services, genetic counselling, directly accessible tests and genetic tests on person not able to consent for the benefit of family members. The CDBI agreed that the elaboration of the draft Protocol on genetic testing will be its priority in 2006 with a view to the finalisation of its first part on genetic testing in the health field. Discussions on genetic tests in the fields of employment and insurance, which are to be addressed in the second part of the Protocol, should then be resumed at the level of the Working Party.

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UNESCO

UNESCO's activities in the Ethics of Science and Technology

UNESCO is currently reinforcing its mission with regard to the ethics of science and technology by promoting ethical principles and fostering the international debate concerning scientific and technological progress. In this context, the main role of the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) is to formulate ethical principles and recommendations to guarantee that technological progress and the sharing of scientific knowledge are fully consistent with human rights and fundamental freedoms.

Joint efforts have being carried out and will be intensified in what concerns the involvement of UNESCO Sectors (Natural Sciences, Social Sciences, Education, Culture and Information and Communication), COMEST and other relevant international and regional bodies. A number of thematic areas are addressed with a view to playing an advisory and standard-setting role, such as: studies on the ethics of outer space and emerging technologies, nanotechnology, studies on the clarification of the precautionary principle and on environmental ethics; as well as ethics teaching. It was also deemed necessary to improve UNESCO's reflections in the context of the construction of the culture of peace and of human safety. Therefore, studies on the possibility of elaborating an international declaration on science ethics to serve as a basis for an ethical code of conduct for scientists is being carried out, in accordance with to the mandate ascribed to COMEST and to the International Council for Science (ICSU) by the World Conference on Science held in Budapest in 1999.

In terms of pedagogical and capacity building actions, two main activities are being developed. The Ethics Education Programme aims at initiating and reinforcing educational activities for the teaching of ethics to scientists and the development of a quality assessment and certification system. Schools of ethics (as networks of experts) are being established with pilot-programmes in the teaching of ethics of science and technology, in order to promote education and to serve as a forum for the exchange of ideas between specialists, as well as to encourage studies, research projects and diffusion of information on the social, ethical and legal implications related to the advancement of science and technology. The first meeting, with experts from Central Europe, was held in Budapest on 21-22 October 2004, and a second meeting, with experts from East Europe, was held in Moscow, on 20-21 January 2005. Furthermore, specific model programmes will be facilitated in regard to ethics of sciences as well as assistance for UNESCO Member Sates in establishing national ethics committees for science and technology, and facilitating the work of existing committees. A meeting was convened in Paris in July 2005 with a group of experts to start a preliminary Advisory Expert Commission on the Teaching of Ethics. The report of the meeting was placed on the website www.unesco.org/shs/ethics. The second Meeting of the Advisory Commission on the teaching of ethics will be held in March 2006. Furthermore, UNESCO and the Third World Academy of Science (TWAS)[7] will organize a joint seminar in June 2006.

Concerning the ethics of science and technology research programmes, expert groups are being set up for the various topics of research (environmental ethics, science ethics, ethics and nanotechnology). The groups' work will culminate in research papers that will be made

[7] Editorial footnote: more information is available at http://www.twas.org

available and widely disseminated. By the end of the biennium, the research papers produced will be compiled into a first volume of a UNESCO series on the Ethics of Science and Technology and made available in all six working languages – Arabic, Chinese, English, French, Russian, and Spanish.

Furthermore, in order to help Member Sates to build capacity in applied ethics, a system of databases has been created: the Global Ethics Observatory (GEO). Four databases will make up GEO:

1. a database of experts in applied ethics,
2. a database of ethics institutions and committees,
3. a database of teaching programmes, and
4. a database of relevant legislation.

The information should be searchable online and available also in the six official languages of UNESCO. The development of the four databases is programmed in order to allow resources to be focused on the establishment of one at a time. The first database (ethics experts) is ready to be launched online via the UNESCO website in English, French and Russian but is awaiting the resolution of minor technical issues before it becomes publicly available. The second database (ethics institutions) is in its final stages of development and should be ready in English and French shortly. Preparation for the English version of the third database (ethics education curricula and programmes) is also nearing completion. UNESCO's aim is to start to launch the databases by the end of 2005.

Scientists, philosophers, jurists, engineers, education specialists, experts with the best reputation and proficiency in their respective areas were invited to assist UNESCO and COMEST in this effort. They are helping UNESCO to identify the state-of-the-art, the significant issues and potential international needs and activities in each area. Their conclusions and recommendations, in a later stage, are the object of international consultations, starting with their submission to COMEST and approval by the UNESCO governing bodies. The composition of these groups of experts takes into due account considerations of professional excellence, multidisciplinarity, gender and regional distribution. The diversity of views is indeed the very raison d'être of COMEST. Any apparent difference between professionals with scientific training and those from a humanities or philosophical background represents a healthy reflection of this diversity and an attempt to reconcile the different perspectives between scientific and philosophical approaches.

According to Auguste Comte, society should be analysed as '*organisms*' with their own linear progress (through religious, metaphysical and scientific stages). There is today a certain general distrust that we can be approaching to an overwhelming third stage. Fears on what the ineluctable predominance of science can cause: cloning, eugenics, new technologies for war, new panopticism... Perhaps Comte had reason in some measure; perhaps these three stages – religious, metaphysical and scientific – are in fact not successive, but concurrent. UNESCO, however, guides its work by the belief that we are at the threshold of a better and deeper dialogue between philosophy, religion and science. It is enough to remember the classic Kant's postulate: '*Thoughts without content are empty; intuitions without concepts are blind (...) The understanding can intuit nothing, the senses can think nothing. Only through their union can knowledge arise'*. Only the harmonious integration between perception and reason produces the understanding, the knowledge and, finally, the agreement among men and among countries.

Simone Scholze[8]

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► *News from*

the World Health Organisation

Ethics at the World Health Organization

The Department of Ethics, Trade, Human Rights, and Health Law (ETH) implement activities collaboratively with departments in headquarters and the WHO's regional offices. The efforts are concentrated in the following areas.

Ethics of Health Systems

ETH is engaged in the policy development of one of WHO's top priorities - to provide treatment to 3 million HIV/AIDS patients by 2005 (*3x5 initiative*).

The role of ETH in this process is to advise the *3x5 initiative* on ethical issues in clinical ethics, standard of care, and equitable access, with a strong focus on the latter. The guidance document '*Guidance on Ethics and Equitable Access to HIV Treatment and Care'* is available in English[9] and French[10]: Training materials are to be elaborated. A case study entitled '*Equity and fair process in scaling up antiretroviral therapy: potentials and challenges in the United Republic of Tanzania'* has been elaborated in collaboration with the German Technical Cooperation (GTZ), and the Ministry of Health of Tanzania. This has been published jointly[11].

[9] http://www.who.int/ethics/en/ethics_equity_HIVe.pdf
[10] http://www.who.int/ethics/en/ethics_equity_HIVfr.pdf
[11] http://www.who.int/ethics/en

ETH is a member of the Technical Advisory Group (TAG) for the development of the Guide for Essential Practice in Comprehensive Cervical Cancer Control at WHO. In this capacity, ETH is advising the TAG on issues ranging from clinical ethics to ethical considerations in cost-effectiveness analyses and equity for the development of this guidance document.

ETH is also a member of the WHO Cancer Control Steering Group, which advises the Department of Cancer Control in implementing a WHO Executive Board resolution on cancer control. Among other activities, a *'Global Report on Cancer Control'* is being developed, to be published in spring 2006.

ETH is involved in an initiative to promote access to opioid drugs for palliative care in developing countries. Partners include other WHO departments, collaborating centres and the International Narcotics Control Board in Vienna. The topics on the agenda for ETH include equity in access, informed consent, cultural perceptions and barriers, and end-of-life issues.

Together with WHO's Department of Communicable Disease Surveillance and Response, ETH is engaged in a project on 'The implications of life science research and development for global health security'. The aim of this project is to involve Member Sates and other stakeholders regarding the health implications of advances in the life sciences and, in particular, the potential misuse of such science to cause harm. The project, which is taking place in two phases, includes an analysis of ethical issues raised by such 'dual use' research and the potential role of codes of conduct in avoiding or mitigating harm. Next month we will jointly publish a report, entitled *Life Science Research–Opportunities and Risks for Public Health: Mapping the Issues*, which marks the completion of the project's first stage. The other main output of phase one was the establishment of a network of experts. Phase two of the project is now under way, in which we are establishing a Study Group, engaging Member Sates through regional meetings, and providing guidance and an evaluative framework.

ETH is collaborating with WHO's Department of Medicines Policy and Standards, in analysing ethical practices in the pharmaceutical sector. A document is being prepared for use in countries involved in assessing these practices, it is entitled *Measuring transparency to improve good governance in the public pharmaceutical sector*.

ETH is helping WHO's Departments of HIV and of Mental Health, to elaborate a guidance document entitled '*Basic Principles for Treatment and Psychosocial Support of Drug Dependent People Living with HIV/AIDS*'. Its purpose is to promote equitable access to high-quality HIV care for IDUs. Publication is expected in the beginning of 2006.

Research ethics

WHO has been engaged for many years in numerous activities in the field of research ethics, running workshops for Research Ethics Committees, promulgating guidelines and standards[12]. Based on collaborations within WHO, ETH contributes to a number of training activities. With the Moroccan Association of Bioethics and UNESCO, WHO organized a training workshop on research ethics in Fez in June 2005. This meeting was also an opportunity to discuss different ethical issues such as the universal declaration on bioethics being prepared by UNESCO. A similar activity was held in Dakar (Senegal) in July 2005, with participants from ten African countries. Three workshops have been held in China jointly with the Harvard School of Public Health. Training activities are planned for 2006 based on the collaboration of ETH with WHO's Department Initiative for research in vaccines (IVR) and WHO's research ethics committee (ERC). A project concerning distance learning is being

[12] http://www.who.int/ethics/research/

prepared; training workshops and seminars will take place in Cyprus and Rumania, in the near future.

ETH is part of the Steering Committee of the Global Forum for Bioethics in Research. The last forum, hosted in Blantyre (Malawi) in March 2005, was an occasion for 120 participants, most of them from developing countries, to discuss the issue of post-trial obligations of researchers and sponsors. The next forum is schedule for 17 and 19 February 2006 in Karachi, Pakistan. More information is available at http://www.gfbronline.com/.

ETH is a partner in NEBRA (Networking for Ethics on Biomedical Research in Africa) collaborating with a group of African and European institutions. This project, funded by the European Commission (6th framework programme - science and society), started in February 2005. After the 1st plenary meeting hosted by MRC-Gambia in Banjul in April 2005, the pilot phase of the survey was implemented. Preliminary results were presented during the second plenary meeting which took place on 31 October and 1 November 2005 in Cotonou, Benin, during which time a long term strategy was elaborated as a basis for future activities in the fifteen countries involved.

Human organ and tissue transplantation

In response to World Health Assembly Resolution, ETH is working with the Department of Essential Technologies to update the 1991 *Guiding Principles on Organ Transplantation*. Regional consultations were held in November 2005 in the Western Pacific and Eastern Mediterranean regions.

WHO participates in the newly formed Global Alliance for Transplantation which seeks to improve knowledge and good practices. Particular emphasis is now being placed on development of a registry for transplant outcomes (with regular follow up), encompassing both organ recipients and living donors.

ETH collaboration with other international organizations, regional bodies and academic centres.

ETH maintains a collaborative relationship with the European Conference of National Ethics Committees (COMETH) and the Steering Committee on Bioethics of the Council of Europe (CDBI), as well as with the European Commission. As a member of UN Interagency Committee on Bioethics and observer for the International Bioethics Committee (IBC) of UNESCO, ETH participated to the process of elaboration of UNESCO's draft Universal Declaration on Bioethics and Human Rights. Collaboration between these international organizations is particularly relevant to activities (capacity strengthening and technical assistance) implemented in the countries.

ETH provides the permanent secretariat for the Global Summit of National Bioethics Commissions which will next meet in Beijing, China in August 2006[13].

In collaboration with the University of Geneva, ETH participates in a research project on *Human Genetic Databases: Toward a Global Ethical Framework* (funded by the Geneva International Academic Network), interviews have been carried out, previous results collected and analysis under way.

[13] http://www.who.int/ethics/globalsummit/en/

Other activities

A large group of academics, healthcare professionals, and graduate students in bioethics have already benefited from a programme for internship at the Department of Ethics, Trade, Human Rights and Health Law and have contributed to activities of the different teams.

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Contributed articles
by Members of the EGE

Electronic implants in the body

'A minority with characteristics such that they could consider themselves superior could be created'

Article contributed by Pere Puigdomènech[14]

We are connected to electronic systems in a multiplicity of ways, and the phenomenon is set to increase still further. Our pockets or briefcases contain mobile phones, hand held computers or electronic personal organisers, and other common **devices** include GPS systems and a variety of technologies for receiving, storing and reproducing music. Other items include the magnetic cards which identify us, open doors and provide access to ATMs. These objects are now beginning to be incorporated into the human body, and science fiction has latched onto the idea by creating beings that combine human nature with mechanical or computerised elements (cyborgs and different kinds of robot). Although we have not yet reached such extremes, the situation is already such that the European Group on Ethics in Science and New Technology felt the time was ripe to reflect in its latest opinion on the technical, legal and ethical issues raised by these applications of the new technologies (available at europa.eu.int/comm/european_group_ethics/docs/avis20en.pdf).

One might well ask why anyone would want to insert an electronic device into their body. The most obvious answer is for medical reasons. Tens of thousands of people in Spain use increasingly sophisticated pacemakers which serve to regulate the heartbeat. Over 3 000 people in Spain have cochlear implants which correct deafness by means of an electronic device which transforms sound into an electrical current that stimulates the auditory nerve. There are other types (less used) of electronic stimulating devices and systems which are implanted to administer drugs or to monitor a clinically significant parameter such as blood pressure. A system of stimulation based on an electrode implanted in the brain, which could serve to limit the impact of conditions like Parkinson's disease, has been approved.

Intensive research is in progress to develop new kinds of prostheses for parts of the human body such as arms and legs. It has, for instance, been shown that an individual's nervous system can be connected to an artificial hand through a computer, enabling the individual to control its movement and even to receive sensory impressions via the system. Work is also in progress on systems which will encode images electronically and transmit them to the optic nerve. Proposals are reaching fantastical extremes such as devices that provoke orgasm (patented in the United States in 2003), not to mention those that combine nanotechnology with biotechnology and telecommunications. If we confine our purview to what already exists, most of us would not object to many of the medical applications that are being proposed, which may help to improve people's health or wellbeing. Clearly, before we can reach that stage, trials are needed which must meet the same criteria as regards quality and respect for the individual as any other medical application.

[14] CSIC-IRTA *(Consejo Superior de Investigaciones Científicas / Institut de Recerca i Tecnología Agroalimentaries* - Higher Scientific Research Council / Catalan Agro-Food Research and Technology Institute), and European Group of Ethics of Sciences and New Technologies

Another major field of applications for electronic implants concern their potential for identifying or locating individuals. Radiofrequency systems have been approved which, when implanted under the skin, enable individuals to be identified and give access to a person's clinical history or allow a payment to be made. Similar systems are used to identify pets and are being extended to farm animals. There are bracelets which enable people to be located, which have been approved as an alternative to custody in some countries. Proposals have been put forward for similar systems implanted in the human body, thereby enabling individuals who are at risk of being kidnapped or getting lost to be located. Nor do the objections to identification systems appear to be obvious. In fact, trendy bars in Barcelona and Rotterdam offer clients – as a VIP privilege - an implanted chip which identifies them and obviates the need for money or a credit card. Surely it is the dream of any anti-terrorist agent to be able to detect any individual at any time, or at least when that individual goes through certain control points.

In this context, the European Group's Opinion underlines the potential significance of medical applications of electronic implants, but recalls that our societies are founded on respect for human dignity and the inviolability of the human body. Citing principles which should guide the development of applications of this type, it recalls that in the Preamble to the European Charter of Fundamental Rights, the European Union '*place[s] the individual at the heart of its activities*' and that respect for the physical and mental integrity of the individual should survive the advent of the new technologies. The Opinion also refers to the right to control one's own body and the risk of external control over bodily capacities and draws attention to the fact that some of these devices are networked, which means there is a risk of the individual's losing control over the way in which they are used and the data generated. For all these reasons, the Opinion calls for these applications to be used within a clear legislative framework - which is non existent in many European countries - and argues that the authorisation of the use of technologies which could easily be misused so as to harm individuals or society must be subject to precaution. Similarly, while the autonomy of individuals must be respected as regards technologies which they consider to be useful or which can open up new opportunities to them, the Opinion recalls that the new technologies should not be used in such a way as to widen existing disparities between individuals on our planet. The division between peoples in their access to food, medical care or telecommunications and information systems is already far too great, but it could be even worse if individuals' actual characteristics separated them further.

Indeed, one of the areas where discussions arise over some of the consequences of these applications is how we define the normal state of an individual. The purpose of a prosthesis, in principle, is to restore a characteristic which an individual has lost. However, for some people, the argument that deafness, for instance, is not a normal state constitutes a form of discrimination against the deaf. Looking further into the future, there are people who suggest that the links between our bodies and electronic systems represent the beginning of an era of enhancement of the potential of our species. There are, in fact, advocates of what is known as transhumanism, based on the proposition that it is the destiny of the human race to transcend itself, by means, in particular, of close links with electronic systems. Leaving aside the discussion on the validity of these positions, it would seem to be important to recall that systems that significantly modify a bodily or mental function could end up creating a minority with characteristics enabling them to consider themselves superior, with the temptation that implies for one group to lord it over others.

It is clear that the development of non medical implants must be carefully monitored. The misuse of such implants represents a threat to human dignity and could violate the principles underpinning democratic society, such as the right to privacy or the individual's right of control over his or her own body: just consider the difficulties which people with such

implants may encounter in controlling the data generated by such devices. The need to keep individual data to a minimum is a principle which must be constantly reiterated in a world where such data are generated, exchanged and stored in exponential fashion. It must be stressed that where circumstances absolutely require their use, this must be done after regulation by Parliament and subject to judicial control. The normalisation of such implants and the use of devices to seek solutions to issues which society should resolve in a responsible manner represent paths which our society should tread only with care and awareness of the direction in which it is moving. This field offers such a wide range of possibilities in the future that we need to remind ourselves - to quote the newly published Opinion - that '*not everything that is technically possible is also ethically admissible, socially acceptable and legally approved*'.

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National and Regional Ethics Committees

► *News from AUSTRALIA*

the Australian Health Ethics Committee[15]

The Australian Health Ethics Committee

The Australian Health Ethics Committee (AHEC) is one of the principal committees of Australia's National Health and Medical Research Council (NHMRC). NHMRC is Australia's leading expert body promoting the development and maintenance of health standards through the provision of evidence based health advice, investment in high impact health and medical research and the consideration of ethical issues in health. AHEC was established under an Act of Parliament with the Minister for Health appointing members from a broad range of stakeholder groups including ethics & medical research, philosophy, social science research, clinical medical practice, nursing/allied health/ law, religion, consumers and people with understanding of the concerns of people with disabilities.

The key roles and responsibilities of AHEC are:

- to advise the NHMRC on ethical issues relating to health,
- to develop guidelines for the conduct of medical research involving humans,
- to promote community debate on health ethics issues,
- to monitor the work of Human Research Ethics Committees (HRECs), and
- to monitor and advise on international developments in health ethics.

Key Events in Australian Health Ethics for 2005.

Human Genetic Information

In March 2003, the Australian Government, through the Australian Law Reform Commission and AHEC, produced a report *Essentially Yours: the Protection of Human Genetic Information in Australia*. In line with the principal recommendations of the report, the Government has now established the Human Genetics Advisory Committee, as an additional Committee of the NHMRC. The report is available at http://www.alrc.gov.au

Review of the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002.

The two Acts came into operation in 2003 and led to the establishment of the Embryo Research Licensing Committee of the NHMRC. As provided for in the legislation, the Government has commissioned a review of these Acts and the details of the review will be available shortly. Both Acts are available at http://www.comlaw.gov.au and information on the committee is available at www.nhmrc.gov.au.

Ethical Guidelines on the Use of Reproductive Technology in Clinical Practice and Research.

Following a review of the 1996 *Ethical guidelines on assisted reproductive technology*, new guidelines came into effect in September 2004 to reflect the rapid developments in science since the original guidelines were developed. The new guidelines, entitled *Ethical guidelines*

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on the use of assisted reproductive technology in clinical practice and research, form part of the legislative framework to regulate research involving excess embryos obtained through assisted reproductive technology embryos under the *Research Involving Human Embryos Act 2002*. The revised ethical guidelines are available at http://www.nhmrc.gov.au/publications/synopses/e56syn.htm.

Guidelines for Research Involving Aboriginal and Torres Strait Islanders.

In 2004, NHMRC released revised guidelines entitled *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*. The new guidelines followed extensive consultation with indigenous communities and were developed by a working party with majority indigenous membership. The new guidelines can be found at http://www.nhmrc.gov.au/publications/synopses/e11syn.htm. To aid in the implementation of the guidelines, a series of workshops were held across Australia and were accompanied by an interactive process to develop a handbook designed to assist communities to participate in research consistent with the guidelines. It is envisaged that the handbook will be available in early 2006.

Revision of the National Statement on Ethical Conduct in Research Involving Humans.

AHEC has commenced a detailed revision of the 1999 *National Statement on Ethical Conduct in Research Involving Humans.* The review is being undertaken by AHEC, together with the Australian Research Council and the Australian Vice-Chancellors Committee. AHEC released a first consultation draft on 18 December 2004. Further information on the review can be found at http://www.nhmrc.gov.au/ethics/human/ahec/projects/statement.htm

Second National Research Ethics Conference.

Over two days in May 2005, the NHMRC hosted the second National Human Research Ethics conference in Canberra. The Conference provided a national forum for researchers, Human Research Ethics Committee members, ethicists, researchers and institutional administrators, sponsors, students and community members to discuss a range of ethical practical issues pertaining to research involving humans, focussing on the theme *Conflicts of interest in human research*. Over 400 participants attended the Conference. Preceding the conference a continuing education day was held for members of Human Research Ethics Committees (HRECs) and researchers.

Review of Australian Arrangements for Clinical Trials and Access to Unapproved Therapeutic Goods.

The independent review into clinical trials and access to unapproved therapeutic goods, jointly commissioned by the Therapeutic Goods Administration and the NHMRC, has been completed. The report is available at http://www.tga.gov.au/docs/html/cltrialrev.htm

New Ethical Guidelines Being Developed.

The NHMRC is currently embarking on the development of two new ethical guidelines:

1. Ethical Guidelines on Cadaveric and Living Organ Donation, and
2. Ethical Guidelines on the Management of People Diagnosed with Post Coma Unresponsiveness (Post Vegetative State).

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► *News from QUEBEC, Canada*

the Science and Technology Ethics Committee

Commission de l'éthique de la science et de la technologie

Publications and events

Opinion Statement on electronic plagiarism in schoolwork. This opinion statement results from the work done by the CEST Jeunesse 2005 (CEST Youth 2005) – presented in the 5th issue of Ethically Speaking – and its content is supported by CEST. The students present the subject under four headings:

1. What is electronic plagiarism in schoolwork;
2. What is education supposed to be in Quebec (education goals and measures concerning plagiarism);
3. Some solutions to put forward and values to promote; and finally,
4. Some other issues to investigate and about which further thinking should be pursued: for example, the presumption of innocence principle, reasons causing plagiarism, and intellectual property.

One important observation for the CEST Jeunesse 2005 is the fact that, although the practice of electronic plagiarism in schoolwork is known to exist, there are almost no rules about how to prevent or sanction it in the field of education. Having defined electronic plagiarism in schoolwork as the fact of copying in one's schoolwork, in its entirety or in part, the content of another production from an electronic source (Web, computer, emails, etc.) without any appropriate mention of the source, the CEST Jeunesse proposes four recommendations:

1. That the Minister of Education provides clear and uniform guidelines on how to use documentary or other information sources in schoolwork and post them on the Web; but also, that he makes sure that students are duly informed about the nature and consequences of plagiarism at all education levels;

2. That teachers be offered continuing education related to information and communication technologies, particularly about facilitating methods for plagiarism; but also, that teachers themselves require schoolwork and adopt evaluating methods that make plagiarism impossible or unprofitable and, besides, that encourage curiosity and the pleasure to learn;

3. That learning institutions administer penalties known to everybody, constructive and adapted to the various levels of education;

4. That all learning institutions, and at all levels of education (from the first school years to graduate studies), adopt guidelines about electronic plagiarism in schoolwork (namely a definition and penalties to be applied) that will be adapted to the various levels of education, widely spread and evenly implemented.

This position statement is available in French on the CEST Website.

Issues Paper and Consultation Paper on the use of biometric data for security purposes: ethical issues to consider. The issues paper has been prepared to provide a survey of the subject and to propose a series of questions concerning a certain number of ethical issues raised by the applications of biometrics in a democratic and pluralistic society. The consultation paper is a summary of the issues paper in its factual elements on biometrics, but with all the ethical issues presented in the main paper. The consultation paper was distributed to all the participants at a public forum held on the 13 October 2005.

Both papers are available in French on the CEST Website.

Public Forum on ethics and biometrics. This forum convened experts to explore the various facets of the subject: public security, biometric technology, legislation, individual rights and freedoms and other ethical issues. The general population was also invited to attend the forum and participate in the discussions. Moreover, everyone can respond to the consultation paper and present commentaries and opinions to the CEST by email, fax and post. The program, papers and a summary of the debates are available on the CEST Website.

Issues Paper on neuroscience and neuroethics. This paper is a preliminary work on a future position statement by the CEST. Its main purpose is to offer a description of the field of neuroscience and its applications, and to propose a series of ethical questions on the subject. The CEST intends to publish its opinion statement in May 2007.

CEST work in progress

Opinion statement on ethical issues related to nanotechnology. This opinion statement will present the field of nanoscience and its applications related to nanomaterials (including nanoparticles), nanoelectronics, nanobiotechnologies and nanometrics. Following a presentation on laws and regulations that can be used for nanotechnologies, CEST discusses ethical issues in health, environment, work organization, economy, governance, etc. and formulates recommendations to public and institutional leaders for the benefit of a responsible management of these new technologies. CEST opinion statement is planned for publication in April 2006.

Opinion statement on ethics and biometrics. Following the forum, a working group has been created to elaborate an opinion statement scheduled for release in October 2006.

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► *News from GREECE*

the Hellenic National Bioethics Commission

Most recent recommendation

Recommendation on the establishment of Ethics Committees that review biomedical research (22 April 2005)

Abstract

Currently, the law provides a system of ethical review in biomedical research only for clinical trials of medicinal products.

In addition, the law provides for Research Ethics Committees (RECs) within the Regional Health and Welfare System (RHWS) (art. 2 Act 2889/2001) with general jurisdiction but only for NHS hospitals. These committees are entrusted specifically with a potential 'first instance' review of clinical trials of medicinal products, issuing an opinion for the NOM Committee.

Finally, legislation was passed some time ago stipulating that Ethics Committees in Health Sciences must be created in all hospitals either public or private (art. 61 (4) Act 2071/1992). However, these are delegating provisions that have remained idle. Pursuant to Act 2889/2001 (art. 5), specifically as regards the NHS, the tasks of these committees are performed by the Scientific Boards of NHS hospitals. Scientific Boards, however, are not suitable for ethics review because they include only professionals from health sciences in violation of the principle of pluralism, on the one hand, and because board members are elected to office, which leaves them exposed to pressure and undue influence against the principle of independence, on the other hand.

As of now the law does not provide for RECs in clinical trials of other – than medicinal products – means or methods of treatment neither for research requiring the processing of biological human samples or biological personal data.

Moreover, it does not set down rules for the structure and operation of RECs, except for the NOM Committee.

In the Regional Health and Welfare System (RHWS) only 23,5% of the RECs stipulated by law are actually implemented. Of the hospitals under the National Health System (NHS), 15% have separate RECs, distinct from Scientific Boards, while in 65% the Scientific Board also doubles as an REC. A number of big hospitals set up as private law corporations (in either the public or the private sector) also have RECs.

At all events, regardless of the public or private character of hospitals, more than 90% of ethics boards are comprised exclusively of physicians with one pharmacist and one nurse or midwife. Law experts, clergy members or representatives of local authorities sit only exceptionally.

In research centres carrying out biomedical research, the establishment and operation of RECs is the exception given that only 20% of such centres have one. Among higher education institutions, one University has adopted a code of conduct for researchers which provides for a REC while at least two others are in the process of adopting a similar code.

Clinical research involving human subjects – testing either medicinal products or other treatments – and biomedical research involving the processing of human biological samples or personal data must meet certain ethical norms on the protection of participants. Ethics review should be efficient and safeguard the rights of participants whilst offering appropriate solutions in order not to discourage research.

In this spirit, the Commission proposed the following.

1. Any form of biomedical research (clinical or involving processing of human biological samples or personal data – in higher education institutions or private/ public hospitals) should be subject to ethics review by a REC at least on one level to ensure certification of suitability.

2. RECs must be independent, they should be established and they should operate in accordance with fixed and internationally accepted rules, compliance to which should possibly be attested by the appropriate body of the supervising authority of each research unit (e.g. the National Board of Medical Ethics of the Ministry for Health, the Bioethics Commission of the General Secretariat of Research and Technology). (The National Bioethics Commission provided draft guidelines in an attached Annex.)

3. Clinical research conducted in hospitals or in higher education institutions should be reviewed on a geographical division level – within the respective geographical district; RECs should be created by law specifically for research in the relevant regional or local sections of the Ministry for Health. The ethics committees provided within the RHWS are probably inadequate because their jurisdiction extends only to NHS hospitals. (Therefore, research should be exempted from their responsibilities.)

4. In the context of clinical trials of medicinal products, the approval granted by a REC should be considered as an opinion to assist the NOM Committee in the performance of its tasks.

5. The review of non-clinical research conducted by research agencies supervised by the General Secretariat for Research and Technology (GSRT) should come under the jurisdiction of the GSRT Bioethics Commission.

6. The review of non-clinical research conducted in higher education institutions should be entrusted to RECs whose establishment and operation, in accordance with the guidelines specified in the provided Annex, are to be encouraged by the Ministry for Education.

7. By way of supplementary measures, the Ministry for Health and the GSRT should encourage (via relevant information campaigns) the establishment of ethics boards in research units (hospitals or other). Review by such boards enhances the credibility of research proposals and facilitates the work of the responsible RECS as specified above.

8. Legislation should be cleared of unnecessary (and idle) provisions. In particular, the jurisdiction of Scientific Boards in NHS hospitals to consider ethical issues causes a typical confusion of duties which is incompatible with international norms.

Special remarks:

After the publication of the recommendation, the Ministry of Health invited the Commission to have a detailed discussion concerning whether there is a necessity to establish Committees on a local or regional level.

In addition, the Commission was asked to provide consultation to specific faculties of the University about the procedure that should be followed in order to create a Research Committee.

Current work

The Commission is currently dealing with specific issues (i.e. advanced directives, living wills) related to the issue of euthanasia.

Future Agenda

The Commission intends to comment on the Draft Code of Medical Ethics (elaborated on the initiative of the Ministry of Health).

Follow-up of training activities

The Commission keeps offering to students, mostly postgraduates, both from human and life sciences, the possibility of training on issues related to bioethics. Training period can last up to three (3) months without recompense.

The scientific officers support the trainees for accomplishing their diploma, while the students carry out documentation and other library-related tasks.

This initiative received immediately the attention of the students, who are accomplishing their tasks with eager and high interest.

Composition of the Commission

Chairman
George Koumantos, Emeritus Professor of Civil Law, University of Athens

Deputy Chairman
George Maniatis, Emeritus Professor of Medical Genetics, University of Patras

Members
Savas Agouridis, Emeritus Professor of Theology, University of Athens
Myrto Dragona-Monachou, Emeritus Professor of Philosophy, University of Athens
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
Dimitrios Roupakias, Professor of Plant Breeding, Agricultural University of Thessaloniki
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► *News from ITALY*

the National Bioethics Committee

2005 Activity report of the Italian National Bioethics Committee (Comitato nazionale per la bioetica CNB)

Opinions

Bioethical considerations concerning the 'ootid[16]', 15 July 2005

The Minister for Health asked the CNB for a specific opinion on this. The problem is important with reference to Section 14 of Act 40/2004 (on medically assisted pregnancy),

[16] Editorial footnote: Ootid is a mature ovum after penetration of a sperm but before the formation of a zygote.

paragraph 1 of which expressly prohibits the cryopreservation of embryos, except in cases referred to paragraph 3, which allows for freezing for reasons of 'force majeure' concerning the health of the woman. Paragraph 8 of Section 14 also recognises the possibility of freezing the gametes only, after obtaining the informed, written consent of the couple. Since Act 40 uses exclusively the terms 'embryo' and 'gametes', never the term 'ootid', the question is whether the freezing of 'ootids' is or is not an infringement of Act 40. The full Committee of the CNB voted by a clear majority that the cryopreservation of 'ootids' is not lawful.

Bioethics and odontoiatry, 24 June 2005

The CNB notes that there are medical ethics which cover specialists in odontoiatry (i.e. dentists). The CNB regrets the lack of attention paid by successive governments to dental pathology, particularly among the elderly and with regard to preventive measures for children and other vulnerable groups. The CNB also notes the lack of dentistry research.

Opinion on cell therapy for Huntington's disease following the grafting of neurons from an aborted foetus, 20 May 2005

The CNB recognises the ethical value of research into foetal tissue obtained following abortion or miscarriage, provided that the medical team carrying out the abortion and the team carrying out the research are quite separate.

Alternative medicine and the problem of informed consent, 18 March 2005

The CNB has looked at the question of alternative medicine from a strictly ethical point of view, without touching on the epistemological aspects. Having reiterated the principle of autonomy, which gives adults complete freedom of choice in the use of alternative medicine, the CNB nevertheless regretted the use of alternative medicine for minors, as their vulnerability and the fact that alternative medicine is not publicly recognised could expose them to undue risk.

Motion: on the assistance to newborn babies and children suffering from an extremely serious disease or handicap and on paediatric euthanasia, 28 June 2005

Following the announcement that a European country has authorised euthanasia for young children (handicapped children in particular), the CNB stated that it was opposed to this practice. Having distinguished the prolongation of life by medical means from euthanasia, the CNB stressed that the ending of a human life on the grounds of the supposed poor quality of that life was not ethical.

Seminar and conference

Biometry (Rome, 21 October 2005). Research seminar with F. D'Agostino (President CNB), E. Mordini, K. Wadhwa, D. Grondin, M. Savastano, C. Caporale, R. Chadwick, L. Marini

Conference on 15 years of the CNB (Rome, 30 November - 3 December 2005)

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► *News from MALTA*

the Bioethics Consultative Committee

The DNA Essence

I of course fully agree that our DNA alone does not constitute new life. If I were to believe that, I would be a genetic reductionist which I am not. However one cannot agree that a new human life exists without the existence of a first definite normal genetic constitutional template which is human. This is analogous to stating that a silicon chip is not a computer, but believe me, there is no computer without the silicon chip! The argument that an individual zygote is more than his DNA complement is usually used by many to justify research up to the 14th day after fertilisation, as they imply that due to environmental reasons there must be implantation for the human individual to exist. I have rarely seen this argument used to rationalize the logic that there is an individual human being from penetration, when there is not yet any final DNA template.

A definite genetic constitutional template occurs at syngamy at the time of pronuclear fusion (amphimixis or karyogamy are the better terms) and as she correctly points out although there is no fusion as we originally understood it to mean, it is the first instance when the two genetic messages from the two parents first come together. Prior to that point all development, including the totally maternally inherited mitochondrial DNA, is controlled by the mother's genes in the fertilised egg and there is not any protein synthesis linked to the new genome. It is only after syngamy that new protein translation from the new constituted genome finally takes place, and it is significant that up to a **short period beyond** syngamy, the whole cell may develop without any nuclei at all! It is also interesting to keep in mind that the development of the new genome only becomes autonomous and active after syngamy (Zygotic Genome Activation), and the fact that it does not occur before that point in time, means that both gene sets must be together for normal functioning to occur. Before syngamy, it is the mother's gene products which are in charge and the new genetic constitution of the embryo does not begin to take control of development until at least two days after that (at the four- to eight- cell stage).

It is important to accept that for a human life to exist *de facto,* both the mother's and the father's genomes must come together for the first time. This is one of the first principle conditions for life to exist, not only human life. It is also interesting to recall Loeb's and Lillie's experiments where fertilisation was initiated very easily, without any sperm at all, simply by changing the ionic concentration of the medium around the egg. This is a very common occurrence in the animal kingdom and this shows that sperm is not essential for initiating fertilisation. In humans, the sperm's genome is essential for normal development and is important in delivering half the coded message, for the computer to work properly, however the computer only works at all after syngamy! '*There is no rest for the messenger until the message is delivered – Joseph Conrad 1920'*. It seems that '*Once fertilisation is accomplished, development and inheritance may be left to look after themselves'.*[17]

Even Cardinal Ratzinger, in a summary document of the Consistory of Cardinals on the threat to life written for the preparation of the Encyclical Letter *Evangelium Vitae*, recalling the definition of the zygote in *Donum Vitae* as the 'moment of the fusion of the two pronuclei', reaffirms that 'from the time that the ovum is fertilised, a new life is begun which is neither that of the father nor of the mother; it is rather the life of a new human being with its **own** growth' and 'in the zygote **resulting** from fertilisation the biological identity of a new human individual is already constituted'[18]. Fertilisation is a process that has a beginning and has an end, and it is not accomplished before it is complete. There cannot be an **individual** human being until fertilisation is complete.

Having settled the deontological argument in this issue, I must now turn to other issues which also exist side by side. I must look at other arguments so as to dispel the *Dubium Facti*. Even well respected theologians accept this reasoning. I particularly call to mind Karl Rahner SJ, who needs no introduction and who goes on to say in the IX volume of his *Theological Investigations* (p. 236, note 37) that '*It would be conceivable that given a serious positive doubt about the human quality of the experimental material, the reasons in favour of experimenting, might carry more weight, considered rationally, than the uncertain rights of a human being whose very existence is in doubt*'. This is also the opinion of John Mahony SJ in his *Bioethics and Belief.*[19] What would in effect recognising the human embryo or zygote at amphimixis imply? Two effects in particular come to mind, but there are other possibilities. The first being *second polar body testing* to prevent serious genetic diseases *such as Huntington's Chorea* or *Muscular Dystrophy*. These are serious genetic diseases which are fatal or at best severely debilitating. They can be prevented by a simple *polar body biopsy*. There is also the possibility to change the genetic composition of the defective gene. Another important possibility is to allow freezing of the penetrated egg at this stage.

I am against the freezing of embryos because it results in the production of supernumerary embryos in suspended animation which then end up with nobody knowing what to do with them. Usually they end up as research material. However, eggs at this stage of fertilisation may be frozen in the pronucleate stage so that if IVF is not successful or a temporary pause in the process itself is necessary for whatever reason, then other eggs in the process of fertilisation are available for the IVF to continue, without again putting the patient through the agony of hyperstimulation and egg retrieval which is associated with an increased mortality and morbidity.

[17] Farley, J., *Gametes and Spores: Ideas about sexual Reproduction 1750 – 1914.* http://zygote.swarthmore.edu/fert4a.html
[18] *The Problem of Threats to Human Life,* Vatican City, April 4-7, 1991.
[19] Mc Cormick, R.A., *The First 14 Days,* The Tablet 10 March 1990, p. 302.

As for cloning and stem cell research, I have already referred in a previous article to the fact that defining the human embryo from penetration will create problems for the human definition of cloned human beings as there is no fertilisation there at all! This would also be the case with stem cell research. I have personally talked to many of my colleagues in the field of molecular genetics, and other fields and most of them single out amphimixis as the first instance of human individual ontological development.

> '*Between the conception and the creation.*
> *Between the potency and the existence.*
> *Between the essence and the descent, falls the shadow.*'
>
> T.S.Eliot (1936).

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► *News from the NETHERLANDS*

the Health Council of the Netherlands

The 2005 Ethics and Health Monitoring Report on embryonic stem cells and other topics

The Centre for Ethics and Health (Dutch abbreviation CEG) is a joint venture of the Health Council of the Netherlands (*Gezondheidsraad*) and the Council for Public Health & Health Care (*Raad voor de Volksgezondheid en Zorg)*. Under the aegis of the CEG, both councils produce short 'alerting' reports, identifying developments that, from an ethical point of view, merit the government's attention. The CEG's annual *Ethics and Health Monitoring Report* provides a compilation of these alerts. They are meant to serve as building blocks for the Health Ministry's annual 'Ethics and Health' policy agenda, which is appended to the national budget each year in September. Via its website www.ceg.nl the CEG also functions as a source of information on ethical issues in the field of (public) health.

On 29 June 2005, the third CEG Monitoring Report was presented to the State Secretary of Health. It contains alerts on six topics, of which the first three were prepared by the Health

Council and the last two by the Council for Public Health & Health Care. The fourth section, on screening in GP practice, was prepared jointly by the two councils cooperating in the CEG. A brief summary of all six sections is given below. The report is in Dutch, but the section on embryonic stem cells is separately available in English.

1. Embryonic stem cells without moral pain?

This spring, Korean researchers announced that they had succeeded in obtaining stem cells from embryos produced by cloning. This involved introducing the nucleus of human skin cells into egg cells from which the nucleus had been removed. It is hoped that in the long term this method can be used to culture patient-specific cell material for autologous transplantation that might prove effective in the treatment of a wide range of complaints. At present, the research is still in its initial stages. However, this research and its possible applications are controversial. Firstly because human embryos are produced that will only be used as a source of stem cells. And secondly because (a large number of) human egg cells are required for the cloning procedure. The question is whether these can be obtained by morally acceptable means. While the discussion is still under way, research of this kind is forbidden in many countries, including the Netherlands.

Against this background, interest has recently arisen in the possibility of obtaining the same result (patient-specific pluripotent stem cells) without the necessity of producing human embryos or asking women to donate (mature) egg cells for this purpose. The ethically most attractive approach is the 'direct reprogramming' of body cells without the intermediate step of embryo production and without the need to use egg cells. This approach, however, seems to be the one that lies furthest in the future. Moreover, it may prove to be necessary to produce human embryos in the development of this approach too.

Many of the other 'embryo-saving' proposals presented in the literature are based on the assumption that non-viable embryos are not strictly speaking embryos at all, so that the harvesting of their contents does not raise any moral issues. It may be asked whether this is not an unduly facile approach to the problem. What is in fact the status of the non-viable embryo? It seems undesirable to incorporate an answer to this into the formal definition of an embryo. This is however precisely what is done in the current Dutch Embryos Act.

One of the proposed ways of getting round the egg-cell problem is to culture the egg cells required from embryonic stem cells. This approach, however, still raises ethical issues when one considers that genetic material cultured from stem cells could also be used for reproductive purposes. This (still speculative) scenario might make it possible to provide better support for couples with fertility problems, but would in its turn represent a major challenge to our traditional ideas about the natural limits of reproduction and parenthood.

However, the primary policy context for this report is the impending evaluation of the Dutch Embryos Act and the discussion of the desirability of rescinding the (temporary) ban on the creation of embryos for other purposes than pregnancy. Far from making this discussion unnecessary, the quest for 'embryo-saving' sources of tissue-matched stem cells only underlines the fact that this discussion can no longer be postponed. The evaluation of the Act must also include consideration of what precisely is to be understood by the term 'embryo'.

2. Ethical aspects of cost-utility analysis

Monitoring the expenditure on health care involves the need to make choices about which treatments are to be included in the health-care package made available to the public. Specific cost-utility analysis (CUA) methods have been developed to provide a uniform quantitative basis for the making of such decisions over the whole range of health services. An important criterion in this connection is the QALY (quality-adjusted life year).

Ever since its introduction in the 1970s, there has been a great deal of discussion about whether this decision-making approach leads to an equitable distribution of health-care resources. For example, older people with their shorter expectation of life would by definition gain fewer QALYs from successful treatment than younger ones, and people with chronic complaints or disabilities would gain fewer QALYs than those for whom complete recovery may be expected. The CUA system does not take into account the severity of complaints or other factors that might be expected to play a role in the allocation of health-care resources.

This charge of possible unfairness has received attention in the recent literature on health economics. Two approaches have been used in an attempt to correct this unfairness. In the first, the arsenal of CUA instruments is extended by quantification of 'equity preferences' existing in the population. This is technically ambitious and is moreover ethically questionable. The second approach is precisely to limit the use of the CUA methodology. The argument here is that while CUA data can provide a basis for decision-making, other aspects such as considerations of fairness should also be taken into account. The second approach would appear to raise fewer problems than the first when it comes to making morally acceptable decisions. But one factor that is still not taken into account here is the fact that the various uncertainties and imperfections of the CUA system itself can lead to all kinds of (hidden) allocation effects. Acceptance of this last-mentioned point means that the CUA system can at most be considered as an aid in a meticulous decision-making procedure based on democratic principles.

Discussion of this issue is highly relevant at present, now that CUA is being used in the United Kingdom as a basis for the approval of new health-care procedures in the National Health Service (NHS). There are also plans to set up a 'national assessment structure' in the Netherlands, explicitly modelled (at least in part) on the British example, for decision-making about the content of the health-care package. The present report urges caution in the use of the CUA methodology in this context.

3. Now with extra bacteria! Food products with health claims

Unhealthy eating habits damage the health of the public. People eat too much and they eat the wrong kinds of foods, which leads to a growth in the prevalence of many diseases. A new trend in supermarkets is the stocking of food products that come with health claims, such as bread with added fish oil to reduce blood cholesterol levels or yoghurt drinks containing healthy bacteria which are supposed to promote healthy intestinal flora. It is possible that these new food products do help to combat the problem of food-related disease.

However, a number of questions arise in this connection. Are the additives used safely? Do they really work? How well founded are the health claims made? Do these 'healthy' foods contribute to widening the health gap between the affluent and those who are less well off? Can consumers make a choice from the wide range of new foods on offer in a way that will contribute to their health? Is there a danger that the importance of food for health is being blown up out of all proportion?

Current Dutch legislation does not have the powers needed to ban products with vague or inadequately based health claims from the market. A proposed European directive promises improvement on a number of points, but it is not yet certain whether this proposal will be accepted and if so in what form. It is definitely open to question whether the average consumer is fully able to estimate the importance of food for his or her health. This makes it important for the consumer to receive information about this new food trend and to be educated about the relevant issues. It is worth mentioning in this connection that food has other legitimate values apart from the contribution it makes to the health of the consumer.

4. Tracking down threats to health: screening in GP practices

More and more methods are becoming available for early detection of diseases, aimed at prevention of these complaints by timely treatment or changes in lifestyle. This report considers the role of the GP in this development. The GP's practice would seem to be the ideal place for early detection of diseases or risk factors. Early detection (screening) targets people who do not yet experience any specific complaints. Furthermore, the GP is the only doctor with whom people from this group already have an ongoing relationship. Screening offered by the GP is therefore accessible, which avoids imposing a threshold. In addition, the GP's information system is in theory an ideal tool for screening and risk selection.

Screening in the GP's practice can occur in different ways: in 'population screening' people from the target group are actively approached and invited to undergo the appropriate test, while in 'case-finding' the investigation is offered at the moment when the client happens to visit the GP. Both approaches differ in one important respect from normal medical care, in that the investigation is offered on the initiative of the doctor and does not form a medical answer to a medical complaint or question from the side of the patient. This makes it even more important that the offer should have a proven added value for the person approached. It may be mentioned in this connection that the GP is better equipped than anyone else to take account of personal issues such as other risk factors applying to the person in question, his or her attitude concerning the condition screened for and the family circumstances.

The fact that screening is offered without an initial request means that extra care must be taken to present the offer in a way which does not worry the patient unduly or put him or her under undue pressure. This is particularly important in the 'case-finding' context. There is a real risk that the offer may be presented in such a way that the person in question feels more or less forced to accept it. Care must also be taken to ensure that the offer of screening does not induce or exploit unnecessary anxiety. Here again, the GP is ideally placed to provide balanced information about conditions and risks, so as to avoid undue worry. This makes high demands, not only on medical knowledge and communicative skills, but also on organization and time scheduling at the GP's practice.

While some variation in the offer need not be ruled out, the impression of arbitrariness must be avoided. If GPs aim at a limited screening package that is offered to a wide target group and organized on a national scale, that simplifies the training required (in particular in the field of information and communication) for GPs and supporting staff in the practice. This also avoids making priorities dependent on arbitrary factors such as support from the pharmaceutical industry.

Prevention of disease has long been seen as one of the GP's tasks. The question is how much extension of this task is desirable. Many people are in favour of GPs playing a bigger role in this field, but GPs themselves are often hesitant to go along with this idea. This hesitation is partly to do with their available capacity and priorities, but is also related to different perceptions of the role of the GP. Should the GP adopt a pro-active stance in monitoring the

health of patients, or should he or she be a provider of medical care who only comes into action when called for? Investigation of various scenarios for the relationship between GP and patient could help to avoid tensions between demand-based care and pro-active screening in the future.

5. Health care professional and police informant?

Imagine that shortly after the murder of the controversial Dutch politician Pim Fortuyn, Volkert van der G. (the person charged and ultimately convicted of the crime) was not arrested, but sought the assistance of a psychiatrist to deal with his feelings of guilt. Should the psychiatrist pass this information on to the police? According to current Dutch legislation he should not. He is bound by his duty of confidentiality towards his patients. The present report, however, reflects a shift in opinion concerning this legislation. Health care workers are increasingly being asked to pass on patient information in the public interest, e.g. for the detection of crime. The boundaries between the detection of health risks, the avoidance of professional anomalies and the detection of crimes seem to be getting blurred.

The professional duty of confidentiality, however, serves a public interest as well as the interest of the individual patients, since it guarantees a climate in which each patient or client can discuss his or her case openly with the therapist without the fear that personal details will be released indiscriminately. But there are limits to the duty of confidentiality. There may be weighty arguments in favour of a doctor revealing details of a case if this is the only way of preventing (future) harm to a third party. The views about the boundary between the duty to confidentiality and the obligation of public reporting seem to be shifting in the direction of making public reporting obligatory. There seems also to be a growing desire for legislation that will make it obligatory to report (suspected) crimes, as is already the case for e.g. child abuse and female circumcision. It is hoped that such changes will simplify the moral dilemmas associated with the professional duty to confidentiality.

These shifts can have consequences for the trust-based relationship between patient and therapist and the accessibility of health care. But they also raise questions about the boundary between confidentiality and public reporting. Will it soon be obligatory for clinical geneticists to report possible genetic risks? And will matters other than child abuse and female circumcision move from the private domain into the public domain? It would seem to be time for a fundamental debate about the boundary between the duty of confidentiality and obligatory public reporting, in order to find a new balance between the interests protected by professional confidentiality and the need to detect and prevent crime. This search for a new balance will inevitably touch on the question of what degree of cooperation with the police and the courts, in the exercise of their professional duties, should become incorporated in the package of tasks expected of the health care professional.

6. Ethics in health-care institutions and in the education of care professionals

The CEG generally reports on ethical questions arising in health-care or scientific practice. It goes without saying, however, that health-care practitioners also encounter moral questions in their daily work. These may be major issues about which there has already been much discussion, such as abortion or euthanasia, but there may be more down-to-earth issues such as professional confidentiality or the patient-therapist relationship. Since health-care work involves so many moral questions, it is important that health-care professionals should possess the skills needed to deal with these questions. The present report reveals, however, that many health-care workers lack the necessary basic knowledge of ethics and ethical skills. Moreover, many health-care workers are not aware of the moral implications of such simple

activities as washing and dressing patients. This can lead in practice to misunderstandings, moral and communication problems and a less than optimal quality of care.

In order to address this problem, a number of health-care institutions are actively involved in projects in the field of ethics, such as regular group discussions on moral issues between members of staff. And practically every student in a health-care educational or training course receives some kind of ethical instruction. However, the involvement of health-care institutions with ethical matters is still extremely limited; and the institutions that are actively involved often find it difficult to maintain these activities on a stable basis – largely because there is generally no basis for these activities in the institution's policy. In the educational field, there is particularly little interest in the teaching of ethics at secondary vocational level (Dutch abbreviation MBO) – the route normally followed for the training of laboratory technicians, nurses and middle hospital management among others. There further appears to be practically no external monitoring of how much MBO graduates have learnt about ethics. This suggests that it is doubtful whether the existing educational programmes can deliver all the statutory learning outcomes – which explicitly include some training in ethics.

The *2005 Ethics and Health Monitoring Report* (in Dutch: *Signalering ethiek en gezondheid 2005*) and an English translation of the section on *Embryonic stem cells without moral pain?* can be downloaded from www.healthcouncil.nl or www.ceg.nl

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► *News from POLAND*

the Bioethics Commission of the Ministry of Health

Published output on bioethics – closing the US-EU gap

The Lisbon strategy, a developmental plan for the EU put forward by the European Council in 2000, established the goal that by 2010 the EU will be 'the most competitive and dynamic knowledge-driven economy'. However, there is increasing concern that this ambitious target will not be met. In fact, President Barroso stated recently that '*We need to get Europe back to work*' (press conference in Brussels, September 2005). Similar statements have been made by former President Prodi. Since knowledge, and therefore science, has been recognized as the prime driving force behind the possible success of the EU, it is of interest to examine the current position of biomedical sciences - and thus bioethics - compared with that of the USA. The EU and USA are the two leaders in these disciplines, so such a comparison could provide useful information on the current trends at the midpoint of the Lisbon strategy.

Recently, two articles which address this problem in some detail were published. Lennart Philipson, who has been a scientific manager on both continents, compared research funding, activity, and creativity in the EU and the USA (1). Research funding in Europe is roughly 10% of that in the US, with comparable proportions of scientists in their populations. Moreover, private and industry donations are much higher in the US than elsewhere. These differences are also visible when the data are expressed as percentages of the respective gross domestic products (GDP): in the US, 2.7% of GDP is allocated to research and development, while in the EU it is 1.93%. These figures are from before the admission of new members in 2004, whose spending is even lower (in Poland, for example, 0.75%). Thus it could be expected that, as a result of EU enlargement, this gap has even widened. However, when scientific creativity was compared (Nobel prizes, citation indices, impact factors), the data suggested that science has expanded in Europe, although it is probably still lagging behind the USA.

Soteriades and Falagas recently examined biomedical research output during the past 10 years (1994-2004), retrieving the necessary data from the databases of the Institute for Scientific Information. Their search focused on biology and biochemistry, clinical medicine, immunology, microbiology, molecular biology, neuroscience, psychiatry and psychology, and pharmacology. Altogether, almost 1.5 million articles published by EU and American authors were included. The research productivity of the EU (adjusted for population) was approximately 70% of the US productivity. However, inclusion of the ten new members in 2004 caused a marked decline in that productivity (to 60%). What is more, the predicted productivity following a possible further enlargement of the EU (Bulgaria, Croatia, Romania, and Turkey) is 55%. Interestingly, after adjustment for funding, it could be expected that the number of published articles should even exceed the output in the US, even though this calculation includes the productivity of the four candidate countries listed above (2).

Given the leading position of American biomedical science, one would expect greater activity there in bioethics, as progress in biomedicine necessitates addressing the consequential ethical issues (e.g. stem cell research, the ethics of clinical research, which is much more widespread

in the US than in the EU, industry support of academic medicine and the resulting problems of conflict of interest, etc.). Therefore, it would be of interest to compare the published output in the field of bioethics (or medical ethics) in the EU and the USA.

I have retrieved articles from three international journals: *Bioethics, Journal of Medical Ethics* (JME) and *Ethics & Medicine.* All of them are international in scope with international editorial boards representing both the EU countries and the USA. *JME* describes itself as a leading international journal covering the whole field of medical ethics, the highest ranked journal globally in medical ethics (IF = 1.35). Over the past five years, the mean ratio of EU-derived to US-derived articles in the journal was 3.2:1 (adjusted for population). In addition, among the top ten most read articles, the EU/US ratio was 2:1. By contrast, in the same period of time the number of American items in *Bioethics* (IF = 0.83) exceeded the EU output by a factor of almost two (1.96:1). A similar trend was observed when the 100 most recent articles published over the past 10 years in *Ethics & Medicine* were examined. The journal states that '*for two decades (it) has offered guidance to a perplexed world from the Judeo-Christian worldview and its Hippocratic medical vision*' and '*gained international prominence and moved to address the developing bioethics agenda from the perspective of Hippocratic tradition*'. Its adjusted US/EU ratio was 2.67:1, with only one article from a new EU Member Sate. *The Lancet* is a leading international biomedical journal with a high emphasis on problems relevant for bioethics. Therefore it was of interest to examine the balance between the EU versus American publications in bioethics in this journal. The search of all *Lancet* journals for the term 'bioethics' yielded 255 positions; interestingly, the US/EU ratio when full articles were compared was identical to that for *Bioethics* (1.96:1).

It should be emphasized that my search in all three journals revealed only a few articles from the ten countries that joined the EU in 2004. In fact, their contribution to articles published in *Journal of Medical Ethics* and Bioethics was approx. 0.6% and 1% in *Ethics & Medicine* (none were published in *The Lancet*).

Finally, I retrieved records from Pubmed-covered literature in response to the term 'bioethics'. Of the 100 most recent articles in this field, the US/EU ratio was 3.2:1. Among them were three articles from the newly admitted states; however, only one of them was in English. A similar search for the term 'medical ethics' yielded an adjusted US/EU ratio of 1.5:1 (with only 2 articles, neither of them in English, from newly admitted states).

Obviously, the results of my analysis are very preliminary and restricted, including only limited data, so drawing definite conclusions would be premature. On one hand, the data derived from a highly specialized journal of medical ethics would suggest that the output in the EU is even higher than that of the US. However, it has been noted that although some peer-reviewed bioethics journals present themselves as international in scope, they remain mainly European or American (3). This provision seems to apply to *JME*. In contrast, when the data from Pubmed and the highest ranking journal (*The Lancet*) were adjusted for population, the published output of the US was apparently approximately twice that of the EU. In addition, there was a rather very low contribution from the ten countries that recently joined the EU (May 2004). In this sense, the situation of these countries may be similar to that of developing countries, as pointed out by Borry et al. (3).

Recently, these authors examined whether there is any under-representation of contributions from the developing world in this field. When the authors retrieved research articles from nine peer-reviewed, international journals (*Bioethics, The Cambridge Quarterly of Healthcare Ethics, The Hastings Center Report, The Journal of Clinical Ethics, The Journal of Medical Ethics, The Kennedy Institute of Ethics Journal, Nursing Ethics, Christian Bioethics, and Theoretical Medicine and Bioethics),* 96% of all articles were submitted by authors from

high-income economies, while only 4% were from developing economies. Thus, economics clearly affects publishing in bioethics. In the case of the newly admitted EU countries, the lower output of bioethical articles is also caused by the decades of totalitarian domination, when sending scientific papers abroad was not always welcomed (and during martial law in Poland subject to official censorship). While it is clear that the latest EU enlargement resulted in a dilution of biomedical and bioethical published output, this effect should be transient. In fact, the economic growth of the countries in this region suggests that lower science funding - a major cause of lower EU productivity - will hopefully be increased. In addition, there are deep and excellent traditions of medical ethics and bioethics in this region, especially in Poland, Hungary, and the Czech Republic, which should be revived and enhanced. This could be accomplished by several actions, such as:

- Allocating more funds for bioethics at the EU level - an obvious condition;

- Organizing international bioethics conferences addressing the most important current issues related to advances in biomedicine - see below;

- Changes in university curricula to include bioethics in the teaching programmes, modifying existing programmes, and adjusting them to current developments (e.g. in clinical research and related problems, such as the current ethical requirements in medical research, placebo, conflict of interest, etc.);

- Establishing fellowships in bioethics fostering international exchange of young scientists interested in this field; and,

- Establishing networks of excellence in bioethics which could allow for more intensive interaction and cooperation between the Western and Eastern parts of the EU.

In fact, in the past ten years, Warsaw has already become a centre of such events, in that we have organized six major conferences:

Scientific integrity – 1995
http://www.iitd.pan.wroc.pl/events/integrity.html
Scientific misconduct: an international perspective – 1998
http://www.iitd.pan.wroc.pl/events/misconduct.html
Conflict of interest and its significance in science and medicine – 2002
http://www.iitd.pan.wroc.pl/events/coi.html
Placebo: its action and place in health research today – 2003
http://www.iitd.pan.wroc.pl/events/placebo.html
The ethics of intellectual property rights and patents - 2004
http://www.iitd.pan.wroc.pl/events/patents.html
The responsible conduct of research - 2005
http://www.iitd.pan.wroc.pl/events/RCR.html

In 2006, we are planning the next event:

The Ethics of Research in Emergency Medicine - 2006
http://www.iitd.pan.wroc.pl/events/EmergMed.html

Each of these conferences was associated with the publication of a special issue of *Science & Engineering Ethics*.

This confirms the assumption that there is a significant potential for creativity among the ten new EU members and that more investment in bioethics would be rewarded with further increases in publishing, conferences, and teaching, as well as in attracting young scientists and physicians to this rapidly expanding field. Therefore, closing the existing EU/US gap is a realistic venture which requires coordinated actions, including decisions to be taken in Brussels and adequate response from the governments and responsible institutions of the EU Member Sates.

(1). Philipson L. Medical Research Activities, *Funding, and Creativity in Europe. Comparison with research in the United States*. JAMA 2005, 294, 1394-1398.

(2). Soteriades ES, Falagas ME. *Comparison of amount of biomedical research originating from the European Union and the United States*. Br Med J 2005, 331, 192-194.

(3). Borry P, Schotsmans P, Dierickx K. *Developing countries and bioethical research*. New Eng J Med 2005,353,852-853.

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► *News from POLAND*

the Committee of Medical Ethics of the Supreme Medical Council of the Polish Chamber of Physicians and Dentists

Report on the activities of the Committee of Medical Ethics of the Supreme Medical Council of the Polish Chamber of Physicians and Dentists during the 2002-2005 term of office

The current term of office of the Supreme Medical Council and the Committee of Medical Ethics of the Polish Chamber of Physicians and Dentists ('the Committee') came to an end in December 2005. At the beginning of January 2006 new authorities of the Chamber and a new Committee were elected. Therefore, this report provides a brief review of the activities of the Committee during its 2002-2005 term of office.

In summary, during the years 2002-2005, the Committee amended the Polish Code of Medical Ethics; it organised a conference entitled Ethical Questions Concerning Prenatal Biotechonology *in Warsaw and held a debate dedicated to this matter; published articles on bioethics; issued its opinion on legislative projects concerning bioethical problems in Poland and Europe; and also worked on some specific ethical and deontological problems. Moreover, the Committee issued its opinion on some documents for the Polish Parliament. The Committee co-operated with the EU's EGE (European Group on Ethics in Science and New Technologies), and with COMETH (the European Conference of National Ethics Committees of the Council of Europe).*

The amendment of the Polish Code of Medical Ethics

The VIth National Meeting of Physicians held on 19 December 2001 adopted resolution number 14 on the need to amend the Code of Medical Ethics, justifying this with the fact that the rapid development of biotechnology creates new ethical problems. In execution of resolution number 14, the Committee published consecutive versions of the Draft Code three times on the basis of proposals that had been received. The public debate on the amendment continued for one year and all those concerned had an opportunity to submit their proposals and to participate in the discussion. The final draft was presented to the VIIth Extraordinary National Meeting of Physicians in Torun, on 19 September 2003. The process of amendment was successful and it can be regarded as a success of the Polish physicians and dentists. The Holy Father John Paul II sent a telegram to the Delegates.

Co-operation with the EGE

On 19 April 2004, the Chairman of the Committee was invited to co-operate with the EGE. The Chairman visited Brussels and met Professor Göran Herméren, the Chairman of EGE, providing detailed information on the Committee's work and accepting further co-operation – particularly, publications in the EGE's Newsletter *Ethically Speaking*.

Co-operation with COMETH

The Chairman of the Committee has attended plenary sessions of the European Conference of the National Ethics Committees of the Council of Europe (COMETH) since the Polish Chamber of Physicians and Dentists was established. In the Committee's first term of office, the Committee was represented by Professor Zbigniew Chłap. Since 1994 it has been represented by Dr Jerzy Umiastowski. In the current term of office, the Chairman of the Committee attended a session entitled *Bioethics Education and Biobanks* in Strasbourg, on 1 and 2 December 2003. The Chairman was not able to attend the next session held in Dubrovnik on 25-26 April 2005 due to unexpected health complications.

The Chairman of the Committee co-operated with the Polish Ministry of Justice in the field of the Ministry's contacts with COMETH.

Conference *Ethical Questions on Prenatal Biotechnology*

This conference was organised by the Committee in the headquarters of the Supreme Medical Council in Warsaw, on 25 November 2004. The purpose of the conference was to formulate questions and to initiate a debate on prenatal biotechnology, including artificial procreation in particular. There is no provision concerning ethical problems of *in vitro* fertilisation in the Code of Medical Ethics, therefore we invited the Polish Gynaecological Society to attend the conference. Numerous important problems were discussed during the conference and essential ethical questions were formulated. The conference materials were published in the *Gazeta Lekarska* magazine, starting from issues number 2- 2005. Besides, ethical questions formulated during the conference were published in Ethically Speaking number 5- August 2005, and they will be made available to members of the Parliament with regard to legal loopholes in this field in Poland.

A representative of the Committee attended a conference entitled *The European Code of Medical Ethics – Utopia or Reality* held in San Remo on 15 and 16 April 2005. This conference was organised by the Italian Federation of Medical and Deontological Councils (FNOMCEO) and the Medical and Deontological Council of the Province of Imperia. The conference was held under the auspices of the President of the Republic of Italy among others. Poland was represented by Professor Zbigniew Chłap, who made a speech entitled *Comments on the Rules of the Polish Code of Medical Ethics with Reference to the Problems of the San Remo Conference*. The conference organisers presented a draft of the *San Remo Charter* to be discussed in the European Union Member Sates. A summary of the conference report was published in Gazeta Lekarska (N° 6/2005).

Other activities of the Committee during the term of office 2002-2005

Amendment of the Code of Medical Ethics

On 14 December 2001, the VIth National Meeting of Physicians adopted resolution N° 14 on appointing a commission to amend the Code of Medical Ethics.

On 9 February 2002, the Committee of Medical Ethics was appointed for the 2002-2005 term of office, on the basis of resolution N° 9/02/IV of the Supreme Medical Council.

On 16 September 2002, the Committee of Medical Ethics of the Polish Chamber of Physicians and Dentists appointed its team for the Code of Medical Ethics amendment. The Committee invited all Polish physicians and doctors' organisations to submit their proposals of amendments to the Code of Medical Ethics.

On 8 January 2003 the Committee carried out a preliminary analysis of the proposed amendments of the Code.

On 31 January 2003, during the first working meeting of the Team for the Code of Medical Ethics amendment, the first working draft of the amendment was elaborated.

On 14 February 2003, the Committee accepted the first draft of the amendment prepared by the Team for the Code of Medical Ethics amendment.

On 21 February 2003, the Committee presented the draft to the Supreme Medical Council.

April 2003 – the draft Code of Medical Ethics was presented in the April issue of *Gazeta Lekarska* periodical, where all those concerned, including associations and organisations of physicians were addressed to submit their further comments and proposals of amendments by 30 April 2003.

On 27 May 2003, the Team for Code amendment met again to prepare the next draft amendment.

On 25 June 2003 a joint meeting of the Team for Code Amendment and the Supreme Medical Council's Committee of Medical Ethics was held and a uniform text of the draft was prepared with new proposals of amendments covered.

On 27 June 2003, the up-to-date draft was presented at the meeting of the Supreme Medical Council. The Supreme Medical Council took the approving cognizance of the draft Code.

The draft code was published in the July (7) issue of *Gazeta Lekarska*, with an address to all those concerned to submit their further comments and proposals by the end of July.

On 6 August 2003, members of the Team for the Code of Medical Ethics amendment were invited to attend the meeting of the Supreme Medical Council. Analyses and opinions received by the Team were presented. The Supreme Medical Council took its approving cognizance of the uniform text of the amended Code and recommended publication of the text in materials for delegates to the VIIth Extraordinary Meeting of Polish Physicians to be held in Torun on 19-20 September 2003.

On 19 September 2003 a telegram was received from the Holy Father, John Paul II concerning the amendment of the Polish Code of Medical Ethics during the VIIth Extraordinary Meeting of Polish Physicians.

Other significant opinions and standpoints of the Committee

Beside the Code amendment related activities listed above, the Committee presented its standpoint and issued its statements concerning – among others – the following issues:

- A draft statement of 23 January 2003 on the World Health Day;
- Numerous opinions concerning Recommendations of the Council of Europe's Parliamentary Assembly on the Human Genome;
- An opinion concerning the *Draft Statement on Sick Professional Physicians*;
- An opinion entitled *On Detailed Requirements Concerning Good Clinical Practice*;

- An opinion concerning the media campaign on physicians in Poland;
- An opinion concerning transsexualism;
- An opinion on the Polish Republic's standpoint concerning respect for human life;
- An opinion concerning the need to establish a National Council for Bioethics in Poland;
- A standpoint on using physicians' images for commercial purposes.

Moreover, the Committee issued a number of opinions concerning other issues in the field of medical ethics and bioethics.

Before the plenary session of COMETH in 2003, the Committee submitted the comprehensive *Questionnaire on the Functioning of National Ethics Committees* which was thereafter published in COMETH material.

During the reporting period, nine 'plenary' sessions of the Supreme Medical Council's Committee of Medical Ethics were held and numerous meetings of working groups took place.

The Committee published information about its activities in such medical periodicals as *Gazeta Lekarska*, *Ethos* quarterly, *Medycyna Praktyczna* monthly, *Medycyna Praktyczna Położnictwo i Ginekologia* and other periodicals. Moreover, the Chairman of the Committee released information to TV and radio.

Jerzy Umiastowski

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► *News from SERBIA and MONTENEGRO*

the Christian Cultural Centre, Centres for Bioethics

The Centre for Bioethics (CCC-BC) was established under the aegis of the Christian Cultural Centre in Belgrade on 10 February 2005.

First inaugurated in 2001, as a non-government organisation, the Christian Cultural Centre (CCC) includes several other Centres: The Centre for Christian Studies, The Centre for Ecumenism, the Media Centre, the Business Centre, and the Centre for Peace and Social Issues.

Following a long period of keen interest in bioethics among the CCC members and friends, we recognised a deep wish to become active in this particular domain and provide a sincere contribution according to the ethical principles based on the Eastern Orthodox Christianity, as the main faith amongst us.

The Centre for Bioethics (CCC-BC) wants to provide its contribution by taking part in the analysis of at actual bioethics problems, providing help in different projects in research work, editorial engagement, publicity and media presentation, also through help in organising dialogues or seminars.

According to the CCC Statute, The Director of CCC-BC, is elected as an expert person by the CCC Council on the proposal of the President of CCC. The Director chooses the members according to their personal qualities and preferences in science and faith.

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► *News from SWITZERLAND*

the Swiss Ethics Committee on Non-Human Gene Technology (ECNH)

The COMMITTEE

Legal basis and mandate

The ECNH was commissioned by the Federal Council by the decree of 27 April 1998 to monitor and evaluate developments and applications in the field of non-human biotechnology and gene technology from an ethical perspective. As such, its mandate covers all applications of biotechnology and gene technology on animals, plants and other organisms and the effects of such applications on human beings and the environment. The ECNH issues statements regarding forthcoming legislation, projects and concrete permit applications of exemplary or fundamental relevance. The advice on enforcement covers projects aimed at the creation, release and commercialisation of genetically modified as well as pathogenic organisms. However, the ECNH also independently addresses issues in the field of non-human biotechnology with a view to assessing the ethical aspects of future legislation and drafting recommendations.

The ECNH mandate comprises three main tasks:

1. It advises the Federal Council and the offices which report to it on ethical matters in the preparation of laws on non-human biotechnology, and makes recommendations on future legislation;

2. It advises the federal and cantonal authorities on the enforcement of federal regulations;

3. It informs the public about the questions and topics it addresses, and promotes dialogue on the benefits and risks of the use of biotechnology.

Since 21 March 2003 the ECNH is enshrined under the new Gene Technology Law (in force since 1 January 2004) as a permanent advisory committee. The decree by the Federal Council will soon be replaced by an ECNH-ordinance.

Statements issued by the ECNH are of an advisory nature and are drawn up for submission to the federal office responsible for the relevant legislative project or permit application. As a rule, the statements are also communicated to the public, with the exception of approval procedures which are still in progress or advisory statements within the framework of an internal administrative procedure based on confidential documents.

ECNH statements are not necessarily unanimous, and minority opinions are registered as such. The main focus of statements of position is on the argumentation. The aim of internal Committee discussions is to determine where and, in particular, why opinions differ. Experience has shown that the significance of the arguments is normally undisputed, and the

differences generally arise in the evaluation of the various arguments. Despite their different ethical standpoints, however, members often arrive at consensus on concrete issues.

Composition of the Committee

The ECNH comprises a maximum of 12 members representing different professions and disciplines. At least half of these members must be professionals in the fields of ethics, philosophy or theology. Scientific ethics covers a multiplicity of different approaches which produce a wide variety of ways of addressing issues on non-human biotechnology. Hence, not interest groups but these disparate ethical approaches must be equally represented within the Committee in order to ensure a balanced analysis of the various standpoints, criteria and standards.

Currently, 7 members represent the fields of philosophical and theological ethics, 3 the natural sciences, 1 medicine and 1 jurisprudence. The chair of the Committee is **Klaus Peter Rippe,** philosopher in Zurich. The chair and the members are appointed by the Federal Council *ad personam* for a four-year period with the possibility of re-election. The third term of office lasts until the end of 2007.

The ECNH regularly convenes on 8-10 occasions for full-day regular meetings. In addition, it holds around one public meeting per year.

Secretariat

The secretariat is responsible for preparing Committee meetings, drafting statements of position and supporting the Committee Chair and members scientifically and administratively in the performance of their tasks. It organizes ECNH publicity activities and maintains contacts with agencies and organizations in Switzerland and abroad which are active in fields related to biotechnology and non-human gene technology.

The secretariat is run by **Ariane Willemsen**. It reports to the chair of the Committee. For administrative purposes the Committee's secretariat is attached to the Biotechnology unit at the Federal Office for Environment.

ACTIVITIES

Recently and currently discussed issues

The complete list of publications and position statements of the ECNH can be downloaded from its website www.ekah.ch or requested at the secretariat.

Gene Technology and Developing Countries

While supporters of green gene technology welcome its promotion as a means of fighting hunger in developing and newly industrialized countries, detractors warn against the negative consequences of this technology in such countries. Both camps regard themselves as advocates of people in the 'South'. To assess the claims of both sides the ECNH discussed the effects of this technology from an ethical point of view.

Switzerland has entered diverse international obligations vis-à-vis countries in the South. These agreements guarantee the citizens of these countries a certain degree of protection. From an ethical standpoint, such obligations are a commitment to justice. All technological

applications must therefore be examined from the standpoint of justice. A key factor in this context is the manner in which the use of such technologies impacts the extent to which the following four fundamental rights are upheld:

- Food security. The basic right to life and personal integrity imply a moral right to food, i.e. access to an adequate, healthy diet;

- Food sovereignty. The principle of human dignity implies the right to self-determination (autonomy). This includes the concept of food sovereignty on the level of the individual as well as on a collective level, i.e. the right of countries to decide, on their own, how they wish to govern trade in agricultural products and to feed themselves in accordance with their own traditions and cultures;

- Protection of biodiversity. The concept of justice also means ensuring that future generations enjoy the same life opportunities as are currently in place. To this end there is a moral obligation to provide a sustainable lifestyle. The protection of biodiversity constitutes an integral part of this obligation;

- Social peace. The right to social peace as an essential requirement for food security, food sovereignty and the long-term securing of natural resources.

The majority of ECNH-members doubt that the potential of green gene technology can be assessed comprehensively today. It concludes that not only this path of technology should be pursued. Other possible solutions for the urgent problems in these countries should be promoted equally. The ECNH demands to intensify as well as to improve coordination of public research, particularly of risk research, which includes the ecological, social and economic context. It stresses the importance to also promote other than gene technological research, especially since other technologies have proven more efficient and have delivered better results with respect to solving the problems of food shortages. To support only one type of technological research is considered to be ethically unacceptable by the ECNH. The developing countries should additionally be supported to strengthen their sovereignty with regard to assessment and approval procedures of new technologies. Furthermore, all attempts to guarantee free exchange of genetic resources for breeding and research should be upheld with regard to securing food security worldwide.

Patenting of biotechnological inventions

The ECNH has been examining the ethical aspects of patenting in the field of biotechnology ever since the Swiss Institute for Intellectual Property submitted an initial internal draft on the revision of the patent law in 1999. The first stage of this examination focused on patents on animals and plants and the implications of such patents. At the second stage the patentability of genes was addressed.

The members of the ECNH unanimously agree that intellectual efforts in the field of biotechnology are worthy of protection. The rationale behind this standpoint is the ethical and, in the ECNH's opinion, justifiable objective of the patent law to promote research in the interests of all members of society and to achieve a balance of interests.

Moreover, the members unanimously agree that the difference between a discovery and an invention is relevant for normative and ethical reasons and is of major importance. While this distinction is enshrined under law, in practice it appears to become increasingly blurred.

Genes are, according to the opinion of the ECNH, even if they are isolated, not inventions. Even if they were considered as inventions, they lack other criteria in order to be patentable (lack of novelty, insufficient level of inventions, no commercial application). In case that nevertheless the political intention is to allow the patenting of genes, the ECNH recommends to protect such patents only to an extent as limited, concrete and precise as possible. The core of an invention is the technical use. Since genes are multifunctional it follows that gene patents are only to be allowed on limited claims for the production and use of gene sequences and proteins with precisely declared functions. An absolute protection of a gene or gene sequence is not justified from an ethical point of view.

Additional important factors for the ECNH are the enshrinement and assurance of farmers' and breeders' privileges. These privileges are founded on ethical grounds and are based on considerations of justice. In the opinion of the ECNH, the traditional right of passing on small quantities of seeds at no charge must also be included in farmers' privileges. An additional key element of the law on patents is the beneficial impact which the patent system has on research. To ensure this positive effect, the ECNH recommends a broad interpretation of the research privilege, particularly in view of the fact that researchers were increasingly criticizing the obstacles which the law on patents posed to research.

Research on primates

Currently the ECNH is discussing the ethical implications of research on primates. The general discussion has been initiated by an application to study the long-term effect of deprivation on young primates to develop a primate model for depression. If such a study is successfully validated, it could pave the way for additional studies to enable a better understanding of depression. Additionally, it could also increase the number of primates used for research. In co-operation with the Swiss Committee on Animal Experiments, the ECNH sets up a working group to discuss not only the specific question of the use of primate models in depression research, but the permissibility of experiments involving primates in general.

Outlook

The ECNH will continue its discussion on research on primates with the intention of publishing a statement. Also launched is a project to evaluate the ethical aspects of nanobiotechnology. Furthermore, the committee will keep on being involved in the discussion on the revision of the patent law.

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► *News from SWITZERLAND*

the Swiss National Advisory Commission on Biomedical Ethics (SNACOBE/NEK-CNE)

Legal basis and mandate

The NEK-CNE is appointed by the Federal Council (i.e. the executive government of Switzerland, a college of seven members covering all major political parties of the country) and has an advisory function to the parliament, the federal government and to the Cantons in all fields of human medicine. The mandate of the NEK-CNE is to identify and highlight ethical dilemmas emerging from developments in medicine and the biomedical sciences, to make these issues amenable to debate, to provide guidance and to formulate opinions pointing the way to possible solutions.

The legal basis for the NEK-CNE is provided by Art. 28 of the Law on Reproductive Medicine of 18 December 1998 and the Ordinance on the National Advisory Commission on Biomedical Ethics of 4 December 2000. In carrying out its tasks, and especially in forming its opinions, the NEK-CNE is obliged to remain independent of political, industrial and scientific interests.

The mandate conferred on the NEK-CNE (in accordance with Article 28 of the Reproductive Medicine Law and the NEK-CNE Ordinance) requires it to clarify the ethical background of major decisions concerning human medicine through a process of differentiated preliminary work leading to specific recommendations. It should also draw public attention to new ethical issues that may emerge due to new developments in medicine. The work done by the Commission is of a consultative nature. It does not decide on research projects. This task is fulfilled by Cantonal ethics committees. The NEK-CNE identifies and tackles ethical issues with a broader societal dimension and seeks to contribute a sound and sustainable basis to the

decisions and rules at different levels of the society and of the institutions involved in medicine.

The rapid developments that are taking place in biomedical research and practice and the changing social and cultural context repeatedly raise new and sometimes urgent questions. It is not generally possible to provide an adequate response to these questions from the standpoint of a single discipline. They demand an interdisciplinary and culturally pluralistic approach which is open to public scrutiny and which takes the different ethical concerns into account.

The recommendations made by the NEK-CNE on regulating research with embryonic stem cells and the public debate that has led to the adoption of a Stem Cell Research Law by public voting in November 2004 was the first topic dealt with by the NEK-CNE after it was set up in 2001. This advisory function in the political arena, in addition, naturally, to opinions on a number of other topics, helped to define the Commission's role as an independent voice within the political process.

Since 2001 it has issued nine major recommendations:

1/2001 Research involving imported embryonic stem cells;

2/2002 First-trimester abortion;

3/2002 Research involving embryonic stem cells;

4/2003 Reproductive human cloning;

5/2003 Living-donor partial liver transplantation: the question of financing;

6/2003 On the regulation of living donation in the transplantation law;

7/2004 On the sterilization of individuals incapable of making decisions;

8/2005 Medical care is an obligation;

9/2005 Assisted suicide.

Last year most of the Commission's time was spent on work relating to end-of-life decisions. The focus was especially on assisted suicide (see below). The results are available to the public in the form of an extensive opinion and have been acknowledged by the authorities and in Parliament.

Composition of the Commission

The commission was assembled on an interdisciplinary basis to represent all sections of society. Its members are all appointed as experts *ad personam*, not to represent their institutions or faith. According to the Ordinance, the Commission may comprise 18 to 25 members; it currently consists of 23 members (11 women and 12 men). Around one third of them have expertise in ethics, one third in medicine and nursing, and one third in biology, law, psychology and patient organizations. The various language regions are represented as follows: 15 members from German-speaking, 6 from French-speaking and 2 from Italian-speaking Switzerland. Its second term of office, which lasts until the 47th legislative period, will be concluded at the end of 2007.

Chair: Christoph Rehmann-Sutter

Members: Christiane Augsburger, Ruth Ella Baumann-Hölzle, Annette Boehler, Alberto Bondolfi, Jean-Claude Chevrolet, Kurt Ebeneter-Fässler, Johannes Fischer, Carlo Foppa,

Sabina Gallati, Olivier Guillod, Daniel Hell, Sylvia Huber, Silvia Käppeli, Bertrand Kiefer, Margrit Leuthold, Jean Martin, Alexandre Mauron, Carola Meier-Seethaler, Hansjakob Müller, Judit Lilla Pók Lundquist, Franziska Probst, Brigitte Weisshaupt

The Commission normally holds 8 plenary meetings during the year, 6 one-day and 2 two-day conferences. They are organized mostly as closed-door meetings. Additionally however it organizes also public events, *cafés philosophiques*, symposia or seminars. Twice a year the meetings are organized in the capital of one of the Swiss Cantons, which provides opportunities to establish valuable and fruitful contacts with the Cantonal Directors of Public Health, specialists from the Departments of Health and the Cantonal Ethics Committees. This is important because the Swiss health care system is organized to a great extent at the Cantonal level.

Office

The NEK-CNE Office reports to the Chairperson of the Commission. For administrative purposes the Commission's office is attached to the Human Research and Ethics unit at the Swiss Federal Office of Public Health (SFOPH). The Office is run by the Executive Secretary, Georg Amstutz, and his deputy, Csongor Kozma. The Secretariat provides scientific and technical support to the Commission, maintains contacts with official agencies and organizations in Switzerland and abroad, and acts as a press office and public information centre. It performs administrative tasks and assists the Commission particularly in organizing the meetings, public events and in providing information for the public.

A new publication on assisted suicide

The Swiss legal system is exceptional in so far as it considers assistance with suicide legal if it is not motivated by selfish motives. This is the only exception that could create a crime. Assisted suicide is legal also for persons who are not terminally ill, the help is not restricted to medical professionals and is accessible also for persons from other countries. About 20-30% of all suicides occurring in Switzerland involve the assistance from a right-to-die organization, in most cases by application of a deadly dose of a barbiturate. In most cases the persons requesting assisted dying suffer from a serious disease. The last recommendation of the NEK-CNE, published in July 2005, may be of interest also for other countries, because it discusses this special situation from an ethical point of view.

The Commission views assisted suicide as a deeply ambivalent matter which presents other people and, more particularly, healthcare professionals with conflicting objectives. The ethical dilemmas that arise in practice are correspondingly difficult. The Commission feels that a general, theoretical approach will not supply a solution to the ethical dilemmas, and that a solution can only be sought in the complexity of the individual case. Accordingly, the individual who is asked to assist with a suicide must allow his or her personal conscience to decide. Assisted suicide must never be allowed to become routine. There is no general rule that could be applied simply in practice to justify assisted suicide. However, two fundamental values have been identified that apply to this personal aspect of the ethics of assisted suicide and to any measures taken on a legislative or institutional level, yet at the same time these two values represent two opposing ideas: concern for the welfare of a suffering fellow human being who is in a hopeless position (in the sense of keeping her or him alive), and respect for his right of free self-determination. This includes also competence for assessing her or his situation. Recommendations and regulations must not only give precedence to one of these ideas; they must also take due account of the conflict between them.

A frequently asked question is how it could ever be possible to distinguish the action of providing assistance to suicide by sophisticated technical means (like optimized medication combined with a device that allows to trigger an infusion) from euthanasia. According the opinion of the NEK-CNE, participation in a suicide needs to be distinguished from an ethical point of view from killing on request, even if the actions may be similar in practice. The Commission believes that ethical reasons support the liberal regulation provided for in Article 115 of the Swiss Criminal Code, which states that assistance with suicide is legal, provided that it is not given for selfish motives. The Commission does not recommend changing the way this point is handled under criminal law, but feels that action is required in order to secure a supervision of the activities of right-to-die organizations by the State. It asks for the introduction of new legislation that ensure compliance with proper criteria for due diligence in examining decisions to assist suicide by right-to-die organizations.

The Commission is also considering a number of special problems, such as the question of whether individuals with mental disorders should be allowed assistance with suicide. It takes a cautious approach on this question and calls for psychiatric and psychotherapeutic treatment to be given precedence in all cases. If the desire to commit suicide is an expression or symptom of a mental illness, then no assistance should be given with suicide. This means that mentally ill people will generally, with rare exceptions, not be given assistance with suicide. Other problems under consideration include adolescents who are not yet legally competent but nonetheless able to make decisions concerning their well-being, assisted suicide in hospitals and homes, the implications for members of the healthcare professions, and the phenomenon referred to as death tourism.

The Commission draws attention to the social risks that will arise as assisted suicide becomes more common. The means of caring for people who require nursing or who are dependent must be organized in such a way, and palliative medicine must be so easily available, that the wish to commit suicide is not encouraged. Suicide should not be viewed as an easy way out of the spiralling costs of providing healthcare. Society has a responsibility to prevent suicide which goes beyond the establishment of legal limits; it also includes support for carers and nursing staff.

Outlook for 2006 – 2007

Opinions concerning research on human embryos and foetuses and pre-implantation genetic diagnosis will be published in the following months. The Commission just began work on the consultation procedure for the law on research in human subjects, and it also launched a major project on equality and health. Its intention is also to continue work on ‘end-of-life-decisions’.

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► *News from the UNITED KINGDOM*

the Nuffield Council on Bioethics

CURRENT WORK

The ethics of research involving animals

In May 2005, the Nuffield Council on Bioethics published a Report on The ethics of research involving animals, which seeks to clarify the debate and aims to help people think through the scientific and ethical issues. It also makes practical recommendations for future policy and practice, and concludes that improving the quality of the debate and promoting the 'Three Rs' (Refinement, Reduction and Replacement) are crucial to reducing disagreement on research involving animals. The Working Party that produced the Report was comprised of academic and industry scientists, philosophers, members of animal protection groups, and a lawyer. Since publication, the report has been well received by a wide range of organisations and has been downloaded from the Council's website over 38,000 times. An electronic version of the Report is available at www.nuffieldbioethics.org/animalresearch

The ethics of prolonging life in foetuses and the newborn.

The Council established a Working Party in October 2004 to consider the ethical, social, legal and economic issues involved in making decisions about care in extremely premature or critically ill babies. Six meetings of the Working Party have taken place and a series of fact finding meetings continues. A visit to the neonatal unit at Homerton Hospital in Hackney took place in July. A meeting with parents and others involved with the premature baby charity BLISS took place in August, and an inter-faith workshop was held in September. Further fact-finding meetings will be held later in the year, including a meeting with representatives of the Council for Disabled Children and visits to special schools for severely disabled children. Visits to France and the Netherlands are being planned for early next year. The Council

expects to publish a Report on the topic towards the end of 2006. Further information is available at www.nuffieldbioethics.org/go/ourwork/prolonginglife/introduction.html

Genetic screening

A Discussion Paper on the ethics of genetic screening has been produced by a Steering Committee to follow up the Council's popular 1993 Report on the same topic. It is envisaged that the Paper, which will provide an update on policy and scientific developments, will be published in the first half of 2006.

FUTURE WORK

The ethics of public health

A new Working Party on the ethics of public health will commence work in early 2006. The focus will be on the appropriate balance between individual autonomy and community benefit when designing measures to improve the health of individuals and populations.

PREVIOUS PUBLICATIONS:

- *The ethics of research involving animals* (May 2005)
- *The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper* (March 2005)
- *The use of genetically modified crops in developing countries: a follow-up discussion paper* (December 2003)
- *Pharmacogenetics: ethical issues* (September 2003)
- *Genetics and human behaviour: the ethical context* (October 2002)
- *The ethics of patenting DNA: a discussion paper* (July 2002)
- *The ethics of research related to developing countries* (April 2002)
- *Stem cell therapy: the ethical issues – a discussion paper* (April 2000)
- *The ethics of clinical research in developing countries: a discussion paper* (October 1999)
- *Genetically modified crops: the ethical and social issues* (May 1999)
- *Mental disorders and genetics: the ethical context* (September 1998)
- *Animal-to-human transplants: the ethics of xenotransplantation* (March 1996)
- *Human tissue: ethical and legal issues* (April 1995)
- *Genetic Screening: ethical issues* (December 1993)

All the Council's publications are available to download from the Council's website at www.nuffieldbioethics.org/publications

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e-JUSTICE

*e*Justice is an independent, deliberative, multi-disciplinary and multinational body Ethics and Technology Committee. It was set up in 2004 under a framework six research programme called *e*Justice. Its role is to explore the challenging ethical issues raised by the expansion of the possibilities of applying Information and Communication Technologies (ICT) within the sphere of judicial cooperation inside and across states and authorities. It is committed to disseminating work on its findings on its own initiative and in response to others.

The Committee represents an innovation and expansion of the scope of ethical inquiry. It focused initially on the ethical issues associated with the practice and potential for exchanging information among legal and law enforcement agencies, including those at the European level and government and private partners in the EU Member Sates. Its work is of broader relevance to the range of issues arising from the roll-out of *e*Governance in general.

*e*Justice has developed ICT tools that offer a secure way of exchanging information within and across authorities and jurisdictions involved in processing and administering legal papers. The tool offers a secure means of tracking legal processes and procedures within and across states, and verifying and authenticating users' identity in line with robust identity management requirements. It potentially offers a way of allowing not just lawyers to communicate and check the progress of papers within their own systems but also to verify their counterparts, counterpart procedures and place in the system in any cross-authority, cross-jurisdictional or cross-country case. Beyond the simple tracking of documents, *e*Justice tools also offer the potential to view part or whole documents in line with appropriate access rules.

The ethics of availability

The EU has agreed that information should be exchanged across frontiers and jurisdictions in line with the principle of availability. This raises numerous concerns of a politico-legal, ethical, societal and civil rights nature.

The *e*Justice Ethics and Technology Committee goal is to understand the tensions between competing objectives with a view to discerning the parameters of a European standard for tracking and processing material that could contain sensitive, personal information. This means that it is concerned both with some of the traditional ethical questions examined by medical ethics and bioethics committees, and with some issues that are peculiar to *e*Governance and politics 2020 in general.

*e*Justice is more than an administrative tool. Its application, potentially within the sphere of the Hague Action Programme 2005 beyond international organised crime to civil litigation, including family law, means that it is a tool that potentially brings *e*Governance to the heart of the household. Judicial cooperation itself potentially brings the EU closest to the citizen in a way that arouses the greatest misunderstanding, suspicion and distrust.

The *e*Justice Committee is therefore aware of the imperative of fostering understanding and trust by demonstrating the responsible route to applying *e*Governance tools in an open, ethical, transparent and accountable way.

Hearings

Members of the *e*Justice team have engaged regularly with different bodies, and discussions with legal professionals from across the world including magistrates, practising lawyers, law enforcement bodies, and within the context of UK Presidency JHA presentations. It contributed to the EU Commission Joint Research Centre report on biometrics[20]. It also submitted a report to the European Parliament's LIBE Committee this summer[21] and made presentations during UK Presidency events.

The *e*Justice Committee has held a number of hearings in France and the UK. The most recent meeting engaged participants from the current and future EU Presidencies. It reached a number of conclusions.

Information and cooperation

Information on the *e*Justice programme is available on the website www.ejustice.eu.com.

*e*Justice partners contribute to other research programmes and pilots in *e*Governance. Of note is the FP6 Challenge programme where a particular effort is being made in respect of understanding the limitations of reconciling liberty with security. Further information is available on the website www.libertysecurity.org

Cooperation with public and private sector agencies and with the EU institutions continues. The *e*Justice Ethics and Technology Committee has invited and enjoyed inputs from the Commonwealth and local authority representatives. It will contribute to the new R4*e*Gov FP6.

[20] Institute for Prospective Studies, Biometrics at the Frontiers: Assessing the Impact on Society, Seville, February 2005, EU21585.
[21] *e*Justice: Quality and Ethics for *e*Governance: 2015 : Making the Hague Programme Work: Principles and Practice for Quality, Acceptability and Action , July 2005.

Future Agenda

*e*Justice ETC seeks collaboration with cognate bodies and programmes. Key issues to be addressed include: ethical *e*Governance 2020 – beyond 'blogoply'; and developing an ethically inspired European gold standard of *e*Governance based on identifiable and understood criteria of accuracy, proportionality, data quality and minimisation, purpose specification, simplicity, relevance, finality, contemporaneity, the precautionary principle, respect for human rights and human dignity.

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European Commission

The European Commission's Dialogue with Religions, Churches and Communities of conviction

Since the time of President Jacques Delors, the European Commission has benefited from an Advisor especially entrusted with conducting a dialogue with Religions, Churches and Communities of Conviction. The Advisor is a member of the policy advisory group set up by President Delors, which is currently entitled the 'Bureau of European Policy Advisers'. The dialogue function has a large remit and comprises several strands of action.

First of all, Religions and Churches constitute – in all the EU Member Sates – key factors in public and social life, both in national and EU terms. It is therefore of crucial importance to inform them at first hand about the policy of the European Commission. In practice, this information action takes various forms, such as a debriefing session for the Brussels based representatives of Religions, Churches and Communities of Conviction after each European Council. Experts explain the decisions taken at the summit and are available for questions. From 2006, two more briefing sessions will be organised for the religious representatives, one on the Commission's annual working programme and one on topics of common concern, such as the social dimension of the renewed Lisbon strategy. Moreover, the Advisor regularly gives lectures on the dialogue and acts as a contact person for religious and non-confessional representatives.

Importantly, the EC in its everyday policy deals with a large variety of issues which influence Religions, Churches and Communities of conviction directly. For a successful policy, it is imperative to bring the problems of the Religions, Churches and Communities of Conviction to the attention of the different Commission Services and vice versa – internal networking and EC-coordination. Making the voices of the Religions, Churches and Communities of Conviction heard during the process of policy formulation inside the European Commission is thus another element of the dialogue.

A further aim of the dialogue is promoting the Commission's policy in order to create a better and detailed knowledge of Europe's policy and support from some of the key multipliers in public affairs. Last, but not least, the President and other Commissioners receive advice on all affairs related to religion and with regard to civil society.

Susanne Kiefer[22]

[22] Editorial footnote: Trainee at the European Commission for the Bureau of European Policy Advisers (BEPA). During her Traineeship Susanne Kiefer has namely been assisting Michael Weninger, adviser in BEPA in charge of questions related to Dialogue with Religions, Churches and Humanisms.

Training Proposals

The Ethics Teaching Office in Montreal

Activities of the *Bureau d'enseignement de l'éthique* in post-doctoral studies

For a number of years the University of Montreal Faculty of Medicine has been running an ethics teaching programme during 'residence' (doctors undergoing specialisation), in response to the demands of the Quebec College of Physicians, the Royal College and the College of Family Physicians of Canada, and, in particular, to provide input into the debate on the ethical issues raised for medical practice by the technical and scientific developments of recent decades, the question of costs and access to treatment.

The programme is organised by the *Bureau d'enseignement de l'éthique*, under the responsibility of Professor Danielle Laudy, and consists in compulsory formal learning in the form of two three-hour structured workshops each year for all the residents. Ms Laudy and the professors of each clinical department do the teaching. The CEÉR (*Comité d'Enseignement de l'Éthique à la Résidence*), the advisory committee made up of Ms Laudy and professors representing each of the departments, is responsible for developing the programme and harmonising it with what is done in the first cycle of medical studies.

Ethics teaching programme during residence: aiming for an ethics of discussion and shared responsibility

The teaching of ethics during residence is designed to instil ethical thinking into everyday practice and to develop skills in ethics. During the time in residence, residents put into practice and integrate the knowledge, attitudes and aptitudes they have learnt and they establish in as many cases as possible an ever closer patient/doctor relationship in which they feel genuinely concerned. For some patients it is the resident who has the privileged information concerning, for example, the patient's aims, desires, beliefs, values.

The aptitudes for communication and the attitudes necessary for a high-quality doctor/patient relationship are pre-requirements for the ethical dialogue. In order to identify and to be able to analyse a conflict of values or an ethical problem, a doctor must know how to explore the reality of the patient, the family and the environment, situating the facts on the scientific plane, the clinical plane, the biographical plane covering the field of values and beliefs, and on the social plane. These psychomotor and affective objectives should have been attained during the pre-doctoral level studies.

Teaching in residence comprises a common programme based on issues of clinical ethics and ethics of research, which concern all specialisms, and on an initiation in questions of public and social ethics (e.g. legalised euthanasia, investing as a society in research on the human genome), followed by a second, more specific strand concerned with the particular needs of each specialism.

Aim of the programme

At the end of the residence, the doctor will have developed the ethical competence required to practice in the profession. In medical practice the doctor will interpret situations from the angle of the ethical issues, judging what ought and ought not to be done, giving special attention to ethical values and being able to implement the decisions adopted.

General objectives

- Integrate the ethical dimension in everyday practice;
- Acquire a command of the knowledge required to analyse the ethical problems encountered in medical practice;
- Resolve the conflicts encountered in medical practice allowing for the values involved;
- Demonstrate systematically the relational skills necessary for taking decisions of an ethical nature;
- Demonstrate the ability to take part in or direct the decision-making process on ethical issues;
- Develop one's own thinking on the major bioethical issues;
- Spell out one's own social commitment.

Specific cognitive objectives

The ethics teaching programme in residence allows for the doctors' various activities and the diversity of their tasks and roles. The areas covered will be the ethical issues connected with clinical medicine, research, management and allocation of resources, health promotion, participation in public policies and the socio-political role of the doctor.

The teaching programme has been divided into different subjects. Some of these subjects have been grouped together to form a common programme for a majority of specialisms. Other subjects have been assigned to certain specific programmes. The specific objectives presented are being devised or introduced. Some subjects simply refer to a potential content and may be changed. A great deal still has to be clarified.

Common ethics teaching programme in residence

For paediatrics, medicine, family medicine, psychiatry, surgery, obstetrics and gynaecology, ophthalmology, pathology and cellular biology, microbiology, anaesthesia and social and preventive medicine.

1. Introduction to bioethics

General objective

Convince students of the importance of ethics in their professional life and in the practice of medicine in general.

Specific objectives

- Discuss the influence of the values conveyed during medical studies on the development of ethical conduct;
- Describe the stages of analysis of a problem of clinical ethics;
- Explain the rules of ethical discussion;

- Provide a comprehensive reply to questions on the nature of ethics, law, bioethics;
- Find the resources to deal with difficulties of an ethical nature encountered in practice.

2. The appropriate treatment

General objective

Build a dynamic representation of 'appropriate treatment' through the various concepts underlying the subject.

Specific objectives I

- Revise the definition of various concepts: *acharnement thérapeutique* (maximum life-prolonging care), futile treatment, refusal or withdrawal of treatment, quality of life, proportionality criteria;
- Revise the definition of various concepts;
- Identify the ethical issues underlying these concepts;
- Undertake a critical analysis of these concepts;
- Exchange of views on the application of these concepts in the reality of medical practice.

Specific objectives II

- Understand the structure of medical decision-making;
- Know and situate the reference markers influencing the decision-making process: patient-doctor relationship, medical/clinical judgment, aims;
- Know the arrangements applying where opinions diverge.

3. End of life and euthanasia

General objective

To enable residents to think about the ethical issues raised by euthanasia at micro- and macro-ethical level.

Specific objectives

- Be aware that the term 'euthanasia' has various definitions;
- Agree on one definition;
- Differentiate between what euthanasia means in practice when applied at the bedside and what it means when public pronouncements are made in favour of euthanasia;
- Produce arguments for and against the legalisation of euthanasia.

4. Relations with industry: ethics and conflict of interests

General objective

Equip residents to deal with potential conflicts of values and interests in their relations with representatives of the health care industry during their professional life.

Specific objectives

- Understand the terms conflicts of values and conflicts of interests;
- Identify potential sources of conflicts;
- Reflect on the ethical issues involved;
- Realise the consequences of these conflicts;
- Adopt preventive measures where a situation might develop into conflicts of values or interests.

5. Management and allocation of resources

General objectives

- Be aware of one's way of reacting on issues of resources;
- Identify ethical indicators to help with reflection in this field.

Specific objectives

a) On the basis of clinical experience:

- Identify the criteria of choice in allocation of resources;
- Define the subject: allocation of resources;
- Situate the doctor in everyday practice in relation to resources and the various levels of decision-making.

b) On the basis of reading and exchanges of views:

- Distinguish the various interpretations of case law;
- Discuss the concept of responsibility;
- Apply ethical principles in the context of allocation of resources.

6. Ethics of research

Objectives

- Integrate the ethical issues of experimenting on human subjects;
- Discuss the differences between recognised treatment, experimental treatment or innovative treatment;
- Understand and apply the essential prerequisites for consent when recruiting patients in a research project;
- Comply with the concepts of copyright and scientific integrity.

Specific programmes for certain specialisms.

Paediatrics, genetics, gynaecology – obstetrics, family medicine, pathology, radiology and psychiatry programmes:

New reproduction techniques

- Illusion of the perfect child;
- Medicine to satisfy wishes;
- Production of embryos to obtain tissues for transplant;
- Sexing and cloning;
- Meaning of procreation and the family;
- Status of the embryo.

Prenatal diagnostics

- Risk of eugenism;
- Marginalisation of the disabled;
- Normality and normativity;
- Genetic counselling;
- Abortion/status of the foetus.

For the genetics programme

- Ethical issues of the human genome project;
- Risks of stigmatisation and exclusion;
- Confidentiality.

For the psychiatry programme

- Sterilisation of the disabled;
- Ethical issues relating to suicide;
- Ethics and internment.

Specific objectives of a psychomotor and affective nature

These aspects are covered in the integrated training programme in clinical ethics, whose general and specific objectives are as follows.

General and specific objectives of the programme

(1) Develop the necessary skills and attitudes for discussions involved in clinical decision-making on ethical matters

- Take into account the specific aspects of discussion meetings with the patient, the family, health care workers and the interdisciplinary team where appropriate. (Objectives and content of the discussion, level of language, venue and time, etc.);

- Recognise the 'position' of the interlocutor;

- Identify the reasons and the values underlying this position by getting the interlocutor to explain them;

- Adjust the reply accordingly;

- Apply communication skills in the various discussion meetings for clinical decision-making on ethical matters: ask open questions, allow silence, check interlocutor's understanding, sum up the meeting;

- Develop a self-critical attitude to the discussion process and decision-making.

(2) When confronted with ethical problems in medical practice, ensure clinical decision-making which takes into account all relevant aspects

- On the basis of real clinical situations, identify the ethical problem(s), analyse the components of the problem, i.e. the clinical and psycho-social facts, the values involved, the model dilemmas and the legal aspects, identify all possible alternatives and give reasons for the decision;

- Apply certain concepts to the analysis of ethical problems encountered in the practice of medicine such as autonomy and self-determination, consent, quality of life, rule of equivalence, futility (utility), justice – equity, etc.

(3) Be aware of the resources available to shed ethical light on clinical decision-making

- The institutional resources, resources in Quebec and documentary resources.

Conduct of the programme

The common programme covers the first three years of residence with about 15 hours a year, made up of six hours of workshops and nine hours of integrated activities (Table 1). The workshops last three hours and involve small groups of 15. The integrated activities take the form of guided reading, specialist learning, journal club, ethical discussions during ward visits or self-teaching modules. This is a major challenge. On the one hand, specific teaching tools must be continually developed to cover these activities; and secondly there must always be a critical mass of professors capable of directing them, which requires systematic training for the teaching staff.

Formal workshops - 6 hours per year

- R1.1 Introduction to bioethics
- R1.2 Appropriate treatment
- R2.1 End of life/euthanasia R3
- R2.2 Ethics and industry
- R3.1 Management/allocation of resources
- R3.2 Ethics of research
- R4 - R5 Specific workshops for the various programmes

Integrated teaching - 9 hours per year

- R1 Discussion of clinical cases
- R2 Reading club
- R3 Discussions/lectures
- R4 Ethics committees, conflicts of values and interests
- R5 Supervision of interviews, role playing, etc.

Training of professors

We saw above that we require a critical mass of able and well-trained professors to run these workshops, which has prompted us to draw up a training programme for them. Two training days have been devised either as one full day or two half days to fit in with work schedules.

Aims of the programme

1. to meet certain needs of professors who have to integrate ethics teaching in their everyday clinical activities;

2. support professors so that they can more easily fulfil their function as role models (serve as a model doctor expressly incorporating the ethical dimension in decision-making).

Specific objectives for the day

At the end of the day participants will be able to:

1. describe the broad lines of the ethics programmes of the Royal College of Physicians and Surgeons of Canada, the College of Family Physicians of Canada and the Medical Council of Canada;

2. describe the guidelines of the Faculty of Medicine for teaching ethics in the first and second cycles and the organisational arrangements for attaining them;

3. spell out their teaching role as part of their clinical activities;

4. refer to usable indicators;

5. discuss a clinical case systematically from an ethical angle;

6. analyse a patient/doctor interview from an ethical angle;

7. plan continuing education activities in ethics adapted to their needs;

8. find resources to help them in difficult clinical situations from an ethical angle.

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