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Starting a debate with women scientists from post-communist countries on ethical issues

Enwise Workshop Report - Budapest, October 2003

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Contents

Within the scope of Enwise activities, a workshop entitled ‘Debating bioethical issues with women scientists from the Enwise countries’ was organised in Budapest, on 2 and 3 October 2003 to discuss sensitive bioethical topics of specific interest to the women scientists from the central and eastern European and Baltic countries. The 48 participants came from 17 countries, representing scientists, philosophers, social scientists, lawyers, NGOs, journalists, members of relevant state bodies and representatives of ethics committees. In the plenary meeting and the parallel sessions ‘Ethics and gender issues in stem cell research and tissue transplantation’ and ‘Ethical and gender aspects of genetic testing, storage and use of genetic information’, the complexity of these issues was presented and debated from various (scientific, philosophical, legal/political and social/societal) perspectives.

Introduction

In 2001, in the wider context of moving towards the setting up of a European Research Area, where the role and place of women scientists had been strongly recognised, the Commission adopted its action plan on science and society. One of the actions, 'Promoting gender equality in science in the wider Europe', acknowledged the need to analyse the specific situation encountered by women scientists from the central and eastern European countries and the Baltic states.

In order to implement this action, the Commission established a group of independent experts in September 2002, known as the Enwise (Enlarge women in science to east) expert group, whose members were senior women scientists from different disciplines, representing academies of sciences, universities, research institutes and administrations, as well as business. Their mandate was to report on the situation facing women scientists in the following countries ([1]): Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia; to integrate the experience of the new German *Länder* and to give a perspective on the Balkan region.

In order to get additional knowledge on specific issues, three workshops were organised as side activities, one on young scientists (Prague, April 2003), one to start a debate with women scientists from the Balkan region (Brussels, November 2003) and one to start a debate with women scientists form the Enwise countries on bioethical issues (Budapest, October 2003), which is reported in this brochure.

The fast development of science and technology — especially in the field of life sciences — has produced in public and scientific discourses important questioning of ethical and bioethical issues, such as human cloning, tissue transplantation, genetic testing, storage and use of genetic information, which involve both scientists (e.g. freedom of research) and everyday people (gender roles and relations, future of our children, human nature, etc.). Ethical issues have thus become a crucial and constitutive part of the action plan on science and society, promoted by the European Commission, as well as of the EU's sixth framework programme on research and technology development (FP6).

Within the Enwise side activities, it was then decided to organise a first debate on these sensitive topics with women scientists from the Enwise countries and to assess to what extent a gender dimension was needed in that debate. A workshop ([2]) entitled 'Debating bioethical issues with women scientists from the Enwise countries' was organised by the Hungarian Science and Technology Foundation in Budapest on 2 and 3 October 2003, which was meant to give new inputs to the debate by recognising the different views of groups of people and scientists with diverse cultural and political backgrounds.

The 48 participants of the workshop came from 17 countries: Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, Croatia and Serbia, as well as from Austria, Germany, Italy and the United Kingdom, representing women scientists, philosophers, social scientists, lawyers, NGOs, journalists, members of state bodies for gender mainstreaming, representatives of medical research councils and ethics committees. Representatives from the Research DG's 'Women and science' unit and 'Ethics and science' unit also took part in the event.

Following a plenary meeting where keynote speakers representing different interest groups and expertise gave introductory lectures, the participants discussed two sensitive topics in parallel sessions: 'Ethics and gender issues in stem cell research and tissue transplantation' and 'Ethical and gender aspects of genetic testing, storage and use of genetic information'. The invited speakers in each session were asked to present the

([1]) Hereafter called the Enwise countries.

([2]) Funded as an FP6 science and society project.

complexity of the problematic from four various perspectives: scientific, philosophical, legal/political and social/societal, in order to give the participants the opportunity to share their opinions in the consecutive discussions and to get in touch with different points of view.

This publication contains the programme of the workshop, the list of participants (with contact data), the short CVs of the speakers and their presentations, as well as the summaries of the two parallel sessions' debates and some short recommendations building on the workshop participants' views. The organisers would like to thank the contribution of the British Council to the workshop.

Programme of the workshop

'Debating bioethical issues with women scientists from Enwise countries' ([1])

Budapest, 2–3 October 2003
Hotel Budapest, 1026 Budapest, Szilágyi Erzsébet fasor 47

Day 1: Thursday 2 October 2003 — Room: Üvegterem

Session 1 *Chair:* József Mandl, Medical Research Council, Hungary

9.00–10.00 Registration/reception and briefing

10.10–10.10 Introductory remarks
Andras Siegler, deputy state secretary,
Ministry of Education, division of R & D, Hungary

10.10–10.35 Women and science activities, with a focus on Enwise
Brigitte Degen, European Commission
Research DG, Women and science unit

10.35–11.00 Ethical issues and FP6
Barbara Rhode, European Commission
Research DG, Ethics and science unit

11.00–11.30 Coffee break

Session 2 *Chair*: Attila Zsigmond, Ministry of Education, Hungary

11.30–11.50 Reproductive medicine, women and autonomy: some ethical issues
Elisabeth Hildt, Germany

11.50–12.15 Bioethical issues in the media. Can women in the life sciences make a difference?
Sylvie Coyaud, Italy

12.15–13.30 Buffet lunch

Session 3 Working groups — Rooms: Üvegterem and Joker

13.30–17.30 Parallel sessions

([1]) Enwise stands for 'Enlarge women in science to east', a Commission initiative which covers the following countries: Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, and Slovenia, plus a perspective on new eastern German *Länder* (former GDR) and western Balkans. More information can be found at: http://europa.eu.int/comm/research/science-society/women/enwise/index_en.html

Parallel sessions

Aspect/Topic	I. Ethics and gender issues in stem cell research and tissue transplantation
1. Scientific	*Embryonic or non-embryonic: hot current issues of stem cell research* András Dinnyés, HU
2. Philosophical	*Bioethics and public reason* Herlinde Pauer-Studer, AT
3. Legal/political	*Ethics and gender issues in stem cell research and tissue transplantation* Sylvia Tomova, BG
4. Social/societal	*Stem cells: media and public opinion in Hungary* Anna Mátay, HU

Aspect/Topic	II. Ethical and gender aspects of genetic testing, storage and use of genetic information
1. Scientific	*Genetic testing, storage and use of genetic information* Mara Marga, LV
2. Philosophical	*Ethical aspects of human genetic databases: Estonian perspective* Margit Sutrop, EE
3. Legal/political	*The role of gender in genetic choices* Judit Sándor, HU
4. Social/societal	*Ethical and gender aspects of genetic testing, storage and use of genetic information* Alastair Kent, UK

15.00–15.15 Coffee break

15.15–16.45 Debate on Topic I and Topic II in parallel sessions

16.45–17.30 Parallel working group discussions to draw conclusions

18.00 Film: ‘Our Cells’ by Tamás Almási, an international award-winning film on *in vitro* fertilisation, followed by informal discussion with the director (in English)

20.00 Reception dinner

Session 4 *Chair:* Dóra Groó, Hungarian Science and Technology Foundation, Hungary

9.00–9.30 State policy on gender equality in candidate countries
Katalin Lévay, Minister for Equal Opportunities
Governmental Office of Equal Opportunities, Hungary

9.30–10.00 Role, tasks and responsibility of the national ethics committees
József Mandl, Medical Research Council, Hungary

10.00–10.30 Coffee break

Session 5 *Chair*: Marina Calloni, University of Milano-Bicocca, Italy

10.30–10.45 Report to plenary session on Topic I

10.45–11.00 Report to plenary session on Topic II

11.00–12.30 General discussion

12.30–13.00 Closing remarks
Brigitte Degen, European Commission
Research DG, Women and science unit

13.00–14.00 Buffet lunch

14.30–17.00 Enwise steering group meeting

List of participants

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Brief CVs of keynote speakers

Sylvie Coyaud (Italy)
French journalist working in Italy. She writes on basic research for the cultural supplement of *Il Sole — 24 Ore,* a financial newspaper, and for the women's supplement of *La Repubblica*, the second largest newspaper. Co-founder in 1975 of Libreria delle Donne, a women's group and bookshop in Milan, she had a weekly science programme on a community radio from 1987 to 2001, and since 2001 she does a daily science programme on national radio. Her short essay on bioethics as discussed in the labs will be published in October in *Aut Aut*, a philosophy journal, and she is presently writing a book on stem cell research together with biologist Angelo Vescovi.

András Dinnyés (Hungary)
He was awarded the DVM from the University of Veterinary Sciences, Budapest, and the PhD and the DSc from the Hungarian Academy of Sciences. He is an invited professor of the Szent István University, Gödöllõ, and serves as head of the research team for applied animal genetics and biotechnology of the Hungarian Academy of Sciences and Szent István University, and as team leader for micromanipulations and genetic reprogramming, Department of Animal Biology, Agricultural Biotechnology Centre. He is a Wellcome Trust International Senior Research Fellow. He is a research scientist with extensive international expertise in the fields of somatic and embryonic stem cell nuclear transfer ('cloning') technology, resulting in scientific achievements in the USA, Japan, Scotland, Belgium, China and New Zealand. He is an expert for EU FP5 and FP6 proposal evaluations, including human stem cell research and ethical issues.

Elisabeth Hildt (Germany)
Assistant professor, member of the Chair for Ethics in the Life Sciences at the University of Tübingen since 2002. She studied biochemistry at Tübingen and Munich, then changed to bioethics and medical ethics and wrote her PhD thesis on philosophical and ethical issues in neural tissue transplantation. Afterwards she was scientific coordinator of the European network for biomedical ethics, an EU-funded interdisciplinary project that dealt with ethical issues in new reproductive technologies. Afterwards she spent some years carrying out research and teaching at the University of Munich.

Borbála Juhász (Hungary)
She graduated from Eötvös Loránt University in Budapest as a history–English major in 1992. She also studied in the UK and the Netherlands. After years of teaching and freelancing, she took her MA in history at the Central European University, Budapest, in 1998, where she also enrolled in a PhD course in comparative history. She has become a devoted expert on women's issues working in a feminist NGO, became engaged in women's history and trained herself as a gender policy expert. Since 2003 she has been working at the government's Office for Equal Opportunities as head of the gender equality department.

Alastair Kent (United Kingdom)
Director of the Genetic Interest Group (GIG), the UK alliance of charities and support groups for people affected by genetic disorders. GIG's mission is to promote the development of the scientific understanding of genetics and the part that genetic factors play in health and disease, and to see the speedy transfer of this new knowledge into improved services and support for the treatment of currently incurable conditions. Prior to

joining GIG, Alastair worked for a number of voluntary organisations on issues concerning policy, service development and disabled people.

József Mandl (Hungary)
Secretary of the Medical Research Council, director of the Department of Science of the Ministry of Health, and head of the Department of Biochemistry at Semmelweis University. He received his Doctor of Sciences degree in 1991. His research interests are biotransformation, drug metabolism, metabolism in the liver and antioxidants. He worked as a research associate at the Department of Biological Chemistry, Harvard Medical School, Boston, USA, in 1982–83. In 1994 he was a visiting professor (Fogarty fellowship) at the Department of Pharmacology of the University of North Carolina at Chapel Hill, USA. He is a consulting member of the medical section of the Hungarian Academy of Sciences, and member of the Presidency of the Medical Research Council.

Mara Marga (Latvia)
Project coordinator of the Latvian genome project since 2003. She graduated in 1985 from Riga Stradins University (formerly Riga Medicine Institute), Faculty of Medicine. Between 1986 and 1990 she worked as a lecturer at Riga Medical School of Nursing, then between 1995 and 1997 as a research fellow at the Institute of Experimental and Clinical Medicine of Latvian State University. In 1997 she became a lecturer at Riga Stradins University/Medical Academy of Latvia, Faculty of Medicine. In 1999 she started work as research assistant for different grants of the Latvian Council of Sciences. In 2002 she became a scientific assistant at the Centre for Biomedical Studies and Research of the University of Latvia. Between 1998 and 2000 she was working as a consultant in endocrinology, diabetes and metabolism at Riga Maternity Hospital, and in 2001 she was elected chief of the outpatient department at the Centre for Endocrinology of the Stradins University Hospital.

Anna Mátay (Hungary)
Freelance science journalist, working mostly for Hungarian television (MTV). Her main interest is science (with special attention to bioethics), health and environment. She received a PhD degree in chemistry and sociology in 1989 and a diploma in the economics of foreign affairs in 1995. She is a member of the National Association of Hungarian Journalists, healthcare division.

Herlinde Pauer-Studer (Austria)
Associate professor in the Department of Philosophy, University of Vienna (since 1997). Her research areas are ethics, social philosophy and political philosophy. She graduated in 1977 from the University of Toronto (MA in philosophy, 1977), in 1978 from the University of Salzburg (MA in philosophy and German literature), in 1983 from the University of Salzburg (PhD in philosophy). She received the *habilitation* in philosophy at the University of Vienna in 1996. She worked between 1991 and 1997 as an assistant professor in the Department of Philosophy, University of Vienna, between 1990 and 1991 as a lecturer in the Department of Philosophy, University of Innsbruck, in 1986 as a lecturer in the Department of Philosophy, University of Graz, in 1984 as a lecturer in the Department of Philosophy, University of California, Irvine, and between 1981 and 1985 as a research assistant in the Department of Philosophy of Law, University of Graz.

Judit Sándor (Hungary)
Associate professor in the Faculty of Political Science, Legal Studies and Gender Studies of the Central European University (CEU), Budapest. She received her JD from the

Faculty of Law in Budapest. In 1990 she was a visiting scholar at McGill University specialising in medical law. She completed the Hungarian bar exam and in 1991 she was an intern in London with Simmons and Simmons. She received an LLM degree in comparative constitutional law (New York Board of Education and CEU). In 1993 she was a visiting scholar at the Hastings Centre (New York), in 1996 a visiting scholar at the Maison des sciences de l'homme (Paris). She participated in three European Commission research projects. In 1996 she received a PhD in law and political science. She was a course co-director at the Inter-University Centre, Dubrovnik and since 2000 co-director at the summer university programme of the CEU. In 1998 (November to December) she had a fellowship at Stanford University, and in 2001 (October) in the Netherlands (invitation by the parliamentary group on health). Her main publications and books are in the field of healthcare law, human rights, reproduction and genetics. She is one of the founders of the Patients' Rights Foundation in Hungary, a member of the Hungarian Science and Research Ethics Council, and member of the Hungarian Human Reproduction Commission. She participated in the working party on biotechnology (CDBI-Biotech), Council of Europe, Strasbourg; she was a member of the high-level expert group on health of the European Commission. Since 2002 she is one of the three international experts who participate in Unesco's drafting of an international legal instrument on genetic data. Currently she participates in three European research projects: Strata-Etan group (December 2002 to December 2003), Public Understanding of Genetics (2002–04) and Privireal (privacy in research ethics and law). In 2003 she was appointed as an expert in biomedical law to the advisory committee on genetics of the Hungarian Prime Minister.

András Siegler (Hungary)
Deputy state secretary of research and development of the Ministry of Education, Hungary. He graduated in control engineering in 1975 from the Budapest Technical University (BTU). Postgraduate studies and fellowships: Trinity College, Cambridge, UK (research fellow, 1978–79), doctoral degree in analytical mechanics (BTU, 1980), research fellowship at Karlsruhe University, Germany (1986), MBA (Purdue University, USA, 1993), degree in economics from the Budapest University of Economic Sciences (1996). Between 1975 and 1996 he worked as a researcher in control science and computer aided design at the Computer and Automation Research Institute of the Hungarian Academy of Sciences. Between 1990 and 1996 he was deputy director of the institute in charge of contract research and international cooperation. He is the author of more than 30 international publications including a textbook, *Engineering foundations of robotics* (Prentice Hall, UK, 1987). From 1996 to 2000, Dr Siegler was vice-president for international matters and technology policy of the National Committee for Technological Development (OMFB), the government office in charge of science and technology policy and implementation. In 2000, following the integration of OMFB into the Ministry of Education, he became head of the department for international R & D matters. Between January 2001 and June 2002, he was acting as chief adviser to the minister in international science and technology affairs and European integration. Following the elections in Hungary and the entry of the socialist–liberal coalition government, he was appointed deputy state secretary for research and development. He represents Hungary in the NATO science committee and in the group of high-level representatives in Eureka. He is in charge of the negotiations on EU accession in the science and research field. He is member of the CREST committee advising the European Council and the Commission on research, and he is the personal representative of the Hungarian research minister to the European Commission's Research DG.

Margit Sutrop (Estonia)
Professor of moral and political philosophy and head of the interdisciplinary centre for ethics at the University of Tartu in Estonia. She has studied journalism and philosophy at the Universities of Tartu, Oxford, Oslo and Constance. She earned her PhD in philosophy from the University of Constance (Germany) in 1997. Her dissertation, 'Fiction and imagination: the anthropological function of literature', was published in 2000. Her current research interests are bioethics, moral philosophy, and aesthetics. She is writing a book on Adam Smith's theory of moral sentiments. She has written on the ethical problems of the human genetic databases and pharmacogenomics. She is the Estonian coordinator of the international project 'The ethical, social and legal issues of the human genetic databases' in the fifth framework programme financed by the European Commission.

Sylvia Tomova (Bulgaria)
Chief legal advisor, Medical University of Sofia, Bulgaria. She graduated from the University of Sofia, Faculty of Law. Her area of interest is bioethics, patient rights, including data protection, and medical ethics. She has been a member of the Council of Europe's steering committee on bioethics since 1991, and of the working group of the same committee since 1994. She has been a member of the Bulgarian central medical ethics committee on drug trials, Ministry of Law, from 1998, of the human genetics ethics commission, Ministry of Health, since 2000, and of the ethics committee, Ministry of Education and Science, since 2003.

Presentations

Elisabeth Hildt
Reproductive medicine, women and autonomy: some ethical issues

The principle of respect for personal autonomy which underlines the importance of individual freedom and choice in private as well as in political life is deeply rooted in liberal western tradition. Autonomy is quite a wide concept, since it encompasses a huge number of different aspects such as independence, privacy, self-realisation, voluntariness, freedom of decision-making and freedom of choice. It also implies that a free agent is responsible for his or her decisions and actions. Autonomy has most often been related to personal self-direction which requires personal rule of the self and the absence of external constraints imposed by others that prevent free choice.

Autonomy may be restricted in numerous ways, such as by lack of information, external or internal pressures, absence of adequate alternatives, etc. Of particular interest in the context discussed here is the question of how far in a concrete situation it is possible for a person to act autonomously without the interference of controlling influences.

In an ethical evaluation of new medical developments directly or indirectly related to human reproduction, the possibility of women to act and decide in a free and autonomous way plays an important role. In what follows I want to discuss two fields in which issues concerning women's autonomy are crucial: prenatal genetic diagnosis (PGD) and neural tissue transplantation.

Prenatal genetic diagnosis (PGD)

The various methods of PGD serve to identify foetal chromosomal anomalies as well as a growing number of monogenetic disorders. Most often, there is no therapy available, so that, in case of a genetic condition considered very serious, the couple has the possibility to choose abortion.

Through PGD women or couples can choose whether or not they want to live with a child who suffers from a certain genetic condition. In recent years, there is a growing emphasis in human reproduction and family planning on individual reproductive freedom; personal autonomy and individual choice are important aspects in the legitimation of PGD.

However, there are also some negative implications accompanying such an emphasis on individual choice and autonomy in PGD. In what follows I want to outline some of these drawbacks.

Decision-making costs and individual implications

Since the question to be decided on after the identification of a foetal genetic abnormality most often consists in whether or not to terminate the pregnancy, aspects concerning the status of human embryos and the practical and ethical problems linked to terminations of pregnancies play a role. What is also important is the fact of having made a decision at all in a very private and central aspect of human existence. For the women involved it may be a lifelong burden to think they may have made the wrong choice, especially since often

only very imprecise predictions can be made with regard to the extent to which the individual, concrete child will be really adversely affected in his or her development.

There are other, more general aspects linked to decision-making and choice that arise from the mere knowledge of the availability and implications of PGD. The knowledge that, with the help of PGD, it is possible to control to a certain extent the genetic status of one's offspring may have far-reaching psychological implications on parents and children. For the children involved, what may be the effects of knowing that they exist because of having passed a test for 'genetic quality control' which made their parents hope to get a healthy, normal child which will not cause too much troubles?

Responsibility for choice and social implications

Prenatal genetic diagnosis offers new alternatives for action in fields which up to now were beyond human influence. With this, new areas of responsibility emerge. The feeling has surfaced that parents who decided against PGD are retrospectively to be made responsible for genetic disorders suffered by the child — disorders which could have been identified, and therefore avoided, with the help of PGD.

In society there is a growing expectation that responsible parents, in cases of elevated risk, should — in their own best interest as well as in society's best interest — undergo PGD followed in the event of severe genetic disorder by termination of pregnancy. In view of this, it becomes more and more difficult for couples to withstand the pressure of undergoing PGD. If a genetic condition has been detected, there are theoretically two options available: the option to go on with the pregnancy, and the option to terminate pregnancy. However, in reality these options do not have equal weight. Instead, the decision to carry out PGD already implies to a certain extent the tendency to terminate pregnancy should a genetic abnormality considered serious be detected.

In order to strengthen the possibility for free choice in the context of PGD it is necessary that both options, i.e. the option to terminate pregnancy as well as the option to have a child suffering from a certain genetic condition, be equally eligible. In the concrete social context, this second option is a realistic and viable one only if there is adequate medical, financial and social support for families with disabled children.

There is also another level on which PGD may restrict individual freedom. It concerns the freedom of those living with a severe genetic disorder. It is well known that one of the main arguments against PGD is that a widespread use of PGD may lead to further discrimination of disabled people.

In sum, it goes without saying that issues concerning individual family planning belong to the sphere of private life, and that it is clearly the individual couple involved that is entitled to make its own decisions in this very private field. However, I consider it highly problematic to refer in a very general way to autonomy in order to legitimate the broad use of genetic testing. Especially at the social level, an increase in choice offered by PGD also leads to various implications that may negatively influence the freedom of the persons involved.

Neural tissue transplantations: the use of tissue from aborted human foetuses

The technique of neural tissue transplantations is considered to be a very promising therapeutic strategy for the treatment of certain neurodegenerative disorders such as Parkinson's disease or Huntington's disease. In the last few years, in clinical grafting studies primarily foetal mesencephalic tissue has been used for implantation in the brain of patients with Parkinson's disease. The foetal tissue has been derived from human foetuses aborted in the first trimester of pregnancy. Although the results obtained are quite encouraging, neural grafting is far from having an unequivocally proven therapeutic effect. In what follows I want to discuss some ethical issues linked with the use of tissue from aborted human foetuses.

The use of human foetal tissue for medical purposes such as neural tissue transplantations is a highly controversial issue. While some authors tend to generally reject the use of material derived from aborted human foetuses, others consider it ethically acceptable. Among this latter group of authors, the following aspects seem to be almost uncontroversial.

- It is only permissible to retrieve tissue from dead embryos or foetuses.
- It is not allowed to keep intact embryos or foetuses alive artificially.
- The decision to terminate pregnancy must precede any mention of the possibility of embryo donation, and there must be no link between the donor and the graft recipient.
- It is necessary that the woman involved give informed consent.
- No profit or remuneration may be involved in embryo or foetus donation.
- Approval of the local ethical committee is necessary.

However, there are some problematic issues which seem to be worth discussing here. One of these deals with the dissociation between a woman's decision to terminate pregnancy and her decision to donate the embryo or foetus. While such a dissociation may be possible in the experimental stage of neural tissue transplantation, it seems almost impossible if neural tissue transplantations or related procedures should ever become a broadly used therapy. If neural grafting were established as a routine treatment, the demand for human embryos would dramatically increase, so that, statistically speaking, a very great number of the women undergoing an abortion would have to donate their embryo in order to satisfy the demand. Then it would seem almost impossible for women seeking abortion to ignore the fact that other persons might profit from the aborted foetus. This possibility of helping other people by donating her embryo will have enormous consequences on a woman's attitude towards abortion.

Another aspect I consider problematic is underlying item No 4 of the 'Ethical guidelines for the retrieval and use of human embryonic or foetal donor tissue for experimental and clinical neurotransplantation and research' adopted by NECTAR, the network of European CNS transplantation and restoration: 'The procedure of abortion, or the timing, must not be influenced by the requirements of the transplantation activity when this would be in conflict with the woman's interests or would increase embryonic or foetal distress'. The very liberal formulation in the NECTAR guidelines reflects not only the expected enormous demand for human foetuses, but also the fact that embryos resulting from routine abortion often are so destroyed that they can no longer be used for grafting. From this point of view, it seems clear that the abortion procedure and its timing will have to be adjusted in order to satisfy the expected needs of transplantation medicine. The NECTAR guidelines support a strategy in which the woman's and the embryo's interests and anticipated suffering are being weighed against the anticipated future benefit for the graft recipient. A balancing strategy like this which includes the killing of foetal tissue donors

has no analogy to ‘normal’ organ transplantations in which organs from already dead donors are used. In a strategy like this, women and embryos are being inadmissibly instrumentalised in order to satisfy the needs of neural tissue transplantations.

In view of these enormous ethical problems linked with the use of tissue from aborted human foetuses — not least concerning the autonomy of women — researchers are intensively looking for other dopaminergic material that might be used instead of foetal tissue as a graft in Parkinson’s patients. Especially the use of neural stem cells and the use of embryonic stem stells derived from so-called therapeutic cloning seem to be very promising transplantation strategies for the future. However, for therapeutic cloning there would be a need for oocyte donation, which is ethically problematic, not least with regard to women’s autonomy. In addition, this strategy involves a direct instrumentalisation of human life, since it involves the creation of human embryos merely for embryonic stem cell production.

Conclusion

In both medical technologies — prenatal genetic diagnosis and neural tissue transplantation — women play a central role, whether with regard to the next generation or as donors for foetal tissue, or perhaps in the future as donors for oocytes. In these new developments it is important not only to consider technological possibilities and demands, but also to take women’s autonomy, and women’s needs and interests, into consideration.

Sylvie Coyaud
Bioethics and the media. Can women in the life sciences make a difference?

There are several definitions of bioethics, of course, but for now I'll use my editor-in-chief's: any issue in biological research, whether basic or applied, on which people (another word in need of definition, but let's skip it) pass a moral judgment, such as 'this research is right and should continue; this one is wrong and should stop'. His favourites, the research which he asks me to write about and possibly 'get a nice polemic raging' ([1]), are: human cloning, both therapeutic and reproductive, even when involving claims made by a wacky sect or Italian doctor; stem cells taken for redundant embryos; patents on organisms or parts of organisms; transgenics pigs raised for organ harvesting and little else. He doesn't care about research with military applications, for instance, although he made an exception for the recent US rules against bioterrorism and their implications for research.

In the 1980s, Italian scientists were not interested in bioethics; in the 1990s, they acknowledged the relevance of national and local bioethical committees. They did so reluctantly, viewing the committees as a necessary nuisance, people chosen according to party politics, untrained in the life sciences, who directly or indirectly funded or starved research projects. Then came Dolly the sheep and biologists found they had better learn how to lobby.

Even though the national committee for bioethics is not representative of public opinion, most biologists no longer reject bioethics as hot air or 'just philosophy'. They take part in the debates about human stem cells which have being going on for four years, condemn reproductive cloning, defend transgenic pigs, etc. Some are eager to appear in print or on television and radio. There is another reason for their eagerness. Public funding for research has been decreasing in the last two years (from a meagre 1 % of GDP). In order to outcompete each other, they want to explain how necessary and promising their work is, directly to the public. So they ask for the journalists' help, and this is where problems start cropping up.

First, scientists — both male and female — think the public is ignorant, that it must be taught about their science in great detail, and get the acronyms right the first time. They think mass media are the ones to do the teaching. This is misconceived: we belong to the news and entertainment market. We can stimulate, and even awaken curiosity, tell of surprising problems and unexpected consequences. We are not part of the education system; we aren't qualified. Anyhow, the public knows — in a broad sense — a lot about what scientists are doing (see the Eurobarometer surveys). They also know that scientists sometimes 'sex up' their results like Tony Blair's aides. For how many years have they been saying that therapies for Alzheimer's or Parkinson's or cancer are just around the corner?

Our second problem is with editors-in-chief and media owners. They do not care about science in general, therefore we are able to report very little of what goes on in the labs. We have to compete for page space or airtime with everybody else, and the rest of the world doesn't stand still just because one of you has just found a great differentiation factor. But, normally, we have a fair amount of freedom. Not on ethical issues, though. Pressure groups also exist elsewhere, they are just different. In Italy, however, the situation is unusual. Most private television channels, radio stations, the largest book

[1] If a newspaper or radio or television starts a polemic, it is repeatedly quoted by other media, and goes up the citation index, so to speak.

publisher, one third of weekly magazines and some large daily newspapers belong to Prime Minister Silvio Berlusconi. The television channels and radio stations of the state broadcasting corporation are run by his appointees. The majority of media, that is, do not want to antagonise the Catholic church ([1]). As a result, secular views can be expressed only in marginal media and do not find a large audience.

The third problem is that even if the owner doesn't mind, and the editor-in-chief smells a polemic, researchers do not speak with one voice. And this is confusing, both for the editor-in-chief and for the readers who tend to expect scientists — dealing with hard data or facts — to agree with each other. We journalists contribute to this misperception. Because we are ignorant, and deluged with overblown press releases by research institutes and scientific journals, we suffer from 'press release fatigue', copy-edit their text, and write about 'the great leap forward' in cell signalling or kinomics or whatever. We forget incremental changes — RNA interference is a good example — and make long stories short by skipping the setbacks and concentrating on the breakthrough. Like the public, we prefer our scientific results simple, straightforward, unquestionable, with no health warning, and no strings attached.

A fourth and more complicated problem is that unless we are politically or religiously biased, bioethical issues have no clear cut answers. Debates aim at a political compromise (or at sinking the existing one). They have little to do with science, but a lot to do with jobs and money in science. Scientists are asked for their views, but they are probably aware that their views are irrelevant, as the Bush administration's decision on stem cells has shown. They are relevant to science journalists who try to be honest, though. Unfortunately, there is no single speaker for the community concerned, because of different creeds and competition for political support and money. Therefore editors-in-chief want interviews with the most famous voice — or face. Usually it is a man's voice. Men have better careers, and more authority. Any editor-in-chief dreams of having a Nobel laureate speak out on each issue, and never mind that the poor laureate ([2]) knows nothing about the latest developments.

How can a network of women in the life sciences make a difference? It does already, in a small way. I am not the only one with my own tiny network of women geneticists or neuroscientists. Unfortunately, they often prefer to remain anonymous. By speaking their minds openly, they risk angering a boss who doesn't want to share the limelight. But if I could ask a foreign scientist among you, and quote her as well as an Italian colleague of hers that she suggests, the Italian might escape blame and consequences. After all, she would be the foreign scientist's choice and responsibility.

What journalists like me would really appreciate is a list of women speakers on bioethical issues. This presupposes that some of you are really concerned, have given the issues some thought, and taken the time to find out how they may affect society, women at large, yourself, your own work. It presupposes you have time to spare, after a day's work and a day's husband or child or housekeeping, that is. We don't need a consensus — there would be no polemic to keep the editors-in-chief happy — but well argued opinions, and a readiness to consider different positions.

([1]) Italy is a Catholic country, but with a birth rate of 1.3 children, where only a tiny percentage of the population follows the church ban on contraceptives or on anything else.
([2]) The two Italians are Renato Dulbecco and Rita Levi Montalcini, respectively 86 and 95 years old.

The conflicting agendas of scientists and media owners result in these four problems, among others, if I stick to my editor-in-chief's definition of bioethical issues. I have one more problem, because my definition is a bit different. It includes moral wrong in your workplace. Researchers often tell me of discrimination, unfairness, retaliation. I can't write about that. If I did they would lose their jobs. But what if some 'European office for integrity in science' were to protect whistleblowers? After all, whistleblowers are needed to kill misbehaviour in science before it gets out of hand and public opinion stops trusting all scientists — male and female. What if a group of scientists with no conflict of interest but with clout and authority were to listen to such sorry tales, investigate them and tell the offenders to stop misbehaving and give science a bad name, or else? Or else: meaning that the offender might not get European funds, for instance?

András Dinnyés
Embryonic or non-embryonic: hot current issues of stem cell research ([1])

What are stem cells?
Definition: 'the precursors of all the different kinds of cells an individual has are called stem cells'

Some potential sources of stem cells
- cells of early embryos
- the umbilical cords of newborn babies
- some adult tissues such as bone marrow

Dogma: 'the earlier we go back in our development, the more able our stem cells appear to be at producing new cells'
- **totipotent**: every totipotent cell has the capacity to develop into a new human being (newly fertilised eggs)
- with rounds of cell division, 'differentiation' begins and cells lose some of their potential to diversify
- **pluripotent**: stem cells in embryos of 50–100 cells can give rise to any tissue type in the body, but not a new individual
- **multipotent**: stem cells derived from foetuses and mature humans are even less versatile and giving rise to a range of cell types

However, this is not entirely true.

A little history
- February 1997: birth of Dolly the sheep announced, the first mammal to be cloned by nuclear transfer from adult cells
- October 1997: birth of Cumulina, the first cloned mouse. Died in May 2000, having raised two litters of her own and having lived for 31 months — or 95 in mouse years
- November 1998: first extraction and culture of human embryonic stem cells (pluripotent cells)

Cloning
There is a distinction between reproductive cloning and therapeutic cloning: both use nuclear transfer techniques, but the outcomes are very different. Therapeutic cloning, if successful, will lead to the production of replacement cells and tissues that are genetically compatible with the patient and so would not be rejected by the immune system. Reproductive cloning will produce a baby who would be genetically identical to one of his or her parents.

Safety of stem cells
• other person's cells
• rejection
• viruses or prion diseases
• differentiated cells transplanted
• 100 % of stem cells are differentiated: tumorogenic!
• traceability, reversibility, selective killing off
• migration and faith of cells within the body, longevity, further multiplication?

([1]) Transcript of a PowerPoint presentation.

• cell therapy: can the genes be switched on and off? Only specific and desired effects?
• xenotransplantation
• shortage of organs (heart, liver, kidney)
• rejection?
• pig endogenous retroviruses
• animal models needed (rabbit, pig, sheep)

Human NT and production of gametes from ES cells
Male ESCs can be turned into eggs as well as sperm; two men could both be biological parents of a child, with the help of a surrogate mother; two out of three such children would be male. The technique would not allow two women to have children together, as female ESCs lack the Y chromosome, without which sperm cells appear unable to form.

How much of developmental plasticity is possible?
Enhance potential of transdifferentiation of somatic cells or adult stem cells for human cell therapy.

Parthenogenetic embryos as ES cell source
- an embryo which is not capable of developing into a baby
- maybe ES cells can be derived
- potential for personalised treatment for woman before menopause (or cryopreservation is needed)

Do we need human oocytes for cloning?
- human oocytes replaced by rabbit oocytes
- ES cells derived
- personalised treatment?
- mitochondrial inheritance?

Scientific rationale and legal control
- last 12 months:
  - cloned rabbit, mule, horse, rat
  - rabbit/human stem cells, differentiation work on stem cells
  - stem cells transformed into oocytes
- legal control is only following scientific progress — how much is wise? (international competition for the biggest future health industry sector)
- somewhere it will be done if there is a real need (IVF clinics all around the world)
- mobility of researchers towards better work environment (more tolerant countries)
- funding: no EC or US government, but private industry is active — giving up the control of the society
- media attitude: often negative and ignorant — bad PR

Herlinde Pauer-Studer
Bioethics and public reason

Introduction

When members of ethics committees or the general public try to find an answer to biomedical questions they often turn to philosophy. By studying the basic moral theories they hope to find an answer to the question whether certain techniques should be allowed or prohibited, which research methods are ethically legitimate or which methods violate basic moral principles and should henceforth be forbidden.

There are impressive examples for this way of looking at things. For instance, the ethical committee in the United Kingdom which recommended that researchers should be allowed to use embryonic stem cells for research made this recommendation on the basis of a utilitarian perspective on bioethical issues. (Embryos in a very early stage of development do not have rights, but the consideration that embryo research might have good consequences and might help to fight certain illnesses is henceforth a strong argument for allowing embryonic cell research.) In my talk I will defend a liberal attitude towards research. But I will argue that we should rely not on a philosophical theory (like utilitarianism) to justify our point of view. Comprehensive moral theories divide people and societies. We cannot force a certain theory on other people, and we cannot expect people to give up their normative conceptions (e.g. religion). Instead, we should try to formulate freestanding arguments that can nevertheless be accepted from the perspective of different comprehensive conceptions.

The two opposing points of view in regard to research using embryonic stem cells are:
i. The position of full protection in all stages of development. Embryos are considered as human beings. They enjoy all the rights of human beings. They do have a right to live and they are not allowed to be used for research. Any step to give up that strict protection would have slippery-slope consequences. No society should be allowed to relativise the principle of the 'sanctity of life'. In addition to this primary moral argument in regard to the moral status of embryos, some secondary considerations are put forward to support the prohibition of embryo research, for example, the argument that this would bring about problematic transformations in the self-understanding of medicine as a whole, that this way medicine would serve economic interests, etc. The meaning and force of these secondary arguments are often quite unclear.
ii. The liberal position. Embryos are not persons. In an early stage of development (certainly the first two or three weeks) they do not have any moral or legal rights as they have neither consciousness nor any possibility to feel pain. If we do accept the important moral principle that harm should be avoided and the welfare of people should be furthered, then we do have an important argument for allowing embryo research (on condition that it is limited to an early stage of development). This research should be regulated in such a way that the importance and meaningfulness of the relevant research projects for improving healthcare is made clear.

I think that the liberal position can be justified; it seems to me more in coherence with other moral judgments we hold, but in looking for a justification of certain positions in bioethics, we have to acknowledge the fact of pluralism. We have to consider that in democracies we do live in value-pluralistic societies, people do have different religions, they uphold different philosophical and moral doctrines. Value pluralism is not simply a

side effect of liberal democracies, it is a constitutive principle of democracy: freedom of religion, freedom of speech, freedom of conscience (*Gedanken-, Gewissens- und Meinungsfreiheit*) are constitutionally guaranteed rights. Hence it becomes important to look for legal and moral principles that can be accepted from the perspective of different comprehensive doctrines (*unterschiedlichen Weltanschauungen*). The specific justification of these principles might be formulated in a different vocabulary — e.g. in religious terms or in non-religious terms.

Public use of reason

We can distinguish between two forms of public reason:
i. The wide form of public reason. Everything that is debated in the non-private, public sphere is already considered as part of public reason. Public reason is according to that interpretation connected with the idea that all participants in public discourse can put forward their claims — and impartial and fair public debate will then decide about the validity of these claims. This wide understanding of public reason does not consider the paradox of value pluralism.
ii. The narrow form of public reason. The narrow ideal of public reason tells us that the basic moral questions of a society should be decided on the basis of those basic values that are constitutive for a society to be a democratic one, namely freedom and equality. According to the narrow ideal of public reason some members of society (e.g. people who hold public office) should try to justify the basic moral and legal principles on the basis of the public values of freedom and equality. People in public office are not allowed to justify the basic principles on the basis of their religious or specific political doctrines.

Freestanding arguments

The narrow ideal of public reason is important for decisions of bioethical controversies. The appeal to freedom and equality often does not help to attain a full justification of positions in bioethics. But we need additional arguments. These additional arguments should be freestanding. Those arguments are freestanding whose validity does not depend on the acceptance of a certain comprehensive philosophical or religious doctrine.

My claim: the thesis that embryos in an early stage of development do not have consciousness, do not feel pain, is a freestanding argument. It is a thesis that is supported by medical knowledge — we do not have to acknowledge any comprehensive conception to consider it as justified. Equally, arguments about consistency are freestanding arguments. If IVF is allowed in a country, then we do have a situation where additional embryos are produced that will not have a chance to survive. So if IVF is allowed, we may ask why it is considered morally acceptable that embryos have no chance of surviving in one case (IVF) where in another case (embryo research) it is considered as strictly forbidden that embryos should have no chance of surviving. To see the inconsistency here and to ask for a justification is an argument that is neutral between different comprehensive conceptions.

Consequences for dealing with bioethical questions

Members of bioethical committees should give up the idea that they are involved in the search for a theologically or philosophically true theory. What they have to do is to come up with a position that can be justified as reasonable by arguments that are acceptable

from different perspectives. The justification of moral principles should be guided by the narrow ideal of public reason. In addition to the values of the public use of reason, freestanding arguments should be put forward.

Sylvia Tomova

Ethics and gender issues in stem cell research and tissue transplantation

Stem cell research is one of the areas of biotechnology which offers new methods to repair or replace tissues or cells damaged by injury or disease and to treat serious chronic disease. Stem cell research is expected to be equally important for basic science to understand cell differentiation and growth as well as for other specific medical applications such as understanding disease development and the development of safer and more effective drugs.

One of the possible sources for stem cells is human pre-implantation embryos. When this research involves the use of human embryos it raises the question of ethical values and of the limits and conditions of such research. Scientific progress confronts ethical concerns and generates public debate on its ethical principles and limits. The question whether it is ethical to do research on embryonic stem cells can be described as a conflict between different values, between rights and obligations or between the short- and long-term interests of different groups. On the one hand, there is interest in new knowledge that can lead to treatment for incurable diseases; on the other hand the question of ethical values when research involves the use of human embryos creates different positions regarding what is and what is not ethical.

Ethical principles applicable to stem cell research

The European group of ethics in its opinion No 15 of 14 November 2000 on 'Ethical aspects of human cell stem research and use' stresses that the fundamental ethical principles applicable to stem cell research are:

- respect for human dignity;
- individual autonomy (informed consent, respect for privacy and confidentiality of personal data);
- justice and benefice with regard to improvement and protection of health;
- freedom of research (which is to be balanced against other fundamental principles);
- proportionality (research methods unnecessary to the aims pursued and that no alternative other methods are available).

With regard to human embryonic stem cell research, the opinion also stressed the importance of:

- free and informed consent from the donating couple or woman (Charter of Fundamental Rights of the European Union, Council of Europe's Convention on Human Rights in Biomedicine);
- approval of the research by an authority (in the countries where it is permitted, embryonic stem cell research is conducted under strict public control by a centralised authority);
- no financial gain for donation (the Charter of Fundamental Rights of the European Union and the Convention on Bioethics prohibit financial gain from all parts of the human body);
- anonymity of the donors and protection of personal data (it is prohibited to disclose information that could identify the donor and the recipient);
- risk–benefit assessments (for example the risk that transplanted stem cells produce abnormalities or induce the creation of tumors or cancer has to be assessed. It is important to evaluate prior to the research the relation between risk and benefit);

- transparency of the research results (the results of such research should be widely spread).

The use of human supernumerary embryos as a source of stem cells raises the issue of the moral status of the human embryo. In the context of European pluralism, it is up to each Member State to forbid or authorise embryo research. In the latter case, respect for human dignity requires regulation of embryo research and the provision of guarantees against the risk of arbitrary experimentation and instrumentalisation of human embryos. It is also significant that women who undergo infertility treatment are subject to increased psychological and physical strain. The demand for spare embryos (supernumerary embryos) and oocyte donation should not increase the burden on women.

The biological differences between women and men are reflected in the health problems they experience. They are directly connected with sexual or reproductive functioning, as well as affecting particular organs (prostate cancer and cervical cancer). There are also sex differences in the incidence, symptoms and prognosis of a wide range of diseases that affect both males and females. These differences are due to the genetic, hormonal and metabolic particulars of men and women. Some indication of why biological differences between the sexes need to be taken more seriously in all areas of health research is given by the following facts:

- men typically develop heart disease 10 years earlier than women;
- women's immune systems makes them more resistant than men to some kinds of infection;
- women are around 2.7 times more likely than men to develop an autoimmune disease;
- male-to-female infection with HIV is more than twice as efficient as male-to-male infection.

Gender aspects in research, including stem cell research

Gender aspects in research have a particular relevance to this theme as risk factors, biological mechanisms, clinical manifestation, causes, consequences for disease and disorders may differ in men and women. The possibility of gender/sex differences must therefore be considered in all areas of health research, unless it can be demonstrated that gender/sex is irrelevant to the health of the subjects or the objectives of the research. Gender/sex issues should be considered in:

- the formulation of research hypotheses, in the development of research protocols, choice of research methodologies and in the analysis of results;
- biological, pre-clinical and epidemiological behavioural studies on human subjects;
- the use of cells, tissues and other specimens, where appropriate;
- the choice of a particular study population, which should be thoroughly justified.

These aspects will be taken into account in the evaluation process.

Sex and gender are major determinants of health in both women and men. They are closely linked with other variables such as age, race and socioeconomic status in shaping biological vulnerability, exposure to health risks, experiences of disease and disability and access to medical care and public health services. Researchers who ignore these differences run the risk of doing bad science.

Strategies for ensuring that research is gender sensitive will vary depending on the type of study being undertaken. However the overall principle should be to make sure that both sex and gender are key variables in all research designs unless there are clear reasons

for assuming that they are not relevant to the problem under investigation. The population of subjects needs to comprise comparable numbers of women and men so that any sex or gender differences can be identified in the analysis. These differences need to be presented in the findings and their implications discussed.

The following points will be central to the process of devising new policies in all research activities:

- sex/gender sensitivity in research design to be included in funding criteria;
- guidelines to be developed to encourage greater gender awareness among health researchers;
- multidisciplinary research to be encouraged across the biological/social divide;
- a range of methods to be supported including both qualitative and quantitative approaches to data collection;
- strategies to be devised for ensuring a more equal gender balance among healthcare researchers;
- policies to be devised for ensuring that women are more actively involved in the determination of research priorities.

A brief indication of the importance of gendered behaviour as a determinant of the health the both women and men is given by the following facts:

- in most countries, men are more likely than women to commit suicide but women are more likely to attempt it;
- women are two to three times more likely than men to be affected by common mental disorders (CMD) such as depression or anxiety;
- men are more likely than women to die of injuries but women are more likely to die of injuries at home;
- the large differential between male and female smoking rates is beginning to narrow as young women take up the habit more frequently than young men.

Being a man may require the taking of risks which can be damaging to health. In many societies the traditional role of breadwinner continues to put men at greater risk than women of dying prematurely from occupational injuries. In order to demonstrate their masculinity they are also more likely to engage in dangerous and/or violent activities including smoking, drinking to excess, driving too fast and indulging in unsafe sex.

Gender influences access to healthcare. In many cases there is evidence of gender bias in the allocation of resources. Females of all ages may be assigned a lower status and will have less entitlement to healthcare. This bias will be especially damaging in poor communities where there is little state provision and care has to be bought with cash. Alongside the cultural and material obstacles to care, individuals themselves may feel unable to seek the help they need. In the case of women, this may reflect their socialisation into a culture of sacrifice which means that they see themselves as being of little value. In the case of men, access to healthcare may be limited by the desire to appear ‘strong’. In order to appear masculine they cannot admit weakness and this may prevent them from seeking necessary help. There is also evidence that once they have accessed a service, women and men may receive treatment of differing quality. Many women have spoken of the lack of respect they experience from workers in reproductive healthcare and this seems to be especially severe among poor women. More research is therefore needed to explore both the gendered obstacles to care and the quality of the services received by women and men in different settings.

European legislation in the field

At the Council of Europe level, Article 18 of the Convention on Human Rights and Biomedicine, signed in Oviedo in 1997, establishes that it is up to each country to decide whether or not to authorise embryo research. Each country is only obliged to respect two conditions: 'to ensure adequate protection of the embryo' — that is to say, to adopt legislation fixing the conditions and limits of such research — and to prohibit 'the creation of human embryos for research purposes'. The Convention is binding only for those countries which have ratified it. In the European Union so far only some countries have completed the procedure and some are in the process of doing so.

At EU level, although there is no legislative competence to regulate research, some directives allude to the issue of embryo research and use. For instance Directive 98/44/EC on the legal protection of biotechnological inventions (patenting on life) stipulates that 'processing for cloning human beings' and 'issues of human embryos for industrial or commercial purposes' 'shall be considered unpatentable'. Directive 98/79/EC on *in vitro* diagnostic medical devices (including the use of human tissues) provides that 'the removal, collection and use of tissues, cells and substances of human origins shall be governed in relation to ethics by the principles of the Convention of Bioethics and by any Member States' regulations on this matter'. At the same level, the Charter on the Fundamental Rights of the European Union approved by the European Council on 14 October 2000 prohibits different kinds of practices related to embryo research. See 'Eugenic practices and reproductive cloning of human beings' (Additional protocol of the Convention on Bioethics prohibiting human cloning).

Ethical issues such as research with human beings (clinical trials in adults and children), use of human embryonic stem cells and use of biological materials of human origin will be dealt with in FP6. Experts in ethics, law and social sciences are encouraged to participate actively in research projects. Transdisciplinary collaboration between all stakeholders should ensure that due account is taken of the ethical and societal concerns, our obligations towards future generations and the rest of the world. It should also allow for mutual education and dialogue, and ensure that ethicists have the means to continuously assess the societal relevance and adequacy of their analysis and evaluation.

In addition to the basic checklists below and any specific criteria or interpretations of the criteria required for a call, the following issues are also addressed for all proposals at any appropriate moment in the evaluation.

i. Are there gender issues associated with the subject of the proposal? If so, have they been adequately taken into account?
ii. Have the applicants identified the potential ethical and/or safety aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results? If so, have they been adequately taken into account in the preparation of the proposal?

An ethical check will take place for all proposals during the evaluation. A specific ethical review will be implemented following the evaluation for proposals recommended for funding and which deal with specific sensitive issues or whenever recommended following the ethical check during the evaluation. The work programme of FP6 attempts, where possible, to reinforce and increase the place and role of women in science and research both from the perspective of equal opportunities and gender relevance of the topics covered.

Anna Mátay
The stem cell debate and public opinion in the Hungarian media

Background

No medical process in Hungary has created as much of a stir and aroused as much public interest as taking umbilical cord blood samples from babies. There is only a small capacity for stem cell storage in Hungary, at St László Hospital. This is for blood transfusion between family members. Until 18 April of this year, a private company offered its services. They store the samples abroad, in Belgium, in a cord blood stem cell bank. The debate started when, following a change in the regulations, hospitals refused to take samples from the babies. The opinion of the Medical Research Council was that medical treatment with stem cells is in a research phase; it is research on human beings at this point, and so each case needs individual permission.

On 22 April, a family expecting a baby in a month launched a lawsuit. After five days in court, on 8 July the sentence handed down was that the Medical Research Council did have the right and authority for its statement. The judge also refused the idea that this decision would hurt anybody's right of personality or autonomy. The judge also stressed the importance of a proper regulation of this issue. Meanwhile the ombudsman delivered his opinion as well: parents must have this unique chance for the health of their children.

The object of the debate

The object of the debate was only the cord blood stem cells, referring to them as stem cells without mentioning embryonic stem cells or making any distinction between adult stem cells and embryonic ones. On the Internet I found 4450 hits for 'stem cell' in the discussion, but only 52 with the words 'cord blood' and 'stem cell' together. So the definition of the stem cells, the object of the debate, seems to be unknown for the media and the public.

Keywords and questions of the debate

On the one hand: is it legal to forbid the storage of the sample which would be thrown away anyway? Does the Council have a right to it? This is an attack against the autonomy of the individual. And on the other hand: medical treatment with stem cells is not in general clinical practice, is not a routine process yet. Hungary does not have the equipment for safe storage.

The time scale of the debate

In the last three years, from 2000 to April 2003, the issue of stem cells was only in science programmes of Hungarian public television, on science pages of printed media and scientific sites on the Internet. Altogether there were just a couple of dozen stories. From 18 April to 8 July (the date of the verdict), every television station, daily newspaper and periodical, relevant online forums, local and national radio stations all sought to debate the issue. But the arguments did not reach the ethical core of using stem cells for medical treatment. It was like a dialogue of the deaf.

The number of publications during the debate

As mentioned already, there were only a couple of dozen publications in the last three years and several thousand in three months. After the decision of the court, media coverage returned to almost nothing.

Number of people reached during the debate

In the last three years, popular science publications have reached some 300 000 to 500 000 people. During the debate fuelled by this court case, the general media campaign reached at least 10 times that many.

The debate shows the power of the media on public opinion and, what is more, the responsibility of the media in leading public opinion and the general knowledge of an issue.

My conclusions are:
- we need a proper public survey on the issue;
- we need more popular science publication dealing with the issue.

Mara Marga
Genetic testing, storage and use of genetic information ([1])

'The primary goal of modern human genetics is to identify genes that control pathways that lead to disease.'
Stephen Rich

Where we are now? The genomic era:
- has affected our naive view of genetic determinism (that complex traits are caused by a single gene);
- confirms that almost all human diseases are complex context-dependent entities to which our genes make a necessary, but only partial contribution.

Are the molecular biologists able to explain the complexity of the genotype-phenotype relationship?

Human genome project or genomic revolution?
- allowed scientists to generate extraordinarily significant information, such as nucleotide-by-nucleotide description of the genetic blueprint of infectious pathogens, experimental organisms (the round worms, mice, the fruitfly, two kinds of yeast)
- has changed the way science is done: every scientist has become dependent on computer science to store, organise, search, manipulate and retrieve the new information

The human genome and the genomic era
- rediscovery of Mendel's laws of inheritance, 1903
- first human genetic disorder described in 1908 by Sir Archibald Garrod (alkaptouria, benign pentosuria, albinism)
- 3 billion (3×10^9) base pairs with 3 to 5 % as coding exons
- that accounts for about 100 000 to 140 000 genes
- Human Genome Project launched, 1992
- sequence of the human genome announced, 2001
- SNP discovery accelerates the advances in disease genetics and pharmacogenetics

SNP map technology — a key tool in genetic research
- SNP — single nucleotide polymorphisms — are single-base differences in the DNA sequence and are the simplest form of DNA polymorphism
- allows to navigate the 3 billion base pairs of human DNA
- high density SNP map can be used for the identification of the disease susceptibility and to anticipate the patient's response to the medication
- SNP map is available in the public domain (http://snp/cshl/org)
- use of SNP maps for pharmacogenetics
- a high density SNP map can be used to more rapidly identify disease susceptibility genes and to correlate information from patients' DNA with their response to medicine (beneficial and adverse)
- SNP information can be used to predict an individual patient's response to that medicine

([1]) Transcript of a PowerPoint presentation.

The genomic era

- now more than 9 000 single gene disorders are identified
- about 5 % of children are born with a congenital or hereditary disorder, almost 40 % of adults are genetically predisposed to common diseases during their lifetime
- genetic predisposition is determined by an individual's genetic make-up which contributes the susceptibility or resistance to the disease
- diabetes mellitus affects 140 million people worldwide now, by 2025 expected 300 million
- now it is possible to reduce the effect on mortality, disability and reproductive fitness, just one third of single gene disorders, about 50 % of congenital abnormalities, 10 % of inherited diseases and 2 % of chromosomal disorders can be treated

Applied genetics

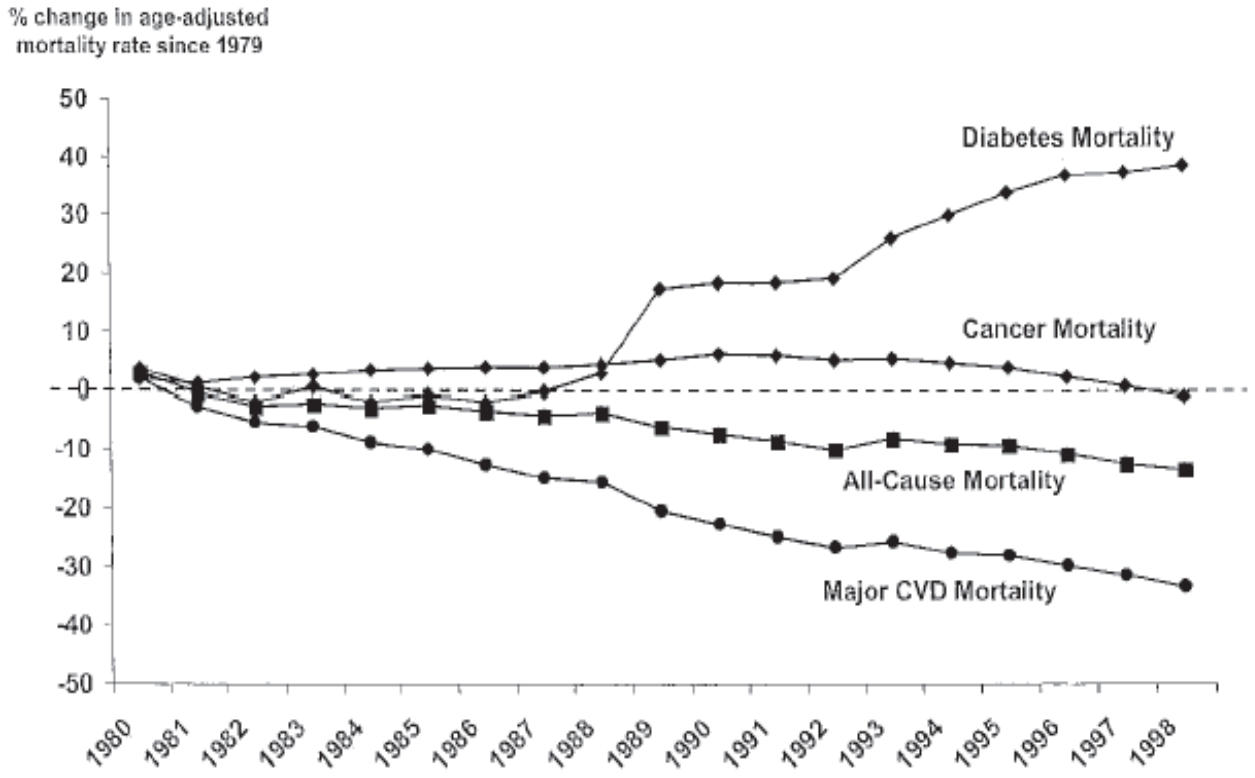
A genetic test is the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect alterations related to a heritable disorder.

- can be accomplished by:
  - directly examining the DNA or RNA that makes up a gene (direct testing);
  - looking at markers co-inherited with a disease-causing gene (linkage testing);
  - assaying certain metabolites (biochemical testing);
  - examining the chromosomes (cytogenetic testing).
- may be used for medical management: genetic test results usually apply not only to the patient but also to the family members
- may be performed in the context of a genetic consultation and should include informed consent, test interpretation and medical and physiological follow-up
- often done by specialised laboratories

In order for genetic testing to yield meaningful results

- multiple test methodologies may be required
- other family members may need to be tested
- genetic consultation may be appropriate

Change in age-adjusted mortality rate since the year 1979 in the United States by cause of mortality



(*Source:* Centres for Disease Control and Prevention Mortality Database)

Genetic basis of type 1 diabetes

- autoimmune destruction of the pancreatic â-cell (the solely source of insulin)
- affecting 0.3 % of the general population by age 20, has a lifetime risk of nearly 1 %
- worldwide 10–20 million people have type 1 diabetes
- determined by genes of a large and small effect
- concordance rates with MZ twins are 50 %, albeit DZ pairs of 5–10 %

Region/ locus	Chromo- some	LOD score	IDDM loci
HLA	6p	65.8	IDDM1
INS	11p	4.28	IDDM2
D16S3098	16q	4.13	
D10S565	10p	2.80	IDDM10
D2S1391	2q	2.62	IDDM7, IDDM12, IDDM13
	6q21	2.36	IDDM15
	1q	2.20	

Adapted from Cox et al. (46).

Type 2 diabetes mellitus
- recognised since 1930
- reflected as an impairment of the action of insulin
- hyperglycemia appears in patients with type 2 diabetes only when pancreatic â-cell function can no longer compensate for insulin resistance by progressively increasing insulin output
- insulin resistance *per se* is a marker and perhaps a determinant of macrovascular disease
- represent polygenic disease; complex inheritance

Elements to be considered in the use of genetic information

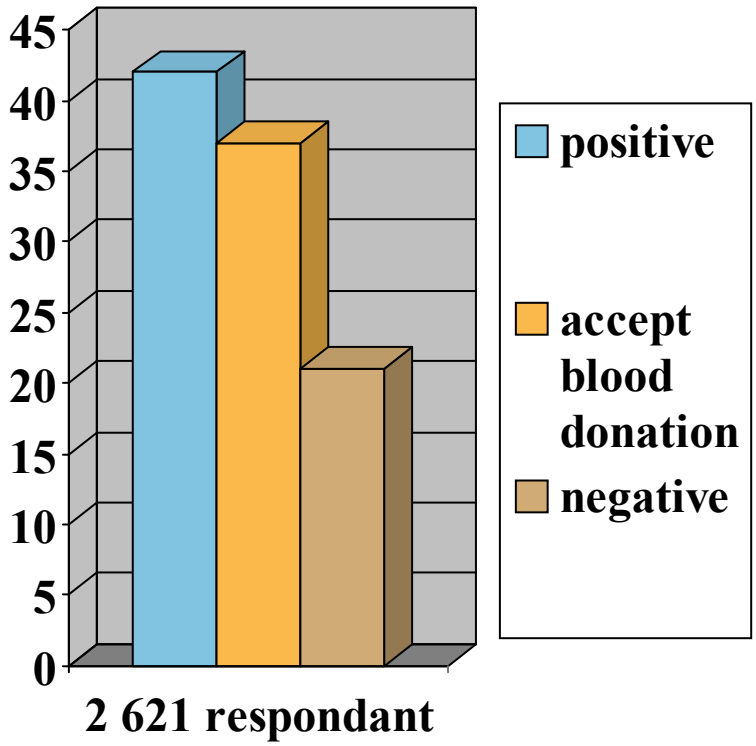
What are potential implications of genetic information?
- the patient may be more likely to require expensive therapy
- the patient may be more likely to be injured by certain types of exposure
- the patient may present a danger to others in future

What principles need to be taken into account, recognising that none are absolute?
- protection of autonomy
- public health
- the importance of inclusiveness
- allocation of costs

Who decides whether test will be done?
- the patient
- the patient's employer or another private third party
- the government

Who decides what to do with the results?
- the patient
- a private third party
- the government

Public attitudes regarding the donation and storage of blood specimens for genetic research
- American healthstyles survey (1998) for health attitudes and behaviour
- 3 130 participants, 2 621 persons (84 %) responded
- 42 % in favour of both blood donation and storage for genetic research
- 37 % in favour of blood donation or storage, not for genetic research
- 21 % not willing to donate blood or have it stored for genetic research under any circumstances



The results of loglinear analysis of the respondents who favoured blood donation and long-term storage for genetic research

- their characteristics were attitudinal
- they believe that genetic research will prevent disease (or 2.9, $p<0.001$)
- they believe in genetic determinism (or 1.5, $p<0.004$)
- they agree they would participate in government research (or 2.9, $p<0.001$)
- demographic characteristics include higher education, white race, living in the mountain/Pacific or mid-Atlantic regions of the USA, and positive family history of a genetic disorder

'Confronted with anomaly or with crisis scientists take a different attitude toward existing paradigms, and the nature of their research changes accordingly.'
— Thomas Kuhn, *The structure of scientific revolutions*

Margit Sutrop
Ethical aspects of human genetic databases: an Estonian perspective ([1])

The Estonian Genome Project (www.geenivaramu.ee)
- project aims to collect the health, genealogical, genetic data of up to 1 million people
- the population of Estonia is 1.4 million
- in 2002–03 a pilot project was carried out in three counties (1 000 samples collected out of the planned 10 000)
- Human Genes Research Act was passed by the Estonian Parliament on 13.12.2000

Financing of the Estonian project
- public–private partnership between a non-profit body of the Estonian Genome Project Foundation as an owner of the data and a public limited company, Egeen, as the exclusive commercial licensee of the database for 25 years
- the costs of implementing the project are estimated at USD 150 million

Egeen
- for its right to commercialise the data, Egeen is obligated to pay an indexed annual payment of 300 000 EUR and additional fees depending on its financial success (unlimited annual profit payment of 0.5 % to 3 % of the turnover of the created IP rights)
- at the beginning Egeen was 100 % owned by EGPF; after the end of the pilot project EGPF's shareholding in Egeen diminished to 2.5 %

Proposed human gene bank projects
- DeCode (Iceland)
- Estonian Genome Project (Estonia)
- BioBank (UK)
- Genome database of the Latvian population (Latvia)
- UmanGenomics (Västerbotten, Sweden)
- Genome Institute of Singapore (Singapore)
- CATaGENE (Quebec, Canada)
- Autogen Ltd (Tonga)

What is a genetic database or gene bank?
- A stored collection of genetic samples, in the form of blood or tissue, that can be linked with medical and genealogical or lifestyle information from a specific population, gathered using a process of generalised consent

The aim of the genetic database
- all proposed projects intend to map genes for common diseases and hope to improve the health of the population involved
- the Estonian gene bank can be used only for scientific research, research into and treatment of illnesses of gene donors, public health research and statistical purposes
- use of the gene bank for other purposes, especially to collect evidence in civil and criminal proceedings or for surveillance, is prohibited

Is the Estonian population representative?
- there are only minor differences between European populations
- the Estonian population is perfectly representative of all European populations

([1]) Transcript of a PowerPoint presentation.

- if the research will be carried out based on the genetic data of Estonians, it can be generalised for other Europeans as well

Comparison of Estonian and Icelandic databases
- Iceland
  - opt-out system
  - presumed consent
  - ownership: licence to private company
  - consists of health records, genealogy, genetic data collected
  - participants have no access to their data
- Estonia
  - opt-in system
  - explicit informed consent
  - belongs to the estonian people
  - consists of phenotype and genotype data collected
  - participants will have a right to know their data

The public perception of the Estonian Genome Project
- sociological survey in December 2002 commissioned by the Ethics Centre at University of Tartu
- part of the international project Elsagen (ethical, legal and social aspects of human genetic databases), fifth framework programme, financed by the EC. Other partners are Iceland, UK, Sweden.

The results of the sociological survey
- 62 % claim to have heard of the EGP
- 7 % consider themselves well informed
- 24 % plan to participate
- 37 % have not made up their mind
- 39 % will not participate
- prognosis: 100 000–150 000 participants

Trusted information sources
- the least trusted information sources about the database project were politicians and journalists
- the most trusted were researchers and employers of the EGP

Double attitude towards the EGP
- a very positive attitude of the public towards the EGP as a national project that is expected to have positive effects on the economy, science, healthcare (blind trust)
- a more hesitant personal attitude towards the project which contains many risks. Many people are afraid of possible discrimination on the basis of genetic data (mistrust)

Critical points about informed consent in Estonia
- aims and methods of research not specified
- how is data protection guaranteed when it is allowed to decode data for several purposes (a.o. renewal, supplementation of data, issuance of the data to the gene donor)?
- how will the disclosure of research results to the participants will be managed?

Promised benefits to the gene donors

- the gene bank provides a gene donor with an opportunity to access his/her health risks and diagnose illnesses more precisely, prevent falling ill and receive more effective treatment in the future (gene donor's consent form)
- personal gene card gives access to individualised medicine (pharmacogenetics): the right medicine to the right patient at the right dosage

The sociological survey shows that 83 % of potential participants plan to ask for the personal gene card, 15 % have not decided, 2 % say no.

No information available

- in which form will the description of the state of health and genetic data be issued?
- what will be done to avoid psychological stress when knowing one's genetic risks?
- who is going to pay for the genetic counselling?
- possible consequences of the development of pharmacogenetics (more expensive medicine possibly not affordable for poorer countries, creation of orphan diseases, etc.)

Judit Sándor

The role of gender in genetic choices

Introduction

The political process of women's emancipation is far from being completed, even in the western liberal democracies. Moreover, our understanding of what exactly forms the basis of this political process, namely the differences and similarities between the biological sexes and genders, is also in a rather preliminary phase. Under these circumstances, the Human Genome Project will provide new possibilities to trace human origins, to get a better picture of ageing and illness, and may also contribute to revealing some of the genetic differences.

The increasing amount of genetic information will also contribute to a more intensive study of hereditary conditions. This will allow us to understand the genetic basis of kinship more thoroughly and to see how different patterns of genetic inheritance affect sexual differences ([1]).

There is, of course, a danger of misinterpretation in any genetic research that may reveal differences or similarities between ethnic and/or gender groups, as it may tend towards constructing social divisions. However, it is not a sufficient reason to forbid genetic research; it requires considerate and multidisciplinary interpretation. In the multidisciplinary analysis, of course, gender-based study has an important role.

In addition to the search for genetic differences between individuals and groups, social sciences should focus also on the *impact* of genetic research, genetic testing, and genetic screening of various groups.

Genetic research seems to promise numerous new therapeutic possibilities, but also other kinds of choices that do not necessarily increase therapeutic options. The dilemmas of whether to undergo testing or screening, whether to enrol in *in vitro* treatments, pre-implantation testing, how many embryos to implant and in what health conditions — all these can be regarded as genetic choices. Amniocentesis, chorion villous sampling or embryo selection following various prenatal tests can be regarded as important genetic choices.

In my short presentation I would like to contribute to the analysis of gender in various genetic choices.

Reproduction and gender

If one explores how various genetic technologies affect the differences between genders, we have to start with the different position of genders in reproduction. Obviously, genetic testing and screening itself often occurs in the context of reproduction. Pre-implantation, prenatal testing, but even genetic testing of an adult before establishing family, might affect in various degrees the choice of establishing a family, and the decision on family planning.

([1]) Now we know, for example, that a portion of the DNA passes via the Y chromosome only from the father to his son, while some genetic information is transmitted via mitochondria from the mother to her daughter.

Potential tests and interventions may effect not only the patients concerned, but more and more the offspring and the future generations ([1]). Every parent would like to have a healthy baby. Due to the emergence of pre-implantation and prenatal diagnoses, now it seems that this wish can at least partially be fulfilled. These technical possibilities, however, have also created many painful dilemmas and choices: should parents make choices based on limited genetic knowledge, and how far should the law promote those choices?

Genetic choices — gender impact

The risk of losing a child, a foetus, or an embryo, or having them in very poor health, necessarily influence genders differently. Many of these tests and examinations occur in the female body. Ethicists refer to this problem as the 'one patient, two patients dilemma', meaning that while the tests aim to detect the condition of the foetus, nevertheless it also affects the female body. Especially difficult dilemmas may occur when the two interests substantially conflict with each other ([2]).

Regulation of assisted procreation ([3]) is based on a technology-driven biomedical paradigm worldwide. One of the assumptions of this approach is that the physical, emotional and moral contributions by men and women in reproduction are equal. This presumption is correct only in so far as the genetic contribution is concerned. But it might be entirely wrong once the physical burdens of the technology are considered: egg aspiration, embryo transfer, pregnancy and childbirth are inseparable parts of reproduction. Challenging this presumption has serious practical and legal consequences. It follows from the presumption of equal contribution that egg donation and sperm donation is similarly regarded. Widows and divorced women are often legally prevented from having access to embryos produced by their own gametes because of this presumption. In this latter case, women who once underwent medical interventions for infertility treatment must start the entire procedure over from the beginning, including hormonal treatment and egg aspiration, regardless of their age and the risks of repeating the entire cycle.

Trans-generational effects

So what are the challenges that we face now? Recent advances in genetics allow medical scientists to identify carriers of recessive traits even before someone would decide to have children. Scientists may also use pre-implantation tests that can detect embryos with high risks of some abnormality. Germ-line engineering in the future may offer techniques to eliminate such genes not only from the 'treated' patient but also from all subsequent descendants. National biobanks and genetic databanks allow the prediction of future healthcare needs for future generations by examining present generations. Our genes may be used to procure genetic information that may result in the development of drugs for the future generations. The last few years have witnessed an important expansion of human DNA sampling and data collecting in order to exploit and study the genetic

([1]) According to Habermas 'the parents' eugenic freedom, however, is subject to the reservation that it must not enter into collision with the ethical freedom of their children'. See Jürgen Habermas (2003), *The future of human nature,* Polity Press, p. 48.

([2]) In an American legal case (the Angela Carder case) a severely ill pregnant woman at one point was not any longer able to tolerate the pain and required the same treatment as the non-pregnant terminally ill patient, which might be dangerous to the foetus. The foetus's representative vetoed the patient's decision.

([3]) Classifications of various biomedical regulations were analysed by Derek Morgan (2000), 'Regulating reproductive technologies: Ten years down the tube', in: Jennifer Gunning (Ed.) *Assisted conception* (Aldershot: Ashgate) pp. 175–200.

information collected. The strategic importance of this activity for genetic research and its applications is obvious. Human DNA, tissue or cell collections, Guthrie cards, as well as various databases that are attached to such biological resources are necessary for a wide range of purposes. In many cases the results will be enjoyed by future generations.

The post-genomic era offers many connections between generations, not necessarily relations that endanger future generations but various forms of transgenerational effects. The existence of numerous intra- and transgenerational effects seemed to become evident with the findings of the Human Genome Project and therefore the question that remains is to find out the most adequate way to represent concerns for future generations.

Women as a target group for biotechnology

From an ethical point of view, there is a disturbing development. Specific groups of patients or health consumers are often used by business-oriented scientists and the pharmaceutical industry to claim acceptance of new research technologies on their behalf. This puts ethicists and lawyers who consider it their mission to protect research subjects and individuals against unscientific or unethical research in a very controversial position. If the only hope for a patient or a family is the further development of stem-cell research, unlicensed gene therapy, or access to a not-yet-registered drug, the concerned patients and family members regard ethical/legal or administrative procedures as obstacles to enjoying their rights. Moreover, some people regard science as a menu of possibilities, and would like to choose the sex of their children without any compelling reason ([1]), or even select gametes and embryos with specific characteristics. Decisions relating to selection and therapeutic choices are therefore fundamentally different, even though they may be offered by the same health professionals.

Recently, pharmaceutical and biotechnological companies are also interested in getting direct access to the gene donors, pregnant women (for instance for umbilical cord blood), to prospective research subjects and to pharmaceutical product users. Whether we like it or not, healthcare has to operate under new circumstances where commercial actors contribute to and seek the benefits of biomedical science, and patients, as consumers, seek healthcare and other biomedical services.

The challenges posed by genetics are felt in nearly every aspect of law, and at the very least force us to re-evaluate terms. Law in part reacts to the current social potential of science, but in addition takes an overview of the basic ethical norms affecting future risks, basic rights and social values, health policy, and scientific research, and then attempts to develop legal norms based upon these.

Legal changes have been much more restricted than is warranted by the pressure for innovation arising from science. If a new technical or scientific development arises, legal thought is likely to tend towards legal incorporation and analysis, rather than the development of new legal institutions.

From therapy towards selection … and eugenism?

The ethical dilemmas are getting even more complex with the appearance of genetic enhancement where individual choices are made not merely in the questions of health and disease; in addition to that also they aim at improvement and selection. ‘Due to the

([1]) Such as the elimination of disease that is inheritable by only one of the sexes.

spectacular advances of molecular genetics more and more of what we are “by nature” is coming within the reach of biotechnological interventions.’ These words by Jürgen Habermas, from his book *The future of human nature*, refer to a new era in which the functions and the scope of biomedicine will change dramatically. By extending the scope of biomedical interventions, the question has to be raised: where does the boundary between healing and enhancement lie? Furthermore Habermas also argues that the new reproductive and genetic choices created a special relationship between generations as parents become procreators, not only in the sense of genetic contributors or as creators but also as determining some of the characteristics of their future children (e.g. sex or lack of some pathological conditions).

One can make a distinction between two different kinds of choices: one is negative choice (may also be called selection) and the other can be regarded as a positive choice (that may take the form of genetic enhancement).

Gender differences in decision-making

Gender differences can be observed also in the level how genetic choices differ in the phase of decision-making. In the gender ethics literature there is a strong claim that women and men make ethical decisions differently. According to Gilligan, men look to and are formed by freely accepted relationships and agreements, while women look to and are formed by contextually given relationships such as family.

Ethics of care and responsibility for future generations often dictate that women take into account the interests of offspring in genetic choices. Apart from the autonomous ethical drive (ethics of care) there are significant external pressures (economic and social) that oblige women to take into account the best interests of the (future) child, public welfare, to avoid genetic risk, socioeconomic possibility to raise children with disabilities, etc.

In the biomedical domain, one of the main rules of ethical and lawful research is that it must be based on the informed consent of the individual concerned. The ethics literature, however, has yet to specify how far consent is really based on merely individual assessment and what are the cultural and gender differences in making such decisions. The contemporary notion of informed consent was based on the individual model. However, one of the most problematic features of genetic characteristics is that they may be inherited by the offspring, affecting the afflicted individual’s carrier and his or her spouse’s chances of having a healthy child. Therefore, genetic information is not only an indicator of one individual’s current state of health; it is also an indicator of that individual’s likely future health.

Closing remarks

I have attempted to provide a model that includes some aspects of gender in the recent development of various genetic choices that become possible due to genetic testing, screening, and various uses of genetic information. I consider the ethical, legal and social implications of genetics as essential parts of the scientific enterprise and evidently it should include gender as one of the aspects. I am sure that there are many possible approaches to benefit from the unique developments in this field of science so that it would not lead to further discrimination based on gender.

Alastair Kent

Ethical and gender aspects of genetic testing, storage and use of genetic information ([1])

Background

- the Genetic Interest Group (GIG) is an alliance of 120+ voluntary groups, large and small, promoting awareness of the link between genetics and health and of the needs of individuals and families affected by genetic disorders for services which reflect current scientific knowledge and best clinical practice delivered in a timely and appropriate way
- patient and family led
- governing board elected by members — all personally involved in the issues
- founded by patient support groups in 1989 in response to a concerted attack on the embryo research provisions in the Human Fertilisation and Embryology Bill (now the HFE Act of 1990)
- now a leading UK pro-science, pro-treatment patient advocacy voice

Perspectives

- genetic disorders rarely a positive choice for parents
- biology goes on working even when we are ignorant of its effect
- most genetic disorders remain intractable at best
- not unreasonable to hope for a healthy baby, or wish to avoid predictable future adverse health consequences for yourself or your family
- for those with a definable genetic risk, the way of avoiding or averting that risk is through research and the application of research outcomes in the form of appropriate products and services
- inevitable gap between discovery of new genetic knowledge and development of ways to avert or prevent the risks that that knowledge indicates to be there — in many cases we find ourselves in this gap now

Issues for families

- discovery of genes which cause or predispose to a particular condition allows the development of specific diagnostic tests
- number of conditions which can be diagnosed in this way has increased rapidly in recent years
- why diagnose if you can't treat?
- not all genetic disease is untreatable; denial of diagnoses prevents access to treatment (e.g. haemacromatosis, familial hypercholesterolaemia)
- knowledge gives explanation, allows understanding and can relieve guilt
- access to self-help groups comes through diagnoses
- non-clinical support (e.g. education, social care) can be more appropriately defined and delivered (e.g. Fragile X, Duchenne muscular dystrophy)
- knowledge creates the possibility for families of planning for future events, choosing between options (where these exist) and can give reproductive confidence to couples at risk

Contextualising the issues

- contrast between media/public perception and scientific reality can make it difficult for families to form judgment — important to have opportunity to access information, advice and support

([1]) Transcript of a PowerPoint presentation.

- often looking for ‘least bad’, not best outcomes
- need to be confident of acceptability of decisions, not feel subject to (overt or covert) pressures to choose one outcome over another

Issues for women
- particular focus on pregnancy related issues (grateful to individuals belonging to GIG’s member groups and to research at the centre for family research at Cambridge)
- abnormality testing is a routine part of prenatal care for most women in Europe and its scope is increasing with scientific and clinical progress
- unless prior knowledge gives reason to think otherwise, most women expect a normal pregnancy and a healthy baby — extension of screening means that more are having to confront the issues raised by foetal abnormality earlier (in 2 to 3 % of pregnancies a significant foetal abnormality is present)
- becoming aware of the abnormality can be straightforward or it can be a fraught process — either because of the current state of medical and scientific knowledge or because of the way in which healthcare is organised

Key issues
- access to information
- interprofessional collaboration and communication
- attitudes and interpersonal skills of professionals

Key facts
- inevitably, prenatal screening is bound up with the issue of abortion — in most European countries abortion is a legal procedure available to women for non-medical as well as medical reasons.
- no need for a genetic diagnosis to end an unwanted pregnancy
- ending a wanted pregnancy because of prenatal detection of an abnormality is stressful and potentially traumatic — akin to bereavement
- despite increasing range of tests available, no evidence of increase in termination for abnormality (in UK approx. 1800–2000 annually for last five years)
- no evidence of women choosing to terminate for (allegedly) minor abnormalities (the cleft lip myth)
- strong evidence for the ability of women to make appropriate choices when given information, opportunity and support (bearing in mind the fact that there is no ‘one size fits all’ outcome)
- not just a pregnancy issue — development of predictive and predispositional genetic testing will be important in other aspects of healthcare — for women themselves (for example with respect to conditions like breast and ovarian cancer) and also with respect to their societal role as guardians of their family well-being

Genetic information is potentially important in non-medical as well as medical areas, although given current knowledge, likely to be some time before applications are widespread. Issues that will have to be addressed include:
- public communication and understanding of the real power of genetic information;
- fair and unfair discrimination in areas like employment and insurance;
- stigmatisation;
- protection of privacy/confidentiality contrasted with right of accessibility by family members, public bodies (e.g. police, immigration officials);
- commercialisation of genetic information.

Conclusion

Genetics does not happen in isolation. The image of the scientist as a disinterested boffin searching for truth no longer holds good (if it ever did). We need to recognise that science takes place in a context legitimated by public assent for the activities of scientists, at least in democracies. There is a responsibility for scientists to secure that assent through a commitment to public dialogue, and to sustain high levels of transparency, especially in potentially sensitive and controversial fields such as genetics, where social and ethical issues are perceived to have particular salience, so that a fair and balanced case for the benefits of genetics can be made and public support sustained for this work.

Borbála Juhász
State policy on gender equality in candidate countries

The question of gender equality in the candidate countries was often seen as an imported question. We, east European women gender scholars and feminists, often struggled with officials, men of power, explaining the meaning of the word, and the importance of a state policy on gender. My personal history, however, is proof that concepts grow from 'import' to 'homegrown' product. As head of department at the Gender Equality Office under the recently appointed minister without portfolio responsible for equal opportunities, who is a sociologist by profession and a feminist too, I can reflect upon the gradual change that occurred in state policy on women and gender equality.

The fruits of 13 years, the time that has passed since the change of regime, always interested the transition researchers; gender issues were always at the forefront of social scientists' scrutiny of our region. Academic research, where coordination is often placed in a west European university and whose language is often English, but obviously includes native scholars and researchers too, gives a more trustworthy picture on state gender policy than many regular country or foreign committee reports since they focus on complying with the expectations or forcing the candidate countries to comply with these. Research that investigates state policies on gender equality or gender mainstreaming mechanisms in the east and central European region includes FP5 projects, such as enlargement, gender and governance (EGG), policy frames and implementation problems: the case of gender mainstreaming (MAGEEQ), and joint programmes such as the equal opportunities for women and men in the european accession process (EOWM) of the Open Society Foundation, Romania, and the network women's programme of the Open Society Institute. All these scholarly endeavours form part of the monitoring process of the candidate countries: how they prepare themselves for the integration into the European Union, especially in the field of equal opportunities given in the *acquis communautaire,* and how the status of equal opportunities — *de jure* and *de facto* — can be assessed.

There is a deeply rooted belief in the region that women's equality had already been achieved during socialism. If we look at women's participation in the labour market, and how the state attempted to facilitate it by setting up childcare facilities, and how by the 1960s women's rights to abortion in most countries was recognised and long-term paid maternity leave was introduced, it supports this argument. In the powerless national assemblies a quota was set up for women, the 'emancipated communist woman' was a strong message, but all this did not change the basic patriarchal pattern of the family (the infamous 'double burden' of socialist women, work and the full workload of childcare and housework) and did not give *de facto* equal status with men. The legendary numbers of participation of women in the socialist labour force, the envy of many west European feminists, was for many east European women more a burdensome duty than an achievement of women's liberation. After the darkest years of communism the family served as a more or less safe shelter from political intrusion, and thus its privacy was heavily protected. This Janus-faced nature of emancipation and the sacredness of the family proved to be very important factors after the transition when statistics suddenly dropped dramatically, and women's labour market participation became lower than the EU average (67.2 % of adult women work in 2000 in the EU, only 60.6 % in Hungary). Campaigning against domestic violence is difficult because the idea of the sanctity of family as a protected private sphere is shared not only by conservative but by liberal circles as well. Any mentioning of a quota representation for women in the public sphere

provoked outcries as a remnant of the communist past where incompetent people gained positions due to positive discrimination.

In the transition period the perception that gender equality had already been achieved was only challenged by a handful of east European gender experts and many Western scholars, who came to the region to investigate the situation of women in the east. Official government attention to the problem was only prompted in the mid-1990s by the preparation for the Beijing Fourth World Conference on Women, where it became clear that the conceptual and legal framework, the institutional structures and the sensitivity of public discourse towards gender equality is very weak.

If we look at the state policies of gender equality in the candidate countries it is obvious that they followed different legal and methodological approaches. Lithuania for example established the Office of the Ombudsperson on Equal Opportunities (meaning the adoption of the Gender Equality Act) in 1999, Bulgaria and Romania introduced general anti-discrimination laws, whereas Hungary at the outset placed the emphasis on labour issues. The enlargement negotiation process meant adjusting the countries' legislation to EU standards on equal pay and equal treatment. Indirect discrimination is prohibited in Hungary and Romania, but the notion of sexual harassment for example is still a new concept for legislators in the region, and its introduction often struggles with obstacles. The Hungarian parliament is just now debating the final version of an anti-discrimination and equal treatment bill.

With or without the legal structures of gender equality, there is a problem with the awareness of these rights and there are very few legal discrimination cases. Other issues concerning women, such as part-time work, involving men in the harmonisation of family and work, and social security schemes, lag behind. Of course no law is effective unless there is a societal understanding to plant it into, unless there are means for its implementation. One of the tools to reach this is gender mainstreaming, the other is a proper institutional background for gender equality. These gender equality offices or departments are usually placed under the auspices of the Ministry of Labour (Czech Republic, Lithuania, Estonia and, until recently, Hungary) or the Ministry of Health, Social and Family Affairs (Hungary between 1999 and 2002, in Romania under the Ministry of Labour and Social Affairs). High-level institutions were established in Poland and Hungary (in the summer of 2003). The Polish one is the Office of the Governmental Plenipotentiary on Equal Opportunities for Women and Men and the Hungarian one is a composite office, the Government Office of Equal Opportunities helping the Minister without Portfolio responsible for Equal Opportunities, where different disadvantaged groups are represented: the Roma, the disabled, and women. Parliamentary commissions on equal opportunities exist in Lithuania and the Czech Republic.

The difficulties these national gender equality authorities face are usually lack of funds, and lack of staff trained in gender studies. Gender issues are generally seen as trivial. Partly because of the belief that during communism gender equality had been achieved already, the level of gender awareness is low. During the transition period when national goals, role models and possible paths forward were being redefined, gender equality did not become a priority. With the exception of a handful of feminist scholars working in academia, and often producing texts in English for outside projects, there were few activists or policy-makers who understood the importance of the question. No wonder that gender issues came to the surface in the mid-1990s as something the EU 'wants us to think about'. This imported nature of the ideas, however, might prove a useful political tool

in the hands of gender experts, as they can confront the decision-makers with the fact that different EU directives support gender issues which should be implemented and the gender aspect is a priority which should be included in our expertise, as this knowledge will be necessary to use in distributing EU funds. EU accession improved the standards of gender equality, mostly influencing the legislative process and the setting up of equality institutions. If these function satisfactorally the general awareness in society for gender issues also grows.

Beyond the progress already achieved, candidate countries need to make sure that gender equality is made explicit and is not lost among broader non-discrimination considerations, something that is simply 'ticked' from the list of EU assignments. One way of doing this is strengthening the institutional mechanism of gender equality, independent from political trends. This is underpinned by a strengthening civil society through women NGOs that critically monitor these institutions, suggest new positive actions and force decision-makers to fully embrace gender equality in practice. In women's issues, civil society and state institutions must work hand in hand.

As the most recent achievement in this field, the Government Office for Equal Opportunities was established within the Prime Minister's Office in May 2003 to represent the issue of social equality on the highest level possible in the Hungarian public administration. The Minister for Equal Opportunities heading the Office is responsible not only for gender equality, but for equal opportunities in a broader sense, including the Roma, the disabled and other minorities. In the field of gender equality the main task of the Government Office for Equal Opportunities is to form, mainstream and implement the policy on gender equality. In the sense of gender mainstreaming it aims to mainstream the policy of gender equality within official government policies. The Office participates in the many-sided activities of European integration, legislation is being prepared, and several ongoing programmes also help women's advancement in the public and private spheres.

The Office has the following priorities: join the ongoing preparatory work of a general anti-discrimination act for the more effective enforcement of gender equality. The operational regulations and spheres of action of the Council for Women's Issues (advisory body comprising representatives of all ministries, NGOs and experts) are also currently under review. In order to publicise the basic theoretical principles and practical information on equal opportunities, we are constantly planning information events and trainings for government officials, NGOs, the Council for Women's Issues and the social partners (e.g. trainings on domestic violence for the police, teachers and public services).

In the process of European integration we participate in the compilation of the national development plan, as well as in the Hungarian documents concerning employment, social inclusion, etc. We also participate as professional counterparts in the Phare programme 'Tackling the gender gap in the labour market' which enhances equal opportunities for women and men by improving the policy environment to support a gender mainstreaming approach and by providing support to the reintegration of women after absence and late integration of economically inactive women into the labour market through the implementation of pilot programmes. Since 1998, Hungary has been active in participating in the Community action programmes on gender equality with successfully implemented projects. We are also looking forward to working in the fifth programme 2001–05.

There are a number of events planned to change general attitudes and preconceptions. The exhibition 'Roma women in Hungary', in June 2003, dealt with the situation of women

in a minority while the international conference ‘Women and men in the European Union’ will be organised in the preparation process for the accession. We also consider the presentation of equal opportunities in the media, and channelling gender equality themes into general public discourse, to be very important. In the field of reconciling work and family the ‘family-friendly workplace’ awards have been given for the fourth time in 2003. We also plan to form a Hungarian women’s lobby to launch the network of women in decision-making in politics and economic life.

In order to approach the widest range of women, it is crucial to involve women NGOs in the work of gender equality as much as possible. We support them financially with project grants every year and we have also started to form a regional network for women NGOs. We are open to all civil initiatives in related fields, for instance in media observation, where discrimination and the prevailing false stereotypes make the need for coordinated action unavoidable.

For the most detailed and focused dissemination of information, the office has a long tradition of publishing materials on gender equality. In 2003 we continue the series ‘The changing role of women’ and the statistical yearbook ‘Women and men in Hungary’ together with the Central Statistical Office. A new publication will be ‘Equal opportunities for women and men in the European Union and Hungary’, as well as a booklet on the CEDAW Convention and all the related official materials in one volume.

It is a pleasure for me to speak at the Enwise workshop in front of scientists. Ever since women achieved the right to study, either by fighting for special exceptions for themselves, or generally for emancipation at the universities, they have been at the forefront of new sciences, whether it be psychoanalysis, sociology, physics or stem cell research. The moment the new science gained recognition and moved to the centre, women were often pushed out of it, and by the time it became a powerful branch of science within academia women were marginalised, with a few exceptions, strengthening the view that science too has a male face. This has changed however. Enwise is only one of the many mechanisms which aim at making sure this shift from centre to periphery should never happen again. I wish you success in this challenging task and responsibility.

József Mandl
Role, tasks and responsibility of the national ethics committees ([1])

The ethical review is based on international and national guidelines, standards and regulations.

Major sources of European and North American bioethical standards
- UNO
- WMA
- Helsinki Declaration
- ICH-GCP
- EU Directives
- Oviedo Convention

Sources determining the health bioethical regulations at national level
- Act CLIV of 1997 on Health Care
- Act XXV of 1998 on Medicinal Products for Human Use
- Act VI of 2002 — Convention on Human Rights and Biomedicine (Oviedo Convention)
- Ministry decrees:
  - 23/2002 (V.9.) — Health Ministry decree on the biomedical research on human beings
  - 24/2002 (V.9.) — Health Ministry decree on the clinical trial of medicinal products for human use and on good clinical practice
  - 34/2003 (VI.7.) — Health, Social and Family Affairs Ministry decree on the Medical Research Council

The structure of the network of ethics committees in Hungary is very complex. There are three different levels of ethical control:

National level — within the Medical Research Council:
- Scientific and Research Ethics Committee (TUKEB): reviews research protocols related to treatment or diagnostic procedures not yet accepted (if invasive intervention is carried out), the clinical testing of medical devices, any research on genetically determined illnesses; it also reviews the research protocols if more than one regional research ethics board would be responsible or where the regional ethics board refers the case to a higher level committee
- Clinical Pharmacology Ethics Committee (KFEB): reviews all clinical trials involving medicinal products
- Human Reproduction Ethics Committee (HRB): reviews all research protocols aimed at the modification of the human genome, related to human reproduction or to prenatal examinations

Providing:
- ethical opinion
- ethical control

Regional level:
12 Regional Ethics Boards (RKEB) nationwide in regional centres and at medical faculties of the universities

([1]) Transcript of a PowerPoint presentation.

Providing:
- ethical opinion
- ethical control

Local level:
Institutional Research Ethics Boards in every health institution where research involving human beings is performed
Providing:
- ethical control:
  - opinion whether the given healthcare institution is able to carry out the research (trained personnel, adequate medical equipment, etc.)
  - supervision of the research by repeated inspections
  - suspension of the research in case of non-compliance with the requirements of the approved protocol
  - protection of the interests of the research subjects (the name of the appointed person has to be indicated on the consent form signed by the subjects)

Each research protocol intending to involve human beings usually has to be reviewed by two ethics committees.

Composition of the ethics committees:
According to the Hungarian Health Care Act, the review of research protocols includes an evaluation both from a scientific and ethical point of view. Accordingly, the composition of the ethics committees has to be multidisciplinary: in addition to medical professionals, representatives of non-healthcare professionals (ethicist, lawyer, clergyman, psychologist) are also members of the groups.

Women in the committees of the Medical Research Council

	Persons	Women	Women (%)	Women MDs (%)
TUKEB	25	8	32	5
KFEB	18	3	17	1
HRB	25	2	8	2
K+F	104	19	18.3	19
RKEB	149	50	33.6	32
TOTAL	335	85	25.4	61

TUKEB: Scientific and Research Ethics Committee
KFEB: Clinical Pharmacology Ethics Committee
HRB: Human Reproduction Ethics Committee
IB: Forensic Medical Committee
K+F: R & D Committee
RKEB: Regional Ethics Committees

Report on the two parallel sessions' debates

Session I:
Ethical and gender issues in stem cell research and tissue transplantation

Chairperson: Mioara Tripsa, RO
Rapporteur: Gábor Pörzse, HU
Speakers: András Dinnyés, HU
Herlinde Pauer-Studer, AT
Sylvia Tomova, BG
Anna Mátay, HU

Scientific highlights

- The latest developments in the field resulted in generation of germ cells (both oocytes and sperm) via cloning technology and embryonic stem cell isolation in animal models. This method would allow males to generate oocytes and sperm, but only oocytes for females.
- The creation of parthenogenetic embryos for stem cell isolation would allow women to have own cell therapy cells from embryos, which would not be able to develop into babies.
- Mixed animal oocyte and human somatic cell embryos might generate embryonic stem cells, therefore it might become possible to generate the cells without sacrificing human oocytes in the process.
- A philosophical approach highlighted the need for 'freestanding arguments' independent from personal views.
- A media case study of a recent controversial debate on umbilical cord blood collection in Hungary highlighted the lack of correct information and follow-up in media, despite the high frequency of reports on the case.

Conclusions

No regulations have been formulated for the very recent scientific developments. A designated scientific correspondent searching for relevant news would allow the EC to shorten reaction time on relevant scientific developments.

Furthermore, such developments highlight the fact that science develops at a much faster rate than ethical and legal discussion and legislation are able to follow. Also, the diversity of the Enwise countries on regulations and public opinion makes such a task extremely difficult. Therefore, a bottom-up approach might be more efficient for the future of stem cell research and applications. It would be based on the fundamental rights of freedom to reproduce, allowing individuals to seek ways to achieve that via newly developed techniques, instead of the presently applied, strictly regulatory approach. Risk assessments and quality control could replace the regulations based on the common ground of a very diverse society.

Strict regulations are driving leading research abroad and underground, as medical needs create a market for 'offshore' high-tech medical services, without any control by society or the scientific community, and restricted only to the richest segment of the society. This situation must be avoided in Europe.

Session II:
Ethical and gender aspects of genetic testing, storage and use of genetic information

Chairperson: Nikolina Sretenova, BG
Rapporteur: Beáta Scholtz, HU
Speakers: Mara Marga, LV
Margit Sutrop, EE
Judit Sándor, HU
Alastair Kent, UK

Exchange of information: patients and scientists/doctors

There is a big responsibility when disclosing information, either from genetic testing or from search results in genetic databases. The system has to be flexible, and take into account:

- that the need for disclosure varies — not everyone requires it, and people can change their minds over time;
- that not all genetic information is equal — sometimes it is only information, and no decisions can be made, no actions can be taken;
- that, if requested by the patient, as complete information as possible has to be provided, making sure that the individuals understand what the results mean, what risks are involved, possible therapies, and what it is to live with that disease — people can be trusted to make sensible decisions if provided with information and the opportunity to decide;
- that there is an important question concerning whom the information should be shared with and disclosed to — results affect not only the individual, but also the family.

There are special conditions for Poland: abortion is not legal. There is increased pressure about stopping prenatal genetic testing.

Society is expected to provide the framework for good genetic counselling, and to encourage the formation of patient support groups, to educate the general public to increase acceptance — this requires financial resources. If this infrastructure if not provided, the danger of coercive decisions increases, e.g. through pressure from family, community, society.

It was recognised that knowing the results of genetic tests/research put an enormous burden on women — decision-making is expected from them. Often it is assumed that women have a duty to know results, for the good of the family. Genetic counselling can follow different strategies by male or female doctors.

Exchange of information between patients and society

In terms of biobanks or genetic banks, sharing of one's genetic information (through providing a sample) can be expected, and usually accepted by the individuals, for the benefit of the society (curing or preventing disease, helping with crime, etc.) and for the benefit of a particular patient group.

Society, on the other hand, needs feedback about the quality of life with a disability, and patient advocacy or support groups have an enormous role in this — make yourself visible!

Exchange of information between scientists/doctors and a third party

This requires strict regulation, especially because anonymity is not always possible, and not always sought. Society is expected to recognise the need for data security and privacy, to provide the criteria and means for secure data storage, as well as to educate the public about possible interpretation of data from genetic programmes. Education is especially necessary since the results can be abused (e.g. for nationalistic interests, but also for the stigmatisation of minorities).

Scientists and society

Continuing communication is needed to make public opinion and scientific opinion known to each other. Informed consent should be given at two levels: from the community, and from the individual. Scientists need to contribute continuously to the education of the general public — responsible leadership of society needs to prompt this contribution, and provide the framework for it. Again, this requires funding. Science journalists are urgently needed to participate in disseminating accurate information.

How can transparency/regulation be achieved?

- provide accurate information to the general public, so that people can understand the purpose of proposed studies or biobanks and the system that regulates them
- ethics committees should be made known, as well as selection criteria for committee members
- gender balanced ethics committees are needed
- representatives of social scientists, philosophers are needed to sit on ethics committees
- international oversight of ethics committees can be beneficial
- ensure objectivity and independence of ethics committees

Conclusions

During the workshop, participants stressed that science is developing at a much faster rate than domestic legislation and regulations are able to keep up with, especially in the Enwise countries, where the transitional shift from communist regimes to market economies resulted in a radical transformation of previous political, cultural, socioeconomic and legal environments. Therefore, a stronger process of democratisation is required, in particular in the bioethical field, where civil society, science and politics are interconnected, where women — and in particular women scientists — could play an important role. A bottom-up approach and the consideration of public opinion were seen as the best means for the correct handling of bioethical issues.

Transparency in bioethical issues should also be ensured by a better representation of different stakeholders (women, social scientists, etc.) in ethics committees and by introducing the role and tasks of these committees to the general public.

Participants underlined, with concern, the lack or the insufficiency of regulation, and of public control, on the outsourcing of ethically sensitive biomedical research in the Enwise countries. Yet in the area of the exchange of genetic information, the responsibility of scientists/doctors and the position of women in related decision-making should also be considered. Concerns about the potential abuse of genetic data for national interests, or for the stigmatisation of minorities, were also expressed during the debates.

Scientists, and in particular women scientists, should pay more attention to the interrelation and interaction of gender and ethics in new scientific developments.

Scientists should not exclude themselves from the education of the general public, nor the media, the role of which was indicated as a priority. Science journalists should provide accurate information in the dissemination of scientific research and should participate in promoting adequate public information campaigns.

Recommendations for the Enwise final report

i. Responsible state authorities (ministries etc.) and/or public organisations should initiate public debates on ethical/bioethical issues, with special emphasis on questions and topics concerning women. Awareness campaigns should also be launched.
ii. Ethics committees should be made better known among the general public and their decisions should be more transparent.
iii. When selecting the members of ethics committees, a gender balanced composition (i.e. at least 40 % female members) and the representation of different viewpoints (social science, philosophy, etc.) should be sought in order to ensure a greater diversity in their composition.
iv. Womens' scientific communities should initiate cooperation among colleagues from different disciplines and promote public initiatives about gender and ethical issues in science. These should focus in particular on informing women about gender aspects of new scientific developments.
v. Scientists should play their role in disseminating information on new scientific developments to the general public and in explaining the possible gender aspects of those results, so that the purpose of research and the systems that regulate it can be better understood.
vi. Science journalists are urgently needed to participate in the dissemination of accurate information on medical and biotechnological developments and in the objective explanation of possible risks. In this context, the Directorate-General for Research should strengthen its network of science journalists and feed it with more information.
vii. The Budapest workshop was intended as a starting point in a series of open debates related to science and society in different societal settings and countries. Further initiatives and follow-up are thus necessary in order to increase public and scientific awareness of ethical/bioethical issues, and it is of course essential to include a gender perspective in all further debates.

European Commission

Starting a debate with women scientists from post-communist countries on ethical issues Enwise Workshop Report - Budapest, October 2003

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