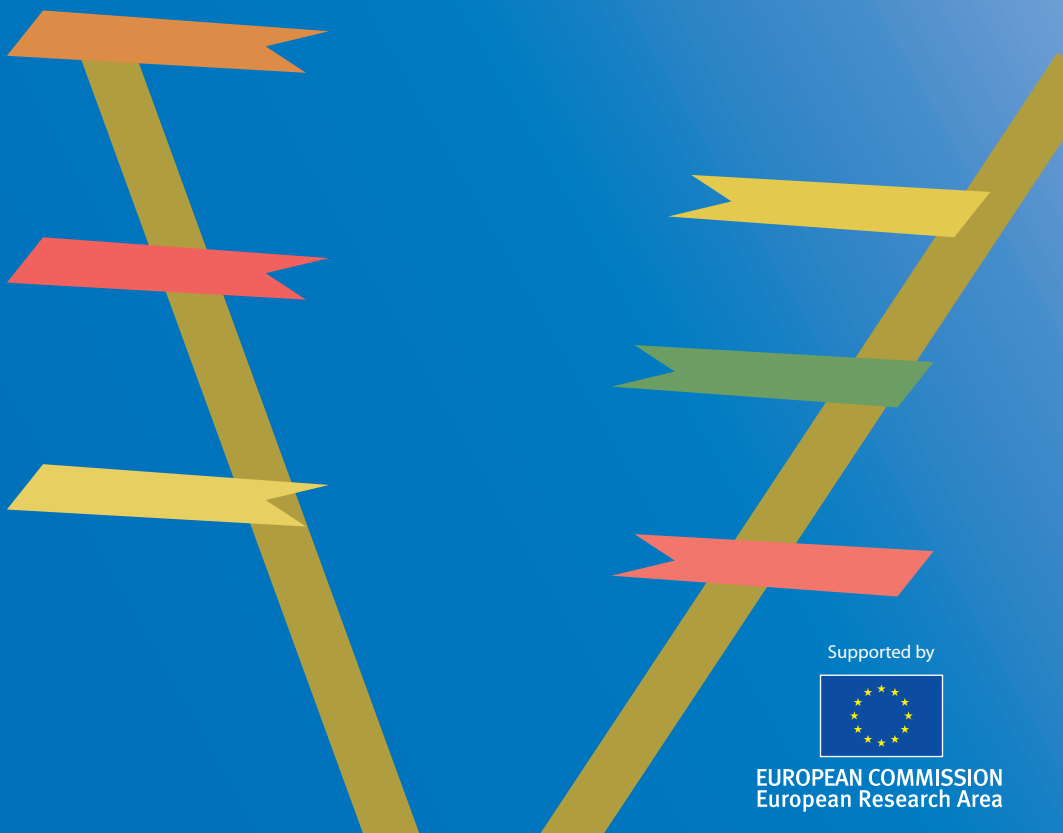
United Nations
Educational, Scientific and
Cultural Organization

open access

National Bioethics Committees in Action



Supported by

EUROPEAN COMMISSION
European Research Area

United Nations
Educational, Scientific and
Cultural Organization

Social and Human Sciences Sector
Division of Ethics of Science and Technology

National Bioethics Committees in Action

Published by the United Nations Educational, Scientific and Cultural Organization
1, rue Miollis, 75732 Paris Cedex 15, France

ISBN 978-92-3-104183-9

Typeset by UNESCO
Printed by UNESCO

Printed in France

TABLE OF CONTENTS

Bioethics Networks: Collaborating Across National Boundaries

Contributors

Harald Schmidt has been Assistant Director at the Nuffield Council on Bioethics since 2002. His academic background spans philosophy, linguistics and history at the universities of Bremen, Oxford and Muenster. He is currently on sabbatical, carrying out research on fairness in resource allocation as a Commonwealth Fund Harkness Fellow in Health Care Policy and Practice at the Harvard School of Public Health. Schmidt is also a Research Associate at LSE Health, working on issues around personal responsibility for health.

Boris Yudin is a professor and a corresponding member of the Russian Academy of Sciences (RAS), where he serves as the Head of Department at the Institute of Philosophy. He is also a Vice-Chairman of the Russian Bioethics Committee under the Commission of Russian Federation for UNESCO. Dr. Yudin is the editor-in-chief of journal «Chelovek» (The Human Being). He represents Russia in the Steering Committee on Bioethics of the Council of Europe.

Rem Petrov is a professor and academician of the Russian Academy of Sciences. He holds the position of Head of the Department of Immunobiotechnology at the Research Center of Immunology Institute. He is chairman of the Russian Bioethics Committee, a former member of the International Bioethics Committee of UNESCO, and currently represents Russia on the Intergovernmental Bioethics Committee.

Jeanine-Anne Stiennon is emeritus professor and honorary dean of the Faculty of Medicine at the University of Mons, Belgium. She is a member and former President of the National Committee on Bioethics of Belgium, as well as a member and former President of the Royal Academy of Medicine of Belgium. Dr. Stiennon is also a member of the International Bioethics Committee of UNESCO.

Vasantha Muthuswamy is a medical doctor of obstetrics and gynecology. She joined the Indian Council of Medical Research (ICMR) as research officer in 1979 and served in various capacities for 29 years until her retirement in 2008 as Senior Deputy Director General and Head of Division of Basic Medical Sciences, Traditional Medicine & Bioethics and Division of Reproductive Health & Nutrition. Dr. Muthuswamy is member of many national and international ethics committees. As the Founder Secretary of Forum for Ethics Review Committees in Asia Pacific (FERCAP), she has conducted a large number of workshops for different stakeholders within India and in more than 25 countries since 2000. Dr. Muthuswamy developed the ICMR ethical guidelines for biomedical research on human subjects.

Jean Martin has been a member of the Swiss National Advisory Commission on Biomedical Ethics since its creation in 2001 and of the UNESCO International Bioethics Committee since 2006. He is a physician trained in public health. Early in his career, he worked eight years overseas (Peru, South-East Asia and tropical Africa). Subsequently, he has been Chief Medical Officer with the Health Ministry of

the Canton of Vaud in Lausanne, Switzerland, as well as Lecturer at the University of Lausanne. He is particularly interested in current bioethical challenges and in medico-legal and human rights issues.

Božidar Voljč is a medical doctor by profession, and a former Minister of Health of the Republic of Slovenia (1992 – 1997). He has also served as a Member of Parliament of the Republic of Slovenia, heading the Parliamentary Counsel for Health Affairs. His international carrier includes various positions held with the World Health Organization (WHO), most recently as a member of Executive Board of the Organization (2006 - 2009). Currently, Dr. Voljč is the Head of Health Gerontology at the Anton Trstenjak Institute in Slovenia.

Jan Helge Solbakk is trained as a physician and a theologian at the University of Oslo and holds a PhD in ancient Greek philosophy from the same university. Since 1996 Solbakk has been Professor of Medical Ethics at the Faculty of Medicine, University of Oslo. He is also Adjunct Professor of Medical Ethics and Philosophy of Medicine at Centre for International Health, Faculty of Medicine, University of Bergen. From 1987-1996 Solbakk served as the first Director of The National Committee for Medical Research Ethics, The Research Council of Norway. In the period of February 2007 to August 2008 he served as Chief of Bioethics at the UNESCO Headquarters in Paris.

Lise Wied Kirkegaard obtained her LLM (Law) degree from the University of Copenhagen in 1994, and her Masters in Professional Communication from Roskilde University Center in 2007. She has a long-standing experience in working in the civil service, such as the Ministry of Health and Prevention and the Ministry of Environment. She has been heading of the Secretariat of the Danish Council of Ethics since January 2008.

Anthony Mullings is currently a Senior Lecturer in Obstetrics and Gynaecology at The University of the West Indies, and a Chairperson of the National Bioethics Committee for Jamaica. He has served in many administrative positions in the hospital, faculty and the University. Dr. Mullings is also a Research Associate in Bioethics Program at the University of Miami.

Yolanda Gómez Sánchez is a Chair in Constitutional Law at the Faculty of Law of the National University of Distance Education in Madrid, Spain, as well as Jean Monnet Chair on European Constitutional Law. She is a former member of the International Bioethics Committee of UNESCO and a current member of the Bioethics Committee of Spain. She is a Director of postgraduate programs on Biomedicine, Biotechnology and Law and Fundamental Rights in the European Union.

Alfred Apau Oteng-Yeboah is the Chairperson of the Ghana National Bioethics Committee. He is a professor at the University of Ghana, Legon. In his previous capacity as the Deputy Director-General of Council for Scientific and Industrial Research (CSIR) of Ghana, he was responsible for the national coordination of research on the environmental and health issues in the country.

Apollonius Osei-Akoto Asare is the Secretary of Ghana National Bioethics Committee and a Programme Officer for Natural Sciences with the Ghana National Commission for UNESCO.

Walter Orlando Lara has a medical background, and is a Director of Department of Regulation at the Ministry of Health of El Salvador. Previously, he has served as consultant at the Pan-American Health Organization and the Inter-American Development Bank.

Volnei Garrafa holds a PhD in Health Sciences and a Masters in Oral Cancer. He is UNESCO Chair in Bioethics and of the Chairperson of Post-Graduate Program (Master and PhD degrees) in Bioethics at the University of Brasília, Brazil. He is President of the Latin American and Caribbean Network of Bioethics of UNESCO – REDBIOÉTICA. He was President of the Sixth World Congress of Bioethics held in Brasília, Brazil in 2002.

Ibrahima Boiro is a professor of biology at the University of Conakry in Guinea. He is also a Vice-Rector for Scientific Research and Director of the Research and Studies Centre on Environment at the University of Conakry. Dr Boiro is the President of National Bioethics Committee of Guinea, and a member of International Bioethics Committee of UNESCO.

Evariste Likinda is a neurosurgeon by specialty, and heads the Department of Surgery at Hospital Centre of University of Mbandaka, in the Democratic Republic of Congo. He is also a Vice-Dean of the Faculty of Medicine of the University of Mbandaka.

Pēteris Zilgalvis is the Head of Unit, Governance and Ethics, Directorate L - Science, Economy and Society, DG Research, at the European Commission. Dr. Zilgalvis obtained his Doctor of Jurisprudence degree at the Law Center of the University of Southern California. He has served as a Regional Environmental Specialist in the Baltic States for the World Bank, Senior Foreign Environmental Law Advisor on the World Bank/Russian Federation Environmental Management Project and Chief Counsel at the Republic of Latvia Environmental Protection Committee (later the Ministry of Environment).

Olga Kubar is the Head of Clinical Department at Saint-Petersburg Pasteur Institute. She is a member of the International Bioethics Committee (IBC) of UNESCO, as well as a member of the Russian Bioethics Committee at the Commission of the Russian Federation for UNESCO. She is also an Ex-Chair and Honoree Member of the Forum of Ethics Committees in the Commonwealth of Independent States. Her primary interest is capacity building of ethical review systems in CIS countries, as well as promoting education and training in research ethics.

Fernando Lolas received his MD from the University of Chile and did postdoctoral studies in psychosomatic medicine, psychiatry and history at the University of Heidelberg, Germany, as well as in the United States. He has been professor at different universities and holds honorary doctoral degrees in Peru, Argentina, and Brazil. He has been the Director of the Bioethics Program of the Pan American Health Organization and is currently the Director of the Interdisciplinary Center for Studies in Bioethics at the University of Chile, a Collaborating Center of WHO.

Introduction

On 26-28 November 2009, an event organized by UNESCO in Mexico City brought together more than hundred experts representing national bioethics bodies from across the world, as well as regional and international organizations working in the field of bioethics. Titled Joint Action for Capacity building in Bioethics (JACOB), this event was a collaborative effort between UNESCO and the European Commission, funded by the Science in Society Programme of the EU's Seventh Framework Programme for Research and Technological Development. It aimed towards reinforcing bioethics capacities of countries that have recently established, or are planning to establish bioethics bodies at the national level.

The national consultative organs often called bioethics committees or councils have become indispensible for addressing a plethora of emerging bioethical issues. The debates, opinions and recommendations generated within such committees are highly sought after by governments that seek to enact policies that optimally balance the tremendous benefits of new scientific discoveries and their potential hazards. Through a constructive, informative and balanced debate, these committees open space for free and open expression of different, often opposing viewpoints existing in various segments of society. Such debates inevitably spill over beyond the confines of committee meeting rooms, and enrich the understanding of a given issue among not only the policymakers and concerned professionals, but the general public as well.

UNESCO derives its mandate to work with its Members States to bolster their national bioethics infrastructure from the Universal Declaration on Bioethics and Human Rights, which states that "independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level". Despite the demonstrated value of such committees in safeguarding the rights of citizens in many parts of the world, they are absent in majority of countries, especially in the developing world. To address this problem, UNESCO has designed Assisting Bioethics Committees (ABC) project, which offers technical guidance and capacity building for the establishment of national bioethics committees, and, once established, for the enhancement of their technical capacities. Besides providing various phases of training for the members of the newly established committees, UNESCO facilitates internships, networking and partnerships with the more experienced committees around the world.

To this date, national bioethics committees in countries ranging from Colombia, Côte d'Ivoire, El Salvador, Gabon, Ghana, Guinea, Jamaica, Kenya, Madagascar, Mali and Togo have benefited from UNESCO's capacity-building assistance. Yet, much work remains ahead; based on the needs expressed by key national stakeholders, discussions are ongoing concerning the establishment of bioethics committees in Bangladesh, Botswana, Cap-Verde, Chad, China, Comoros, Malaysia, Malawi , Mauritius, Niger, Nigeria and Trinidad and Tobago.

The trend towards the formal establishment of national bioethics committees in countries around the world is certain, but it by no means suggests uniformity in the nature of these committees across different regions. The information pulled together in this volume is a clear testament to the diversity

of such bodies, manifested in their organizational structure, size, composition, mode of establishment, rules and procedures, funding sources, and many other characteristics. UNESCO recognizes this diversity, which reflects uniqueness of culture, history and traditions, and tailors the capacity-building assistance to the individual country needs.

Nevertheless, several fundamental principles are discernable as common features of all effective national bioethics committees. Perhaps the most readily distinguishable common feature of such committees is its broad scope of enquiry – in contrast to various other types of ethical review bodies that may operate within the same country, a national bioethics committee does not specialize in any single field, such as the review of medical research protocols, but is rather open to undertaking a broad spectrum of bioethical issues that are salient to the society. Moreover, each national bioethics consultative body represented in this volume is committed to the following three principles – independence from undue external influence, multidisciplinary composition, and pluralism of viewpoints represented on any given issue.

And yet, even these fundamental principles are not immune from variation in their interpretation and application to concrete situations. The authors of the papers in this volume ponder over questions that every committee has had to face. How can a committee ensure its independence when it *is* dependent financially on a particular funding source? What is the most effective multidisciplinary formula for balancing the representation among scientists, philosophers, policymakers, medical and law professionals, religious denominations and lay persons? Where is the limit to seeking pluralism through expending the spectrum of ideologies and beliefs represented in the committee? The reader will find unique approaches employed by each committee to address these challenges.

This book is organized in three sections. The first section includes papers that present multifaceted views on the activities of experienced national bioethics committees. Representatives of committees from Norway, Russia, Denmark, India, Slovenia, Belgium, Switzerland and the United Kingdom share their experiences, pointing out the important characteristics of their consultative bodies, underlining factors that facilitate or hinder the effective work of their committees, and also mentioning the lessons learned for the newly established committees to consider.

The second section is a retrospective of experiences of newly established committees from Spain, Ghana, Jamaica, Democratic Republic of Congo, El Salvador, Brazil and Guinea. The authors convey insider's views on the incentives, as well as the obstacles encountered in the process towards the establishment of national bioethics committees in their countries, and discuss the challenges they face after the official inauguration. The final section brings together papers that discuss regional networks of national bioethics committees and explore the opportunities for collaborating across national boundaries.

The articles complied in this book reveal that bioethics is increasingly prominent on the political agenda of governments around the world, which creates an atmosphere conducive to awareness-raising on pressing bioethics topics and positive interventions from the national bioethics committees. The governments are recognizing and welcoming the indispensible role that national bioethics committees play in shaping and guiding bioethics discourse and practices at the national level. UNESCO and European Commission, in partnership with other organizations working in the field of bioethics,

are committed to continue their collaboration to help countries establish robust national bioethics infrastructures by offering various means for capacity-building, including fostering regional bioethics networks for the exchange of knowledge and ideas.

This publication is a part of this commitment. It has been prepared not only for the members of the national bioethics committees, but also for all stakeholders in the government and the civil society. It is our sincere hope that the book will contribute to the better understanding of the role that the national bioethics committees play as platforms for providing guidance to policymakers, as well as for stimulating increased awareness and informed debate on crucial bioethical issues amongst the general public. The papers presented in this volume, together with the presentations delivered at the JACOB conference and other relevant information, are available online at www.unesco.org/bioethics.

Experienced Bioethics Committees in Action

The Nuffield Council on Bioethics of the United Kingdom: 18 years, 18 reports

Harald Schmidt

Introduction

Unlike many other European countries, the United Kingdom does not have a single government-sponsored national bioethics committee. Rather, a number of organisations and committees work in a complementary manner to consider and advise on ethical issues raised by different areas of science and medicine. One of these organisations is the Nuffield Council on Bioethics.

The London-based Nuffield Council on Bioethics was established by the Nuffield Foundation, a private charitable trust, in 1991. Since 1994, it has been funded jointly by the Foundation, the Medical Research Council and The Wellcome Trust on a five-year rolling system. The funding bodies do not influence the Council's choice of topics, nor its policies or recommendations.

The Council's terms of reference require it:

1. to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
2. to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body; and
3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

The Council has published 18 reports and discussion papers on a range of bioethical issues, including dementia, the forensic use of bio-information, public health, neonatal medicine, animal research, genetic screening, genetically modified crops, clinical research in developing countries, and pharmacogenetics. It is currently considering the issues raised by online medicine and medical profiling, such as commercial genetic testing and body imaging, with a report due in autumn 2010. The Council has also just set up a new Working Party to explore the issues raised by new approaches to bio-fuels. This group will report in winter 2010/11.

How the Council works

Independence is one of underlining principles of the Council. The other is quality. The way the Council works has been designed specifically to ensure that its reports are thorough, authoritative and provide a novel, policy-oriented approach to difficult ethical dilemmas.

The Chair of the Council, currently Professor Albert Weale FBA, Professor of Government at the University of Essex, is appointed by the Nuffield Foundation in consultation with the other funders. The other members are appointed independently by the Council itself. The 20 current members are drawn from a range of fields of expertise, including science, medicine, sociology, philosophy, media and law. They serve on the Council for three years, with the possibility of an additional three-year term. When

vacancies arise, the Council advertises for new members in the national press, through its widely-distributed newsletter and on its website. The Council's Membership Sub-Group, independently chaired currently by Sir Graham Hart, Former Permanent Secretary at the Department of Health, considers and makes recommendations to the Council on future members.

Members of the Council meet quarterly to discuss general business and the progress of current projects. The Council considers possible topics in more detail at its annual 'Forward Look' meeting, and holds focused workshops on selected topics. For an issue to progress to a full examination by the Council, it should be novel, complex, timely, and an area in which the Council can make a distinct contribution.

Once a topic has been identified, the Council establishes a Working Party to examine and report on the issue. The Working Party is usually comprised of 10–18 experts from relevant disciplines. It typically includes two members of the Council and may also include lay members. It meets regularly in roughly two-month intervals over a period of one to two years. The discussions are informed by meetings with stakeholders, visits to relevant organizations, and a public consultation. The Working Party produces their report in consultation with the Council. The Council reviews drafts of each report before it is submitted for external peer review and then approves the final report prior to publication. Each Working Party is supported by two dedicated secretariat staff, typically one Assistant Director and one Research Officer, with the Director monitoring overall progress. The Secretariat comprises eleven full time staff.

In preparing its reports, the Council is not bound by the values of particular schools of philosophy or approaches in bioethics, such as the 'four principles of bioethics'. Rather, ethical frameworks are developed on a case by case basis by Working Parties in consultation with the Council. Explicit frameworks, norms, and principles are then applied consistently to the issue in hand, to underpin the conclusions and recommendations reached in each report.

After a report is published, the Council initiates a programme of follow-up activities, planned and organized mainly by the secretariat's Communications Manager. Initially, media coverage, presentations at conferences and communication with a wide range of stakeholders aim to ensure effective dissemination of the report. As part of this, the Council produces a range of accessible summaries of its reports, available in printed, online and video format. Where permission has been given, responses to the consultation are also made available online, so that readers can judge the Council's work in light of the views submitted. All resources can be downloaded free from the Council's website, and printed copies are available at no cost to developing countries.

In the longer term, the Council monitors and encourages uptake of its recommendations by the appropriate organizations, often through formal and informal meetings. One year after publication of the report, the Working Party is reconvened to ascertain the impact and advise the Council on whether further targeted action would be desirable.

The Council's work is not just focused on reaching today's influential stakeholders – it also seeks to work with future ones through a dedicated education subgroup, which is again supported by a secretariat staff. The group seeks to encourage discussion of bioethics topics among young people, mainly by supporting teachers in the classroom and getting involved in extra-curricular activities.

Position in the UK policy framework

The landscape of policy-making in bioethics in the UK has changed significantly during the Council's history. A review of the regulatory framework for biotechnology was carried out by the government in 1999, after which it decided not to create an official national bioethics advisory body. This decision was taken on the basis that the Nuffield Council, together with other scientific advisory committees, the ethics committees of professional bodies such as the British Medical Association, and some parliamentary committees, already fulfilled the role. Instead, the Human Genetics Commission (HGC) and the Agriculture and Environment Biotechnology Commission (AEBC) were established to advise the government on developments in biotechnology in those respective areas. The AEBC was disbanded in 2005, but the HGC continues to be an active and influential organization. The Council meets with members of the HGC regularly to exchange information about current and future work. The proposal to set up a national bioethics committee has re-emerged occasionally during Parliamentary debates, but has never been approved.

Though not itself a formal national committee, the Council has, through its international activities, been able to compare its work with that of national bioethics commissions in other countries. It has become clear that there are a number of advantages in being a non-government appointed body. The Council is widely perceived as being genuinely independent, and its reports are consequently viewed as non-biased. Experiences in other countries indicate that closeness to Government can be a problem for the way the opinions of national ethics committees are perceived. National committees often experience difficulty in establishing a membership that reflects the various social and political stakeholder interests without diminishing their effectiveness.

In addition, the way the Council works allows it to focus on deeper analyses of issues that are relevant in the longer term. National commissions are clearly useful to governments when there is a need for advice on short term issues of narrow scope. However, the Council is able to anticipate controversy, rather than respond when debates have already become deeply entrenched.

Policy impact

The Council is a non-statutory body and policy-makers are under no obligation to take the Council's recommendations into account. The Council may seem to lack 'teeth'. However, national committees do not necessarily have more influence than independent bodies. Few governments would establish a committee whose recommendations would be directly binding. In practice, most national ethics committees have a purely advisory status and understand their role in a similar way to the Council.

Nevertheless, the evidence indicates that policy makers often do take notice of the Council's work. For example, judges at the European Court of Human Rights recently endorsed the Council's recommendations against storing DNA profiles and samples of innocent people on the UK's National DNA Database (Nuffield Council on Bioethics 2007). The Court of 17 judges unanimously ruled that keeping the samples and fingerprints of two UK men, who had been arrested but never convicted of any crime, constituted a breach of their human rights. The judgment was based solely on a violation of Article 8 of the European Convention on Human Rights – the right to respect for a private life.

In addition, a Working Group led by the British Association of Perinatal Medicine was set up to consider the Council's recommendations on the care of extremely premature babies (Nuffield Council on Bioethics 2006). The group included professional bodies and organizations representing parents. It published its conclusions, which closely matched the Council's, as professional guidelines in 2009 (Wilkinson et al. 2009).

A review of the uptake of recommendations in nine reports published between 1993 and 2005 revealed that on average 53 percent of the Council's recommendations had been taken up. Of course, any analysis of the Council's effect in influencing policy is subject to limitations and the Council cannot claim that changes in policy that coincide with Council recommendations necessarily represent evidence of its influence. However, research and personal contacts often reveal that the Council's work has played a role. Likewise, there may be cases where there is no direct evidence of policy-makers drawing on the Council's conclusions and recommendations, although, in fact, its reports have been considered in relevant deliberations.

On the international scale, the Council is frequently invited to make presentations of its work at European and international meetings, for example by the Council of Europe, the European Commission and the International Association of Bioethics. With reports on genetically modified crops and healthcare related research, the Council has also sought to address ethical issues of relevance in developing country settings, and actively collaborates with international organizations such as the World Medical Association and the World Health Organization. It is also involved with UNESCO's Assisting Bioethics Committees (ABC) Programme which supports developing countries in establishing national ethics committees or similar bodies. The World Health Organization commented that the Council had "contributed significantly to policy development in the area of international research ethics..." (TDR 2007).

Conclusion

Biological and medical research continues to develop at a rapid pace, giving rise to new questions, or novel variations on older ones. The field of bioethics has become more prominent as an area of research, public discussion and debate. It is no longer a subject that can be confined to science, medicine and academia, and the Council must respond to this by ensuring that its work continues to reach a wider audience, promoting understanding and debate about some of the most profound and difficult issues of our day.

REFERENCES

Nuffield Council on Bioethics. 2007. *The forensic use of bioinformation: ethical issues*. London: Nuffield Council on Bioethics. www.nuffieldbioethics.org/forensic. (accessed 27 October 2009).

Nuffield Council on Bioethics. 2006. *Critical care decisions in fetal and neonatal medicine: ethical issues*. London: Nuffield Council on Bioethics. www.nuffieldbioethics.org/forensic. (accessed 27 October 2009).

TDR (Special Programme for Research & Training in Tropical Diseases) sponsored by UNICEF / UNDP / World Bank / WHO. 2007. *Ethical challenges in study design and informed consent for health research in resource poor settings*. www.who.int/tdr/publications/publications/seb_topic5.htm (accessed 27 October 2009).

Wilkinson, A.R.; Ahluwalia, J.; Cole, A. et al. 2009. Management of babies born extremely preterm at less than 26 weeks of gestation: a framework for clinical practice at the time of birth. *Arch Dis Child Fetal Neonatal Ed* 94: 2-5.

The development of bioethics in Russia

Rem Petrov and Boris Yudin

Introduction

The emergence of Russian bioethics dates back to the late 1980s, which means that we can now hail the twentieth anniversary of bioethics in Russia with some justification. Since then, specialists in diverse fields of knowledge have come to focus on the ethical and legal problems raised by the latest scientific discoveries and technological advances in biology and medicine.

In fact, Russia's history of producing comprehensive research on the social and ethical consequences of scientific and technological progress on the one hand and, the ethical dimension of medical practice on the other hand, stretches much further back. But these two areas of research had always been distinct from each other and there was little interaction between them until they began to overlap in the late 1980s, marking the dawn of bioethics in Russia. Since then, the field has developed through interdisciplinary dialogue and cooperation between biologists, physicians, philosophers and lawyers. The Russian Orthodox Church soon also became an equitable partner in that dialogue.

The development of bioethics in Russia has been anything but simple, however. One major obstacle to the development of the field was the lack of familiarity with the term "bioethics" and its meaning, among not only the general public but also scientific experts and political and public figures. Corporate interests had a part to play as well. A significant proportion of physicians struggled to accept that consumers of medical services might wish to be involved in the apparently exclusive world of medicine. Problems were compounded by the cross-sectoral and interdisciplinary nature of bioethics, which means that a broad discussion of bioethics issues (and, indeed, the simple fact of raising them at all) requires contact and cooperation between diverse specialists. A further stumbling block was the widely held opinion that, against the backdrop of the tough financial and economic climate and its effect on the national health-care system in the 1990s, bioethics discussions were somewhat out of place: ethics was the exclusive domain of the leisurely and affluent. Some of these difficulties have been overcome or minimized, while others continue to be problematic.

Formation of Russian national bioethics infrastructure

In the nascent years of Russian bioethics, the ethical and legal issues surrounding human organ and tissue transplantation sparked widespread interest and controversy. As early as 1990, the All-Union Scientific Centre for Surgery of the USSR Academy of Medical Sciences organized a round table on human organ transplantation attended by physicians, philosophers, lawyers and specialists. Materials for the event were published in the popular science journal *Chelovek* established by the Presidium of the Russian Academy of Sciences (cf. "Take my heart…" 1991). Since its inception in 1991, the journal had published articles on bioethics. Shortly after the round table, a major bioethics conference was held in Moscow under the auspices of UNESCO, and transplantation issues were high on the agenda. In 1992, Russia adopted a substantive law on organ and tissue transplantation, giving legal force to many of the provisions on bioethics that had been discussed.

At the same time, there was burgeoning cooperation between Russian specialists and their foreign counterparts in Europe, Canada, the United States of America and Japan. One of the first encounters was devoted to the ethics of the human genome project.

On 15 March 1992, the Department of philosophy, sociology and law of the Russian Academy of Sciences established the Russian National Bioethics Committee (RNKB). The first co-chairpersons of the Committee were the biologist, Academician Aleksandr Baev and the philosopher, Academician Ivan Frolov. They were eventually succeeded by Academician Rem Petrov. The bioethics division of the Institute for Human Studies of the Russian Academy of Sciences was responsible for administering the Committee. The Institute was one of the leading bioethics centres in Russia from its inception until 2004, when it was restructured as the Department for comprehensive human studies in the Academy's Institute of Philosophy. Thereafter, the running of the Committee was taken over by the division, set up in that department, for humanitarian appraisals and bioethics.

The history of the Committee's founding is interesting. In accordance with the primary aim of this multidisciplinary institution, it was to be organized under the Presidium of the USSR Academy of Sciences. But since the very use of the word "bioethics" was unfamiliar to the leadership of the Academy, no decision was taken regarding the establishment of a Committee. Only later did Ivan Frolov propose that the Committee be set up under aegis of the Department of philosophy, sociology and law of the Russian Academy of Sciences. (Soon after the collapse of the Soviet Union in late 1991, the post-Soviet Russian Academy of Sciences started to take a leading role in developing the basic sciences in Russia. Similarly, the Russian Academy of Medical Sciences – RAMN – took over from the All-Union Academy.)

Academician Boris Topornin, who headed the Department of philosophy, sociology and law of the Russian Academy of Sciences, supported the establishment of the Committee and a decision was finally made in favor. Subsequently, committees on biomedical ethics were established under the Russian Academy of Medical Sciences and the Ministry of Health of the Russian Federation. Yuri Lopukhin, an academician from the Russian Academy of Medical Sciences, chaired both committees, which prepared seminal texts such as the three-tome "Biomedical Ethics" edited by Valentin Pokrovsky and Yuri Lopukhin (first volume: 1997, second volume: 1999, third volume: 2002). The authors became leading specialists representing the most diverse fields of medical science.

The 1990s saw a proliferation of medical associations, each attaching great importance to bioethical issues, and the Doctors' Association of Russia even adopted a code of ethics. Similar measures were adopted by the Russian Psychiatric Association – a brave step forward at a time when the reputation of Soviet psychiatry was in tatters as a result of the persecution of dissidents by so-called punitive psychiatry.

Activities of the Russian National Bioethics Committee

In 1993, at a session of the extended bureau of the RNKB, a declaration to the scientific communities and leaders of Russian science was adopted, affirming that Russian science should standardize the regulation of biomedical research involving humans and animals in order to be actively involved in international science. In particular, the declaration stated that it was necessary to carry

out expert assessments of requests for permission to conduct such research, and to found ethical committees for that purpose in all scientific institutions involved in research. It was expected that such ethics committees would be established from grass-roots level by researchers themselves. Following the publication of the declaration, researchers contacted the RNKB requesting organizational and methodological assistance for the establishment of research ethics committees, but the declaration could not be said to have had a significant impact. Only later it became evident that it was far from enough to issue a call on the part of non-governmental organization in order to tackle the task of establishing a system of ethical expertise for research projects in a country as vast as Russia.

Among the scientific events organized by the RNKB was a major conference held in 1994 on ethical and legal issues of biomedical research. It awakened the public interest and another conference was organized in the same year, this time on therapy and care for the terminally ill patients.

Ethics of Human Genome Project

One of the targeted actions of the RNKB was the study of the ethical and legal problems of the human genome project. From 1995 until the completion of the Russian human genome programme, the Committee had an active role to play. This collaboration culminated in the publication of the collection entitled *Ethical and legal aspects of the human genome project: international documents and analytical material* (Ivanov and Yudin, 1998). At the ninth annual conference of the human genome project, held in Chernogolovka in 1999, participants of the project adopted the Declaration on ethical principles for conducting research and medical interventions relating to the human genome (Yudin, 2000).

Analysis of legislation

The RNKB took an active part in expert assessments of legislative and other regulatory documents, both national and international. Examples include acts on psychiatric assistance and the protection of human rights (1992), on the health-care legislation of the Russian Federation (1992), on the prevention and control of infectious diseases (1998), and on the temporary ban on human cloning (2002). The act on the prevention and control of infectious diseases contained many provisions on the protection of vaccinated patients, drafted and published previously in the report of the RNKB (1994).

Bioethics education

The development of bioethics in Russia advanced considerably with the introduction in 2001 of mandatory bioethics courses for all students of medicine and pharmacology. The Ministry of Health took the lead and organized a number of conferences on bioethics. The training and further education of teaching staff for bioethics is still highly topical.

Over a number of years, the issue of exactly who should teach biomedical ethics – physicians or philosophers – was hotly debated; medical schools adopted various approaches. A few years ago, a particularly thorny affair was splashed across the pages of Russia's leading medical newspaper, the *Medical Gazette*. In our view, cooperation was more important than opposition or competition between physicians and philosophers on the issue. And today that opinion is becoming more prevalent.

Another problem worth mentioning was the teaching of bioethics in biology and biotechnology higher education institutions and faculties. Today, bioethics issues frequently arise not only in connection with the latest technological achievements in medicine, but in the context of applying biotechnology in agriculture and industry, sport, space exploration, and the protection of the earth's biosphere. The boundary between bioethics and environmental ethics has always been somewhat indistinct, and today it is blurred. Bioethics courses are already being taught in many educational institutions that train specialists in the biological sciences and technology. However, much more could be done to devise bioethics courses and apply them in all higher education institutions and to train teachers qualified to deliver such courses.

The interdisciplinary nature of bioethics

Given the interdisciplinary nature of bioethics, consideration should go to the need to educate lawyers, sociologists, psychologists and journalists. Representatives of these disciplines and professions often need to know about bioethical problems and, as demonstrated by the recent scandal in a Moscow hospital in connection with the removal of organs from a dead patient for transplant purposes, not all such professionals have the required level of knowledge. In their thirst for sensation, some journalists break the ethical rules of their profession, presenting society with an image of physicians as people who are prepared to commit criminal acts to obtain transplant organs. The incident dealt a harsh blow to Russian transplant surgery – within a few months transplant operations in Russia had all but ceased, and highlighted the need for building the capacity of the media to engage in a well-informed and constructive public debate on various bioethics topics.

One of the features of bioethics is its close link with the legal sciences. Ethical consideration of the social and human problems posed by new biotechnologies often points to a need for legal regulation. In all cases, conflicting interests need to be reconciled when parties interact.

By way of example, let us consider human organ transplanting. Here the parties include the recipient, for whom an organ transplant might be the only means of survival, and he or she must often endure a long wait for the operation; secondly the donor (whether alive or dead) from whom the organ is removed, and his or her relatives; thirdly, the transplant surgeon carrying out the operation, who is acting in the recipient's interests; fourthly, the physicians caring for the donor, who are acting in his or her interests (in case of the dead donor, until brain death has been certified); and finally, the health professionals acting as intermediaries between the medical team caring for the donor and the team performing the transplant. Of course, the interests of all parties cannot always coincide, and legal regulations are called upon to settle any conflicts of interest.

Cooperation with international and regional organizations in bioethics standard-setting

In general, the past few decades have seen a sharp rise in the number of regulatory acts governing biomedical and biotechnological activities. Some acts of domestic legislation are listed above. In addition, an increasing number of legal documents on bioethics are being drafted and adopted by international organizations, including intergovernmental organizations such as the United Nations, UNESCO, the World Health Organization, UNAIDS, the Council of Europe, the European Union, and

non-governmental organizations such as the World Medical Association, the Council for International Organizations of Medical Sciences (CIOMS), the International Association of Bioethics, and so on. At a regional level, the Inter-Parliamentary Assembly of the Commonwealth of Independent States (CIS), to which Russia is a member, has adopted a number of regulatory acts (model laws) on bioethics.

Russian specialists in bioethics play essential role in drafting of some international legal instruments. They were actively involved in preparation of such documents as the Universal Declaration on the Human Genome and Human Rights (1997) and the Universal Declaration on Bioethics and Human Rights (2005). As part of the process of preparing the second document, a UNESCO regional seminar was held in Moscow in January 2005, and several of its recommendations were reflected in the final version of the Declaration. Rem Petrov has for a number of years served on the UNESCO International Bioethics Committee (IBC), a body that comprises the leading world experts in the field. The Committee at present includes the doctor of medical sciences Olga Kubar. Russia was also represented on another UNESCO body, the Intergovernmental Bioethics Committee (IGBC).

From 1998, Russian representatives began to take part in the work of the Steering Committee on Bioethics of the Council of Europe (CDBI). Specialists from Russia took part in working groups established under the auspices of the CDBI for the preparation of separate legal acts.

Among the legal acts adopted at the time by the Council of Europe was the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, otherwise known as the Convention on Human Rights and Biomedicine, which was adopted in 1997. It was a fundamental instrument that covered a broad range of bioethical issues and paved the way for the adoption of more detailed additional protocols for regulating some of the problem areas of biomedicine. A number of additional protocols were subsequently drafted and adopted on the prohibition of human cloning (1998), human organ and tissue transplantation (2001), biomedical research (2004), and genetic testing for medical purposes (2008).

Unlike previously mentioned declarations, the Convention and its additional protocols are legally binding for countries that have ratified them, so that their domestic legislation must comply with the international standards set out in these instruments. All these standards are intended to protect the health, rights and dignity of patients and participants in biomedical research. Unfortunately, Russia has not yet ratified the Convention or any of its additional protocols. Meanwhile, at various conferences and seminars in Russia, multitude of resolutions have been approved requesting to join to the Convention, submitted later to the lower chamber of the Russian parliament, the State Duma. The reasons for non-ratification are purely bureaucratic: the Convention and its protocols are essentially interdepartmental documents, but up to now no single department in Russia will take responsibility on its own for implementing the necessary agreements.

With respect to Russia's position regarding the additional protocol on the prohibition of human cloning, the situation is rather different. A commission established by the Ministry of Industry and Science led by Rem Petrov prepared Russia's position on the issue. Ratification of the additional protocol prohibiting human cloning was considered to be inappropriate; a regulation was therefore adopted to establish a temporary ban, or moratorium, rather than a permanent one. The aim was to ensure the

flexibility required to respond effectively to technological advances in the field and to take account of possible subsequent changes in opinions of Russian citizens on the matter.

In 2002 an act was adopted to bring the temporary ban into force for a period of five years. The act received high praise from the Council of Europe itself but expired in 2007 and so far no replacement legislation has been adopted on human cloning. In October 2009, however, at a session of the Presidium of the Government of the Russian Federation, it was decided to extend the ban. In March 2010 the law was adopted by the Russian Parliament.

The Universal Declaration on Bioethics and Human Rights: implementing the principles

The activities of the bioethics community in Russia have intensified since the adoption of the Universal Declaration on Bioethics and Human Rights. UNESCO went beyond the adoption of the Declaration by setting itself the task of facilitating the implementation of the Declaration's principles in various countries. With the support of UNESCO, Russia has implemented or is in the process of implementing a series of projects to advance bioethics.

The first of these projects was a major international conference entitled "Social Justice in Health Care: Bioethics and Human Rights", which was held in the Moscow University for the Humanities in early December 2005, about six weeks after the adoption of the Declaration. The conference had been organized by UNESCO's Division of Ethics of Science and Technology. The event demonstrated that Russian bioethics had began to open up new problem areas related to participation of civic society in formulating, implementing and evaluating health-care policy as one of the most crucial areas of contemporary life (Yudin, 2005).

Another project supported by UNESCO sought to increase the knowledge of journalists reporting on bioethics issues and to produce draft recommendations for covering such issues in the media. The Russian media increasingly often contain coverage of bioethical issues that is devoured by the general public. Unfortunately, the media whet the public's appetite with appealing but often inaccurate information on issues such as the potential of certain biomedical technologies and the risks associated with them. Many people base major decisions about their health and that of their relatives on information found in the media. During implementation of the project, which was supported by UNESCO's Moscow Office and the Russian Union of Journalists, specialists in bioethics Pavel Tischenko and Boris Yudin held a series of seminars and master classes for journalists in 2006-2007 in Moscow, Dagomys, Barnaul and Kazan. Two guides on bioethics issues for journalists were published (Tischenko and Yudin, 2006; Tischenko and Yudin, 2008). The project continued with a master class for journalists held in Armenia in 2008.

One of the realities of the modern world is the significant number of natural and human-made disasters claiming many victims. A common response is for armies of aid workers from all over the planet to arrive on the scene. In the course of the rescue operations, it sometimes happens that deep cultural rifts between the local population and aid workers give rise to difficulties and even conflicts, with particularly serious effects in what is already an emergency situation. During implementation of the project, which was supported by UNESCO's Moscow Office, a manual was prepared including ethical principles and recommendations to be followed in order to avoid such conflicts, and relevant

information was provided on the standard-setting documents of UNESCO and the World Medical Association.

It is worth mentioning one further project supported by UNESCO. The aim was to analyse the existing legal and regulatory framework for protecting human rights and dignity of those involved in biomedical research. The analysis was carried out to identify existing deficiencies and gaps in domestic legislation and to make recommendations to improve it. During implementation of the project, information and analytical materials were collected, along with international materials (most of which were being published in Russian for the first time) and Russian regulatory legal acts governing biomedical research. In addition to this, a draft federal law on biomedical research was elaborated (Yudin, 2007).

A major project was implemented with the support of UNESCO and the participation of bioethics specialists from CIS countries, setting out methods for the ethical regulation of biomedical research. The project culminated in the publication of the book, in Russian and in English (Kubar, 2007).

With the support of UNESCO and the Fogarty International Centre Fund operating under the United States National Institutes of Health, a Russian bioethics website was created at www.bioethics.ru/. It contains much useful information on bioethics projects in Russia, Russian and international science events, domestic specialists in bioethics, relevant academic faculties and centres, and so on.

The Russian Bioethics Committee under the National Commission of the Russian Federation for UNESCO

Shortly after the adoption of the Universal Declaration on Bioethics and Human Rights, Russia began to prepare the establishment of the Russian Bioethics Committee (RKB) under the National Commission of the Russian Federation for UNESCO. The Committee was established by a decision of that Commission's General Meeting on 25 April 2006. It was chaired by Rem Petrov and comprised biologists, medics, philosophers and lawyers.

The RKB is an independent interdepartmental body. Its diverse mandate includes:

- drafting a national position on bioethics issues;
- assessing international documents and projects relating to bioethics, and promoting their ratification by the Russian Federation;
- expert appraisal of international and legal documents and legislative and regulatory acts of the Russian Federation to assess their compliance with bioethics obligations of the country
- monitoring compliance with international and domestic bioethical norms when carrying out biomedical research and in practical health care; and
- identifying and analysing new trends in development of bioethical norms and international practice to ensure that Russian ministries and departments respond effectively to change.

Following its establishment, the RKB has actively pursued its mandate by launching an initiative to extend the period of validity of the federal law on the temporary prohibition of human cloning; advocating the ratification by the Russian Federation of the Convention on Human Rights and Biomedicine (with reservations on Article 20, 2, ii); carrying out an expert assessment of the Convention's draft additional protocol on genetic testing for medical purposes; adopting a position

on euthanasia; initiating, organizing and conducting the first Russian congress on bioethics (with international participation) entitled "Bioethics and human rights" (held in Kazan, Republic of Tatarstan, September 2008); and holding a debate on ethical and legal issues surrounding the transplant of human organs and tissue in Russia, and formulating proposals to amend existing legislation.

The RKB issued a statement on euthanasia following a proposal put forward by one of the members of the Council of the Federation (one of the chambers of the Federal Assembly) regarding the adoption of legislation to legalize the withdrawal of life-support treatment under certain circumstances. The proposal was hotly debated in the media.

The statement by the RKB in May 2007 affirmed that "Russian legislation prohibits euthanasia, and this rule is broadly consistent with the position of Russia's medical community. However, there has recently been increased support for legalizing euthanasia. This position is also backed by some doctors, lawyers and politicians". To some extent, such views could be explained by the current demographic situation in which the Russian population is ageing. In many cases, patients suffering from incurable diseases (particularly cancer patients) lack access to the medical care matching international standards.

Supporters of euthanasia justify their position by saying that it is important to recognize a person's right to die in dignity, control his or her own life, and end it when it becomes unbearable; they also emphasize the need to care for patients in severe physical and mental distress. The problem of euthanasia, when seen in this light, has entirely objective roots, and sociological data show that many Russian citizens are in favour of legalizing it.

The RKB takes the view that it would be unwise to make hasty decisions on the matter that might have far-reaching and harmful social, legal and moral consequences. At the same time, the solution is not to suppress the issue or attempt to push through a behind-the-scenes decision based on the opinions of a minority of experts. In the view of the committee, any legal measures in this field should be adopted only if they have been understood and accepted by the Russian society at large.

In this connection, the RKB proposes to work with the active participation of the media to launch a broad public debate on euthanasia and how to deal with patients with incurable diseases and their families. The debate will help to inform Russian citizens about these issues and clarify the attitudes of the medical community, social and political movements, religious faiths, and the general public.

Conclusion

One of the main aims of the RKB is to facilitate coordination between and consolidation of the Russian bioethics community, which is now extremely diverse in disciplinary and geographical terms. Bioethics has developed beyond Moscow and St. Petersburg, spreading to Volgograd, Yekaterinburg, Kazan, Krasnoyarsk, Makhachkala, Novosibirsk, Samara, Tomsk, Yakutsk and other Russian cities.

The fast-growing community of Russian bioethicists is facing many problems requiring a comprehensive analytical approach and broad social debate. Over time, the number of problems requiring bioethical consideration will increase. Today, for example, the bioethical perspective is used to analyse the problems posed by new technologies – not just biomedical ones, but nano-biotechnology, genome intervention, and those that stand at the crossroads between the cognitive sciences and

neurophysiology. Our expectations of all these technologies far surpass any results obtained, but it is not too early to consider potential social and moral consequences – which are often far from positive – before they become irreversible.

Noteworthy too is the present-day trend for biomedical technologies to be increasingly used to solve problems far beyond the traditional scope of medicine. This may concern, for example, enhancing high-performance sport, solving personality problems with pills, and strengthening mental or physical capacities.

REFERENCES

Ethical and legal aspects of the human genome project: international documents and analytical materials. Ivanov, V. and Yudin, B. (eds.) Moscow, RNKB, 1998.

Kubar, O. (ed.). 2007. Ethical review of biomedical research in CIS countries (social and cultural aspects). Saint-Petersburg, Phoenix Publishers.

Round-table discussion. 1991. Take my heart – I'm dead! (*Vozmite moe serdtse – ya umer!*), *Chelovek*, No.4, pp 93-101.

Tischenko, P.D.;Yudin, B.G. 2006. *Bioethics issues in the media*. Moscow. Eslan publishers.

Tischenko, P.D.; Yudin, B.G. (eds.).2008. *Bioethics and media: recommendations for journalists*. Moscow. Union of the Russian journalists' publishing house.

Yudin, B. G. (ed.). 1994. *Vaccinoprofylaxis and human rights*. Moscow, RNKB.

Yudin, B. G. 2000. The Human Genome Programme in Russia and its ethical principles. *Law and the Human Genome Review* 12: 237-241.

Yudin, B.G. (ed.). 2006. *Social justice in health care: bioethics and human rights*. Moscow, Moscow University for humanities' publishing house.

Yudin, B.G. (ed.). 2007. Analytical materials for the project "Analysing the regulatory legal framework in human rights in the context of biomedical research and drafting recommendations for its improvement". Moscow, Moscow University for humanities' publishing house.

The Belgian Advisory Committee on Bioethics

Jeanine-Anne Stiennon

Introduction

The Belgian Advisory Committee on Bioethics was formally established on 15 January 1993 under a Cooperation Agreement between the Federal Government, the French-speaking Community, the Flemish Community, the German-speaking Community and the Joint Commission for Community Matters. It commenced activities in January 1996.

The Committee is independent of the authorities by which it has been established. Its duties are twofold:

1. to provide advice on research matters and their applications in the fields of biology, medicine and health care; these different matters are to be studied from the ethical, social and legal points of view, particularly from the standpoint of respect for human rights; and
2. to keep the public and the authorities informed about these issues.

Structure of the Committee

The Committee's membership is multidisciplinary and pluralist, and lasts for a period of four years. Its composition ensures balanced representation of ideological and philosophical movements, the genders (male and female) and professional fields of specialization (such as academics, doctors, philosophers, legal experts, sociologists, etc.). To strike a linguistic balance, there is an equal number of Dutch and French speaking members (the latter include two German-speaking members).

All members act in an individual capacity and are in no way accountable to the institutions or groupings by which they have been nominated. Full information about the Belgian Committee can be found on its website: www.health.fgov.be/bioeth.

The functioning of the Committee

Article 35 of the Committee's regulations provides that Committee opinions shall reflect the various viewpoints expressed. The final text of opinions is not put to the vote but is adopted by consensus. Article 36 provides that the Committee may decide, at the last meeting on a topic, to allow a reasoned, individual and anonymous note to be annexed to the opinion. The Committee's operating methods with regard to consensus and dissenting views differ from those followed by other national and international committees. Gilbert Hottois, a philosopher who is a member of the Committee and a former member of the European Group on Ethics in Science and New Technologies (EGE), has conducted a highly relevant comparative analysis of the way in which the Committee and other ethics committees operate. (Hottois, 2009)

The non-consensus rule

Since it began its activities in 1996, the Belgium Committee has taken the view that it has no mandate to forge compromises between the different viewpoints expressed by its members, reflecting as they do the great diversity of Belgian society. Owing to its advisory function, the Committee is in contact with political authorities that have an elected democratic mandate and are thus in a position to make compromises and regulations on bioethical matters.

The Committee, as a pluralist and multidisciplinary body, has decided that it will examine the issues submitted to it without seeking consensus on the viewpoints expressed. On the contrary, each member is expected to reflect on the ethical content of problems on the basis of his or her convictions and personal and professional experience. Every viewpoint shared by at least two members is included in the opinion, together with the supporting arguments. If a viewpoint is upheld by only one member, the decision may be taken at the last meeting on the subject to annex it to the opinion in the form of an unsigned individual note.

Over time, all members have understood that the aim is not to convince other members of the correctness of their own view, the important thing being to listen to and understand the basis of the others' positions and set forth their own as clearly as possible. Opinions are drafted by select committees and submitted to the Committee in plenary meeting, at which new considerations, reflections or interpretations may be put forward. The opinion may be reviewed in the light of these contributions. The final opinion is approved by consensus at a plenary meeting.

This is a fairly complex and time-consuming process, but in practice it has given everyone the opportunity to develop a genuine respect for others' ideas in a climate of tolerance and calm discussion, with the very real benefits this brings. Following the non-consensus rule, the Committee issued 49 opinions between May 1997 and April 2009. Although they express the plurality of views, many opinions have elicited unanimous positions on specific matters.

Special characteristics of the Committee's approach to consensus and dissent

Given the Committee's pluralist approach to delivering opinions, it is interesting to analyse the extent to which final opinions delivered in a climate of untrammelled analysis conjoined with a precise discussion procedure roughly reflect the viewpoints of Belgian society.

In the study by Gilbert Hottois mentioned above (Hottois, 2009), an analysis of the first 32 opinions (1997-2004 period) identifies seven unanimous or near-unanimous opinions and five opinions in which there was clearly a divergence of views. The other opinions combine agreement on some points with disagreement on others. The 17 opinions delivered during the 2005-2009 period bear out this analysis, although profound divergence of opinion was less common.

Consensus opinions have essentially related to scientific and technical issues and have been based on some major principles of bioethics and fundamental human rights that are widely shared in Europe. They have not concerned the embryo or the end of life, issues on which views have diverged, although convergent positions have emerged on specific points in these cases too.

Conclusions

The particular features of the operating methods implemented by the Belgian Advisory Committee on Bioethics, a national body responsible for drafting general opinions for use by the legislative authorities and for public information, highlight the importance of consensus on procedures under which dissent on the actual substance of an opinion may be expressed. These methods allow expression to be given to the very great diversity of ways in which the ethical aspects of life in society are formulated and evaluated by the various sectors of the population.

Belgian society universally subscribes to the concept of freedom with responsibility within the framework of the Universal Declaration of Human Rights. It nonetheless wishes to have the nuances of views on the subject to appear in the public debate and be recognized both legally and sociologically so that, within the limits of the law, they can reflect the independent experience of citizens as relating to their ethical aspirations.

The ethical thinking behind the advices issued by the Committee has been taken into consideration by the Belgian authorities in the drafting of certain legislation. Among the legislation concerned is the euthanasia law of 8 May 2002, the in vitro embryo research law of 11 May 2003, the law on human experimentation of 7 May 2004, the law on medically assisted procreation of 6 July 2007 and the bio-bank law of 19 December 2008. Information about this legislation can be found on the website of the Belgian Official Journal: http://www.cass.be/loi/loi.htm.

REFERENCES

Belgian Advisory Committee on Bioethics webpage www.health.fgov.be/bioeth

Hottois, G. 2009. *Dignité et diversité des hommes*, Vrin, Paris, 198 pp.

The Central Ethics Committee on Human Research in India

Vasantha Muthuswamy

Introduction

"Ethics" is a generic term for referring to the moral code of conduct in a civil society. It not only concerns the rules, customs and beliefs of a society but also the scholarly efforts to interpret and follow them. According to the Oxford Dictionary, ethics has been described as "a set of principles of morals; science of morals; and rules of conduct of a group, organization or an individual". Ethics and values have found interesting expressions in different cultures and societies throughout the evolution of humankind. Within these societies, ethical codes of conduct have been prescribed to different professions. The ethical code of conduct for medical professionals and physicians existed since times immemorial, the most ancient reference being found in the *Caraka Samhita* of *Ayurveda* (1st –2nd century AD) in India, which describes the physician's duties towards patients and others working in the profession. However, the most well known code for medical professionals is the "Hippocratic Oath" (600 AD) of the Greco-Roman period. All such codes have been founded on the basic concept of "non-maleficence" *i.e.* "do no harm" which was the driving principle for all physicians in handling of their patients, resulting in a fiduciary relationship between the two. Thus, medical ethics is a conglomerate of moral obligations which govern the professional practice. Most of the Medical Councils around the world have thus prescribed the codes of conduct for medical professionals for their respective countries.

The Medical Council of India, which is the statutory body established under an Act of Parliament and is vested with the power to regulate standards of medical education and practice, promulgated the Code of Ethics in 1956 (MCI 1956), to be followed by all the registered medical practitioners in the country. Any violation of the Code may lead to penalties, including cancellation of registration. The document describes the decorum, duties and social ethics of physicians and prescribes the standards of conduct appropriate to a good physician. Such a professional decorum, surrounded by an aura of scientific knowledge related to health and diseases, and based on the idea that all physicians were decent, responsible, competent and trustworthy persons, satisfied society for centuries. The prestige associated with this profession in most societies is based on its contribution to the well-being of the society and on the tradition of adhering to the principles of doing no harm, dedication to relieving pain and suffering, and maintaining confidentiality, trust and fairness.

The Indian Council of Medical Research (ICMR)

The Indian Council of Medical Research (ICMR) is the premier autonomous body of the Government of India for planning, promoting and coordinating biomedical research in the country. Until recently, the ninety-eight years-old ICMR has been playing a conventional role in carrying out its mandate of supporting intramural and extramural programmes of research – basic, applied, as well as operational. However, the Council has been adapting new strategies from time to time for

strengthening research capabilities in the country. Today, the basic strategy of the Council is focused on fostering a "research culture," with the sub-strategies of (a) improving existing infrastructure or developing new infrastructure where necessary (b) advocacy and lobbying (c) awareness building on research, from the highest level to the community (d) fostering community support and (e) promoting an environment conducive to innovative research.

The origin of the ICMR goes back to 1911, a year when "the Indian Research Fund Association" (IRFA) was set up in response to the plague epidemic of the late 19th and early 20th century in India. The organization subsequently expanded its activity to deal with leading health problems in the country, such as malaria, nutritional deficiencies, viral diseases, reproductive health, and cancer, and became the Indian Council of Medical Research in 1949 after the country's independence from colonial rule. Subsequently, it developed an institutional network by establishing 21 permanent institutes around the country dealing with specific diseases and six regional centers tackling the health problems of the specific regions such as the desert, north east, tribal region, remote tribal islands etc. During this period, it also developed into a formidable funding agency for supporting medical and health research in the country. In fact, this was the only agency funding medical research in the country for the first 50 years until the establishment of other agencies, such as the Department of Science and Technology, the Department of Biotechnology, and the Council of Scientific and Industrial Research.

Keeping with the new developments in science and their implications on human and animal rights, the guidelines for ethical practices in studies involving human and animal subjects have evolved over the years. A policy document on ethical issues involving research on human subjects was released as early as 1980 by a Central ethics committee at the ICMR headquarters at New Delhi, which functioned for over 20 years examining proposals related to reproductive health.

The recent advances in science and technology, which transformed what until recently used to be considered science fiction into reality, brought about numerous ethical dilemmas. New developments in biotechnology, genomics, genetic engineering, organ and tissue transplantation, new reproductive technologies, cloning, medical devices, recombinant products, surgical innovations, and life support systems pose challenges to the conscientious researchers and call for careful scrutiny by appropriate scientific and ethics committees. These new scientific developments have rendered the 1980 ethical guidelines inadequate in addressing the related ethical challenges. The revised "Ethical Guidelines for Biomedical Research Involving Human Subjects" (ICMR 2000) published in 2000 elaborated on 12 general principles and provided details on 5 specific areas: clinical trials, epidemiological research, human genetics research, organ transplantation and assisted reproductive technologies.

The latest developments in biomedical science and practice necessitated further review and updates to the existing guidelines – a task which led to the publication in 2006 of "Ethical guidelines for Biomedical Research on Human participants" (ICMR 2006), available on the ICMR website (www.icmr.nic.in). The latest version elaborates on clinical trials, describes different types of ethical review procedures, the nuances of stem cell research and therapy, and the global issues related to bio-banking. The document requires all institutions conducting medical research to follow these guidelines in word and spirit and to ensure the approval of all research proposals by a duly constituted institutional ethics

committee (IEC). The roles and responsibilities of these ethics committees and the details of the ethics review procedures are elaborated under the chapter on "Ethics Review Procedures".

Efforts are underway to give these guidelines a legal status, thereby mandating the creation of ethics committees in all institutions, with an aim to conduct quality ethical review of biomedical research on human participants. Any violators of guidelines would be subjected to penal provisions. It should be noted that the amended Drugs and Cosmetics Act of 2002 and the amended Medical Council of India Act of 2002 already include the compliance to ICMR ethical guidelines as a mandatory requirement for clinical trials and research by physicians. The pending bill proposes the establishment of the Biomedical Research Authority and the renaming of CECHR as the National Ethics Committee, with a mandate to register and monitor all the Independent Ethics Committees (InECs) and Institutional Ethics Committees (IECs) / Institutional Review Boards (IRBs) in the country.

The Central Ethics Committee on Human Research (CECHR)

A new Central Ethics Committee on Human Research (CECHR), set up by the Director General of ICMR in 1996, assumed the responsibilities of a national ethics committee by evaluating and providing views on nationally relevant and sensitive issues on clinical research for the Ministry of Health, as well as for other Ministries and Departments of the Government of India. Some of the recent policy decisions taken by the National Ethics Committee relates to HIV vaccine trials, rotavirus vaccine trial, combined anti TB – anti HIV drug trial, national HIV surveillance, transfer of biological tissues, leishmania vaccine trial, etc.

A Bioethics cell was set up within the Council to address various bioethics issues, including revising existing and developing new guidelines for ethical issues stemming from recent advances in science and technology, such as stem cell research and therapy, assisted reproductive technologies, bio-banking and safety evaluation of foods derived from genetically engineered (GE) plants. Furthermore, research methodology workshops, good clinical practice courses, biostatistics courses, training in animal and human ethics, specialized teaching and training in modern biology are also pursued vigorously in various medical colleges and research institutions to bring about capacity building amongst researchers. The Council has international collaboration with number of countries in the area of Bioethics. The Bioethics cell also maintains linkages with the Forum for Ethics Review Committees in Asia-Pacific (FERCAP) and Strategic initiatives for Capacity in Ethical review (SIDCER) – the initiatives supported by international agencies such as World Health Organization (WHO), UNESCO, and UNAIDS. Large-scale capacity building activities are undertaken by way of training programmes and workshops organized to educate the different stakeholders in research from India as well as from other countries in the region, thereby playing a leading role in promoting Bioethics education and training.

The CECHR web-site lists the activities undertaken by the Bioethics cell, provides format for different submissions for the ethics review, and gives details of the different standard operating procedures related to the activities of the Institutional Ethics Committees. It also provides linkages to relevant international sites on various topics of bioethics both for Animal welfare and Human experimentation.

Development and application of a core bioethics curriculum

The ICMR received a Fogarty planning grant from the National Institutes of Health, U.S.A., to develop a bioethics curriculum. Through the Medical Council of India – the statuary body for medical education in modern medicine, this core curriculum was to be uniformly applied throughout the country. Subsequently, a four-year training grant for applying this curriculum at various levels for dissemination of bioethics education was also received. Resource persons were identified to carry out countrywide training exercises for students, faculty, researchers and ethics committee members.

This sponsored bioethics training programme has three main components. One is the sensitization programme, starting from undergraduate medical students to postgraduate medical and life science students, institutional ethics committee members, researchers, and faculty members, both national and international. A total of 1800 trainees benefitted from these short-term courses. Two international workshops were conducted during 2006 and 2007 for participants from South Asian countries.

The second component under the training grant is short-term training for the trainers. It was conducted during the third and fourth year of the programme for eight weeks for the faculty and researchers. 32 participants from different parts of the country belonging to different fields of expertise attended this course and formed a network.

The third component involves a six-month course taken by the trainee at various universities of core strength in the chosen topic, along with a distance education module through the Indira Gandhi Open University, with which an agreement was signed in 2007. For the third component, a new Fogarty grant has been recently approved by the National Institutes of Health, USA. (Kumar 2006)

The World Health Organization/ICMR training workshops were conducted through a three-day common module having the essential principles and practices of ethics in biomedical research at health science universities and medical institutions in six states of India to familiarize the participants coming from both medical and non-medical backgrounds, which is just a beginning considering the vastness of the 29 Indian States. The progress has to be made in a phased manner, and the trainers were encouraged to carry the programme forward in their own institutions.

Evaluation of the medical research ethics infrastructure in the country

Quality ethics review forms the basic foundation for ensuring safety and well being of the research participants. In order to survey the existing ethics committees in the country, a questionnaire was circulated to medical colleges and ICMR institutes in 2000. Only 32 responses, including those from ICMR institutes, were received. The results of this exercise indicated that the ethics committees were not functioning well at that time in most institutions, despite the fact that ICMR had brought out the first ethical guidelines in 1980. Some were not even aware that the guidelines existed. In most of the institutions, maintenance of the minutes of the meeting and record-keeping were very poor. Even though there was no charge or fees for review, the independence and competence of these ethics committees was questionable in most cases.

In 2003, to assess whether the situation changed after the release of the guidelines and the series of workshops on bioethics for faculty members, some of whom were also members of ethics

committees, a 20-point questionnaire was circulated to about 1200 institutions, both public and private. The questionnaire was drawn up based on the operational guidelines issued by the WHO/TDR along with the ICMR guidelines. Based on 223 responses received, 179 institutions had a functioning ethics committee with various degree of competence. The state of Maharashtra has the highest number of institutions with ethics committees indicating sizeable research agenda, and, of course, the pharmaceutical companies are concentrated in this area. The other area of significant development is the state of Andhra Pradesh in the south-east, although the response from there was very low. There are also many biotechnology companies in Karnataka state, in the south-west. The lowest number of responses came from the eastern region. Forty of the good performing committees were selected for further onsite survey from these six States and recommendations were made for further improvement.

The mushrooming of independent ethics committees is a new development in India. This started initially in Mumbai but it is now spreading to other cities as well, mainly due to a high number of clinical trials being outsourced to India, as well as due to the institutions now offering diplomas and degrees in clinical research. As the multinational agencies and clinical research organizations are flooding into India in great haste, the regulatory bodies and the funding agencies are facing a challenge of managing the situation and dealing with the violations. For this reason, a number of workshops were conducted with the involvement of multiple stakeholders, including the media. Currently, there is a pressing need for strategies to develop sensitization programmes, update guidelines, formulate new ones and seek international collaboration for capacity building for ethics review.

Another survey was undertaken more recently to assess the status of ethical review clearance for ongoing clinical research and clinical trials projects funded by the Indian Council of Medical Research. The survey was designed to analyze the content and format of the ethics clearance certificates and to assess the ethics committee structure, composition, functioning, review procedures and record keeping, in order to identify their strengths and weaknesses. The secondary objective was to create awareness and improve the ethical review process among stakeholders in clinical research including the researchers, ethics committee members and institutions. For this purpose a questionnaire was designed and sent to the institutions conducting ICMR-funded clinical trials or research. Replies received from 36 institutions, including medical colleges, research institutes, and non-government organizations were complied, evaluated and analyzed. In addition, the ethics committee approval certificates were obtained for 107 of the 123/149 funded projects and analyzed for the format and content. Many IECs were found to be functioning well, with the written standard operating procedures and a satisfactory review processes. However, there is tremendous scope for improvement of the performance of these committees. Following the analysis of certificates, a uniform format has been developed for all IECs certificates, in order to enhance their consistency and completeness.

Good compliance with ethical standards that ensure the safety of research participants will cultivate their trust while satisfying the quest for knowledge among the researchers. The study reveals that awareness about ethics committee's role in the institution has increased significantly, indicating a reassuring trend. However, the study has brought forward the need to further strengthen the IEC framework by providing adequate financial support for their operation, conducting regular meetings,

ensuring adequate archiving facilities, offering access to appropriate bioethics trainings, enhancing the awareness about ethical guidelines, and implementing standard operating procedures.

Ethics of pharmaceutical research in India

Recent events worldwide have challenged the integrity of research on pharmaceutical products and have triggered calls by legislators, medical associations, the International Committee of Medical Journal Editors (ICMJE), the World Health Organization (WHO) and others, for increased accountability and transparency in health products research and development. India, which is projected to have accelerated growth in this sector with the entry of a number of major global and domestic players and a stronger research focus placed on pharmaceutical industry, is poised to face formidable challenges. Building the right kind of capacity to meet the anticipated demand for clinical trials in India is an important issue.

Along with the optimism for growth in the pharmaceutical industry is the concern that vulnerable populations may be exploited. On the one hand, access to experimental drugs, exposure to latest therapies, improvement in equipment and infrastructure, and creation of new knowledge assets are among the many benefits of the present growth in this field. On the other hand, new, difficult to meet expectations and the displacement of local resources away from basic healthcare are among the costs and risks associated with this enterprise. The regulatory regime in India has to identify ways of creating a balance between these benefits and risks. Ethics Committees, ethical guidelines and norms, and independent review boards are all different ways of ensuing compliance with established ethical guidelines and good practices.

Meeting the growing needs for ethics review

Ethics committees cannot conduct their task responsibly unless they get the data needed to evaluate ethical behavior. Evaluating conflict of interest and addressing cultural specificities in obtaining informed consent from vulnerable populations are amongst the most critical issues. There is a risk that research participants may not be in a position to provide informed consent due to the lack of their independent capacity to adequately evaluate the associated risks and benefits in the form of medical care during the trials. Punitive measures and/or legal liability may help in the implementation of the ethical guidelines in trials. Training of ethics committee members, accreditation of these committees and the development of stringent guidelines with detailed operating procedures are necessary. A smart, innovative, and transparent regulatory mechanism focused on human subject/participant protection is needed urgently in India in order to meet the growing ethics review demands stemming from a very fast expansion of clinical trials industry in the country.

The global demand to register all clinical trials has been echoed by the ICMJE. The ICMJE has made registration of trials a necessary prerequisite for publication of their results and findings. Furthermore, the WHO has suggested a structure of the registry with a minimum required data-set to be followed by all countries. An Indian registry, which features the minimum data-set suggested by WHO with additional requirements was set up in July, 2007. All stakeholders from industry, national laboratories and regulatory authorities were consulted in the development of such a registry in order to enhance

compliance. High quality data management was provided by a specialized information technology company. Some initial problems were successfully addressed and procedures were streamlined to achieve high efficiency. Today, more than 700 trials have been registered in the Clinical Trial Registry India (CTRI) following the directions from the Drug Control Authority making it a mandatory requirement from mid-2009.

International collaboration in biomedical and health research involving India, particularly over the past four to five decades, has assumed a very important aspect of global research. Until the late eighties, international collaboration involving India essentially meant a recipient status for India in a donor-recipient relationship. India needed the collaboration in order to obtain funds, equipment, as well as reagents, training, and very often the intellectual inputs for designing studies and data analysis. This situation persists even today with regard to a number of institutions. However, there are now many institutions with some of the best expertise, facilities, and funds available in the world, and are capable of dealing with developed country collaborators and institutions on an equal footing. But these are too few to be considered the norm. This leads to a distinct possibility and a genuine concern amongst ethicists regarding a high risk of the exploitation of Indian scientists, as well of the study subjects, by unscrupulous foreign collaborators.

What is special about international collaboration that merits specific consideration in the application of the bioethics principles? While the basic principles of autonomy, beneficence, non-maleficence, and equity or justice should be equally applicable irrespective of the location of the research activity, an extraordinary focus has been placed on the ethics of international collaboration during the 90s, with the focus on:

- Nature of collaboration
- Distribution of benefits
- Cultural, economic, political, ethical perspectives
- Countries at different stages of development
- Increasing volume of international collaborative research
- Increasing capacity for research in the "south"
- Increasing recognition of the potential of health research for development

The ICMR Ethical Guidelines for Research on Human Subjects (2000) and its revised version in 2006 lay emphasis on the following in the context of international collaboration: capacity building; community participation; protection of vulnerable population; careful planning of joint clinical trials; availability of best possible nationally available care as standard of care; assessment of equitable burden and benefit for study populations; equal respect for the rules and regulations of both countries; and following appropriate procedures for transfer of biological samples with appropriate Material Transfer Agreements (MTA).

The Forum for Ethical Review Committees in Asia and the Western Pacific

The Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) was set up in 2000 to provide education to ethics committee members, with ICMR in India being the founder member. A number of countries, such as Thailand, India, Indonesia, Nepal, Korea, Taiwan, Sri Lanka,

and Philippines have opened up their national chapters under the FERCAP initiative. In 2002, an ICMR–FERCAP workshop was organized to develop standard operating procedures for institutional ethics committees. The initial 43 identified schedules were finally streamlined to 25 schedules by FERCAP. The Indian Chapter — FERCI (Forum for Ethics review Committees in India) was established in 2002 and has been registered as a society to foster communications between ethics committees in India, act as a national collaborating agency, organize meetings and symposia, assist in the development and implementation of standard operating procedures, facilitate training opportunities and coordinate with other global bodies. Other regional fora similar to FERCAP have been created in various parts of the world: FLACEIS in Latin America, FECCIS in Eastern Europe, PABIN for the African countries and FOCUS for Canada and the United States of America. A number of nongovernmental organizations and other public and private sector bodies have joined these regional fora to form a "Strategic Initiative for Developing Capacity for Ethical Review" (SIDCER), supported by WHO TDR, OHRP, pharmaceutical industry, and other stakeholders.

The aspiration to maintain high ethical standards should be nurtured by the entire medical and scientific community. As more sponsors and researchers recognize the importance of ethical review, it has become timely to consider an accreditation system requiring the continuing self assessment, self improvement and auditing of IECs. With the globalization of biomedical research, the number of international agent overseeing IECs will increase through auditing or inspection. This will help to build capacity for conducting biomedical research of the highest attainable quality in terms of both science and ethics. SIDCER initiated an IEC/IRB recognition programme in 2004 based on the document, *Surveying and Evaluating Ethical Review Practices* (WHO/TDR, 2002). Under this programme, 53 IRBs have been recognized in different countries to do quality review of research proposals, including two in India. India has been collaborating with WHO and UNAIDS in bringing out various guidelines, as well as with UNESCO in its Assisting Bioethics Committees (ABC) programme.

Conclusions: Looking into the future

The advances in medical and health sciences and their ramifications on human lives have led to the evolution of bioethics into an independent and multidisciplinary field of study. A new breed of trained bioethicists is dominating the health care institutions in recent years. Law, philosophy and social sciences are closely linked with medical decision-making, research involving human participants and the care of the terminally ill patients. The idea of justice and fairness in human relationships and respect for life in all its forms make the subject of bioethics important in education and research. Teaching of bioethics has become an integral part of medical and life sciences curriculum in many developed countries since early 1980s.

In India, teaching of code of ethics has received little attention. It needs to be embedded at various levels of teaching in medical and life sciences curriculum for creating awareness and sensitization of the students about ethical issues confronting biomedical researchers. Efforts are ongoing to introduce teaching of medical ethics in all curricula of medical, paramedical and life sciences. Until such time, it is necessary for the students to look up relevant websites and consult guidelines and the few available text-books on the subject. Taking into consideration the existing needs in bioethics teaching,

the Indian Council of Medical Research, under the ICMR-WHO biennium programme, has prepared bioethics teaching material. Experts in different subjects have been involved to develop this teaching material related to the ethical issues on various topics, which also include case studies from India and abroad. The compendium has been divided into various chapters including: historical background, role and responsibilities of ethics committees, ethical issues related to clinical trials, genetic research, organ transplantation, assisted reproductive technologies, epidemiological research, international collaborations, social science research, publication practices, and animal experimentation. The chapters include classical cases, common policies and practices, national and international agreements and controversies, unsettled issues and reference to ICMR guidelines wherever applicable.

Clinicians and medical professionals are mostly confronted with the problem of how to apply ethical principles to practical decision making that affects patients during the conduct of research. Special efforts are being taken by the ICMR to generate information on the present practice of review of research proposals in the country and to further develop capacity in this area in collaboration with national and international agencies. Short term and long term training programmes in the area of research ethics are available for those interested in the topic. Any medical practitioner or medical researcher who has undergone such training will be better equipped to protect the rights of the members of the society.

However, a National Bioethics Committee with a broad mandate in bioethics, similar to the independent, multidisciplinary and pluralist committees promoted by the Universal Declaration on Bioethics and Human Rights and supported by UNESCO, does not yet exist in India. The Central Ethics Committee of ICMR deals with research ethics, rather than with global or national bioethics issues. A National Bioethics Committee was functioning under the Department of Biotechnology (DBT), Ministry of Science and Technology, focusing on research ethics issues related to biotechnology projects funded by the Department. The Committee issued a document titled *Ethical Policies on the Human Genome, Genetic Research & Services*, which was harmonized with the Ethical Guidelines for Biomedical Research on Human Subjects developed by the Indian Council of Medical Research in 2000. Nevertheless, a systematic and thorough investigation of bioethical issues facing India requires the creation of a national bioethics body with a broad mandate and scope of enquiry.

REFERENCES

ICMR. 2006. *Ethical guidelines for biomedical research on human participants*. New Delhi, Indian Council of Medical Research.

ICMR. 2000. *Ethical guidelines for biomedical research for human subjects.* New Delhi, Indian Council of Medical Research.

ICMR. 1980. *Policy statement on ethical considerations involved in research on human subjects*. New Delhi, Indian Council of Medical Research.

Kumar, N. 2006. Bioethics Activities in India, *Eastern Mediterranean Health Journal*, 12 (Supplement 1) (Pages 56 to 65):

MCI. 1956. Code of Medical Ethics framed under Section 33 of the Indian Medical Council Act (revised 2002).

Muthuswamy, V.; Ganguly, N.K. 2002. Ethical Values in Biomedical Research. In: MM (ed.) Building a Vibrant India Democracy, Development and Ethics. Tata M.C. Graw. Hill Publishing Company Limited.

Salhan, S. (ed.). 2004. *Ethics in obstetrics and gynaecology, second edition, Text book on Obstetrics*. Jaypee Brothers Medical, New Delhi.

WHO. 2000. Operational guidelines for ethics committees that review biomedical research. Geneva: WHO (TDR/PRD/ETHICS/2000.1).

WHO. 2002. *Surveying and evaluating ethical review practices, a companion guideline to the TDR WHO operational guidelines for ethics committees that review biomedical research.* Geneva: WHO.

The Swiss National Advisory Commission on Biomedical Ethics: dealing with questions of principle and practice

Jean Martin

Establishment and mandate of the Commission

Increasingly rapid scientific progress and the new possibilities opening up in medicine have created tensions between what can and what may be done. Health-care professionals, researchers, patients and society itself increasingly face crucial issues. In many cases, the traditional principles of medical ethics are not providing the necessary answers. Legislators' room for manoeuvre is often limited and unclear, particularly in view of the complexity entailed in assessing the developments and interests involved. The goal of bioethics is to examine these issues, in an interdisciplinary effort to ascertain what constitutes responsible action at the boundaries of the biological sciences, medicine and health care considered in their social context.

The Swiss National Advisory Commission on Biomedical Ethics was established by the Federal Council (government) in 2001, under Article 28 of the Federal Act on Medically Assisted Procreation. When the law was debated (it was adopted in December 1998), the Federal Parliament considered that it was important to have a standing ethics committee, an independent, extra-parliamentary deliberative body that would be responsible for monitoring human health issues (including, but not confined to, issues of assisted procreation).

The ordinance (Federal Council implementing regulations) for the Commission requires it to monitor the development of biomedical methods and techniques in research and practice and to take positions by formulating advisory opinions on the relevant social, scientific and legal issues.

In particular, the Commission is required to:

- keep the public informed;
- encourage public dialogue on ethical issues;
- draw up recommendations or directives for medical practice;
- draw attention to legislative gaps and implementation problems and, where necessary, submit proposed amendments; and
- advise Parliament, the Federal Council and the cantons on request.

In the light of the new knowledge and possibilities that are opening up, the Commission endeavours to produce ethical judgements that are both clear and conducive to discussion. Its opinions are meant to foster debate and ultimately contribute to the well-being of the people concerned and of society. Preparing opinions and recommendations and communicating them to the intended audiences are now at the forefront of its mission.

The work of the Commission is not intended to replace the political process. Instead, by clarifying ethical issues, it allows policy-makers and the public to arrive at an opinion. Its recommendations are thus not legally binding and in no way impinge on the legislative and executive powers of the Federal Council.

Nor is it a responsibility of the Commission, other than in exceptional circumstances, to issue opinions on particular research projects. This is a task for the cantonal ethics commissions and/or the research ethics commissions established by medical and health-care institutions (different types of committees have very different missions – see UNESCO, 2005).

The Commission is composed of 18 to 25 members, who are ethics specialists in the fields of biomedicine and public health (including nursing sciences) and others (law, theology, psychology and patients' associations). This multidisciplinary and multilingual body (Switzerland has three official languages) is required to represent the various conceptions of ethics and to seek consensus positions. It cooperates with other national commissions, including the Federal Ethics Committee on Biotechnology in Non-Human Domains, and is supported by a secretariat (attached for administrative purposes to the Federal Office of Public Health). Except for attendance indemnities, its members work on an essentially voluntary basis.

The Commission meets about 10 times a year in one-day plenary meetings. It also sets up internal working groups to study specific topics.

Illustrations of the work of the Commission

The question of how responsibilities for health matters are apportioned between different authorities has been raised in a number of Commission papers. When it was established in 2001, a project was submitted to the National Fund for Scientific Research, the main public institution supporting research, by researchers in Geneva wishing to work on imported embryo stem cells. The issue was highly politicized and there was major media coverage highlighting the potential benefits or, conversely, the dire risks. The legal situation was unclear. Under the Federal Act on Medically Assisted Procreation of 1998 it is forbidden to take cells from embryos for research purposes; this provision aimed then not so much at stem cell research as at pre-implantation genetic diagnosis (PGD). The National Fund postponed its decision while calling for a discussion of the legal and ethical aspects of the project. Some months later, the Fund contacted the Commission and requested it to take a position. The Commission then undertook a lengthy discussion of the primacy of the political process, stressing that an issue as important as the availability of the human body and the limits to be laid down could not be left to the sectors directly involved, that is, scientists; such fundamental problems must be decided by the legislature. It also noted that, so long as the implications of possible regulations were not clarified, it was important to avoid creating a precedent. The Federal Parliament then adopted a law on stem cell research, authorizing such research within certain limits. The law was the subject of a referendum (in Switzerland, any law may be subjected to popular scrutiny if a specific number of citizens so request) and it was approved by a large majority of the people.

In this case, the issue was the need for the political process to retain the power to set major rules in a key area; scientists argued against this, noting that the therapeutic potential of the research was justification for commencing it as quickly as possible.

There are two further examples in the area of transplantation: first, organ donation (unpaid – it is illegal to sell an organ in Switzerland) by living donors to relatives; and, second, the use of pre-implantation genetic diagnosis (PGD) to create a "saviour sibling" – an embryo with genetic

characteristics such that, after birth, its cells can be used to help to cure an older sibling. The ethical concern, in both cases, is the fear that potential donors or the parents (in the case of PGD) might be put in a no-choice situation by being impelled as a matter of "conscience" to agree to requests. Initially, the Commission did not concern itself mainly with the legitimacy of the procedures concerned, but concentrated on the conditions under which people take decisions. These conditions must be determined precisely and publicly. How can it be ensured that the donor's or relatives' decision is genuinely voluntary and independent? These individuals must be free to decide and act without moral constraints shaped by the system. Where living donation was concerned, the Commission suggested that an ombudsperson position be established, among other measures; it remained divided over the saviour sibling issue.

On these issues, it therefore focused on public/political responsibility, proposing institutional bodies that would protect individuals' right to make independent decisions in the face of any "moral code" influenced by the situation; the aim here is to protect people from appeals to "medical need" that could become all-powerful (this section has been translated and adapted, with the author's permission, from Rehmann-Sutter, 2009).

Lessons for the work of a national bioethics committee

Based on the experiences of the Swiss National Advisory Commission on Biomedical Ethics, as well as of committees/councils in other countries, certain necessary elements can be identified to ensure "good practice" and the successful operation of a national body of this kind.

The committee and its working conditions: membership and appointment procedure

Article 19 of the Universal Declaration on Bioethics and Human Rights adopted by the UNESCO General Conference in October 2005 calls for the establishment of ethics committees that are independent, multidisciplinary and pluralist (reflecting a plurality of opinions). The desirable and usual situation is for the members of a national bioethics committee (NBC) to be appointed in a personal capacity, even if they owe this appointment to their membership of a particular profession or spiritual family, for example. They are not delegated by the groups to which they belong and are not required to defend (in a corporatist or "unionist" fashion) the interests of these groups. Their mission is, after listening respectfully to the views of others, to make their personal contribution to the discussions and decisions of the committee in the general interest without being accountable to anyone else. The expression of professional, political or religious opinions is wholly admissible, but not in the form of dogmatic *pro domo* pleading.

This being so, it is clearly best to avoid *ex officio* appointments because people chosen in this way will be bound to see themselves as delegates of a group or authority and will lose some of their freedom to express themselves. Nor is it desirable for members to be co-opted; this procedure is unlikely to ensure the necessary diversity of opinion or genuine independence for members.

The document setting up the committee will contain provisions on its composition and the disciplines or characteristics it should embody. These include medicine/biomedical research, nursing,

law, ethics/philosophy and other human sciences (theology, sociology/anthropology and psychology, for example – even economics). It is good for some members to be drawn from the general population (civil society), including patient representatives.

The number of committee members varies. In the experience of the Swiss committee, bodies with 15 to 25 members are the most efficient. When committees are too large, there is the risk that interminable debates will render them ineffective. In a small committee, the membership and the views expressed may not be pluralist enough – and pluralism is, together with independence and multi/inter-disciplinarity, an essential condition.

The matter of the term of appointments needs to be settled. It is good for members to be appointed for limited periods, of four to six years, perhaps renewable once or twice. It does not seem advisable for members to be appointed for life, even if in theory the assurance that they will remain in their post at all events is a guarantee of independence (the Supreme Court of the United States of America is an example that comes to mind). There is too great a risk that an institution which was only very slowly renewed and was ineluctably ageing would become ossified and would be lacking in initiative and originality.

There is the matter of the likelihood of incompatibility between NBC membership and other duties. In Switzerland, neither the members of the national Parliament nor federal civil servants may be members of extra-parliamentary national commissions (such as the ethics commission).

Criteria for membership

The membership is to consist, then, of individuals from various backgrounds who are active in different fields. In addition to their specialized knowledge, a prime qualification is that they be widely seen as thoughtful people who are good listeners, have considerable experience of life and are capable of operating on an interdisciplinary basis, debating constructively with colleagues in different fields. There must be a gender balance as well as a balance between philosophical and religious views and the main sections of society in the country.

An effort should be made to include members of different ages/generations, while bearing in mind that "experience is the one thing that cannot be learnt from books"; members who are too young may be insufficiently experienced.

Generally speaking, it is essential to form a properly balanced group of people with recognized ethical standards who, while holding and capably defending strong opinions of their own, can practise dialogue and cooperation. The inclusion of controversial or doctrinaire figures of the kind who might be prominent in a parliament must be avoided. For the NBC is not a parliament but a group of "sages" working in concert behind closed doors on complex ethical issues. Thus, people's capacity for dialogue is as important as the discipline in which they have their background.

This position is in agreement with UNESCO's guide for national bioethics committees, which states that "Once the role of the Committee has been determined, it must be filled in order to function. The quality of membership will obviously be crucial in determining its success. Well chosen members can often make even badly designed institutions work; poorly chosen members can doom even the best designed structure" (UNESCO 2006, p. 22).

The importance of committee's independence

The NBC must be genuinely independent, both intellectually and practically (including finance), so that it operates without restraint or oversight. Similarly, it does not require prior authorization ("imprimatur") of other authorities before making its position on a subject public.

Conflicts of interest are an increasingly present cause for concern, and rightly so, in the debate on civil and political processes. It is essential that there be as much disclosure as may be required about any ties that could trammel committee members' (or candidates') ability to express their true opinion. There must be confidence that they will not act as lobbyists for any interest group, whether it be a profession, an economic or industrial sector or a political, religious or ethnic grouping.

NBCs do not take decisions on the same basis as the public authorities. They do not issue binding rules but formulate opinions and recommendations for the authorities and at the same time, because of their public character, for society at large. These texts may be aimed at professions, educational institutions or indeed economic actors, as the case may be.

Who may request opinions of the Committee

The official text establishing the NBC may require it to produce studies on particular topics; such tasks must be implemented. It may provide for it to be instructed by specific authorities (parliament, ministers, etc.). The committee must obviously be free to take up issues that it considers important.

It is also desirable that the Committee is accessible for ordinary citizens, members of the public. In these cases, it may, but is not obliged to, take up the matter if it considers that the enquiry is relevant and falls within its remit. As a matter of principle, however, no enquiry should be dismissed out of hand on the ground that the enquirer has no authority to make such requests.

Choice of topics to consider

Bioethics is a very wide field, addressing all kinds of issues. Even if it is desirable for few or no restrictions to be set on the topics that may be selected by the committee, priorities must be established, not least because resources (availability of members, funding) are limited. Logically, one would expect the NBC to concentrate on bioethical issues that are of particular importance to the country concerned, in its present circumstances or in the future (immediate and longer term).

International conferences have shown how particular issues of keen interest to ethics specialists in one part of the world may be of less interest to other regions. Besides, there is no need to reinvent the wheel: it is well worth monitoring the positions taken by other committees elsewhere to see if they are relevant to the country's conditions and can thus be adopted, subject to adjustments. Such endorsement of opinions issued elsewhere contributes to the emergence of positions that are shared as widely as possible around the world.

Consideration will be given to the *practical consequences* of the opinions required from the NBC (assuming they are followed, especially by the government). Thus, situations in which people may experience unnecessary suffering or refusal for specific benefits until the opinion of the NBC is known should be dealt with as swiftly as possible.

Process of deliberations: procedure

An NBC is a group of experts, usually academics, who are used to deliberating on complex subjects. The main requirements are to listen carefully, show respect for others (even if one disagrees with them on principle) and, most importantly, work constructively towards agreement.

It is important for the chairperson to be able to move discussions forward, treating speakers with respect but knowing when to interrupt them if they are unproductive. He or she will ensure that all members have their say. It is not always necessary to have particular rules to determine when and how often each member may speak, or even to restrain those who are too talkative; however, where necessary, it must be possible to take measures against members who use devices to block discussion (filibustering).

Value judgements and other doctrinaire condemnations of colleagues' opinions are to be absolutely avoided, as of course are personal attacks of any kind (objections may be vigorous, but must relate to the ideas expressed and not the person).

Seeking consensus

One fact of life that committee members will know from experience is that in the field of bioethics and care-giving, there are some problems for which there is no optimum solution but only bad and less bad options. What is needed is perseverance in seeking the least bad option.

It is highly desirable for most NBC opinions and recommendations to be arrived at by consensus, this being the most substantial common denominator that can be achieved on a particular issue by positively formulating a position that everyone can support without being forced to betray their own convictions. This can often be done by thorough, measured discussion. If consensus cannot be reached despite these efforts, the majority will decide whether it is advisable to publish an opinion despite the dissenting views of one or more colleagues (such views being recorded). It is necessary to discard the idea that a person who has different views is an adversary (or worse, an enemy). It is normal and logical to have disagreements and to entertain opposing views.

Formulating opinions

If it hopes to win the ear of the authorities and public, the committee must formulate conclusions/recommendations that are as clear and precise as possible. Since these recommendations are advisory only, the authorities that might put them into effect will be less willing to do so if the NBC's statements are vague and lacking in coherence and direction, or if they have failed to convince a clear majority of the committee.

Formulations embodying an agreement will be adopted much more readily when the committee (or its secretariat) contains people who are skilled at drafting them. Trying to secure agreement among 15 or 20 people on the finer points of a text inevitably involves frustration and can take time.

Publicity of the committee's work: private or open meetings

As a rule, the NBC's meetings should take place in private. It is when colleagues who have come to know and trust one another work together in confidence that debates are most fruitful. When

an audience is present, positions are not expressed as frankly (for fear that they will be reported elsewhere) or may be couched in populist, theatrical terms; being observed creates pressure that adversely influences members and impairs the quality of their work.

The confidentiality of debates must be ensured. Thus, it is not acceptable for a member to bring opinions expressed by colleagues in a meeting to the attention of the public (conversely, all are entitled to make their own views public, as long as they say the same things inside and outside the meeting room).

The presence of non-members as mere observers not participating actively is not really recommended (not least because of the confidentiality issue). Active participation by non-members may take several forms:

- hearing of outside experts on a subject that is before the committee, in which case, the expert makes a presentation, answers questions and leaves;
- there may be people with a standing invitation to participate in meetings because their position involves duties similar to the committee's (in Switzerland, the person responsible for bioethical matters within the federal health ministry has a standing invitation to NBC meetings, participating in debates only when requested to do so). The advantages and drawbacks should be studied carefully. It would be counterproductive, for example, if a person in this position were to be perceived as a critical observer spying on the NBC's work. As a rule, it is for the committee itself to decide whether or not outsiders should be invited to join its meetings;
- larger-scale outside participation is desirable in the form of public meetings held by the committee, namely open debates, seminars and symposia, so that any person concerned and the media can become acquainted with it and its work and put questions and comments to it directly, be they favourable or critical. For example, the French National Consultative Committee (CCNE) holds public open days once a year.

Communication and contacts

The committee's opinions and recommendations are of a nature to be made public and widely available for all; adequate facilities should be made available for this. A variety of methods can be used, such as publication and distribution of reports, regular information bulletin, website and press conferences.

There is some leeway that should be used creatively. The Swiss NBC has tested some debating methods that are a departure from the "traditional" publication or press conference, such as conducting discussions at a major event (National Exhibition) and *cafés philosophiques* on the subjects "The perfect life: ideal or nightmare?", "What can research do? What should it be allowed to do?" and "Should life be prolonged at any cost?"

Local and foreign ties should be maintained. Each year, the NBC holds a two-day meeting in one of the 26 cantons of the Confederation, allowing it to forge contacts with the authorities and professionals in the region. A public event dealing with a bioethical topic is held on this occasion.

Participation by NBC members in international meetings is desirable, with a view to engaging in networks and sharing and contrasting experiences; personalized collaboration, particularly at regional level, is sometimes more productive than attending major conferences.

Education needs for the committee members

"Experience, in short, has refuted the old assumptions that life had sufficiently prepared members for their task or that their pre-existing moral and social values rendered them impervious to change, or that self-education by committees was at best redundant" (UNESCO 2007, p. 9).

"Members of NBCs may be persons of distinction, but few are experts in all the areas of their committee's purview – and fewer still are learned in bioethical inquiry. One of the members' main tasks, then, becomes self-education. Much of this proceeds informally – members learn from each other, talk with knowledgeable outsiders and canvass existing literature. Some self-education, however, is formal, as seminars may be convened, materials distributed, or outside speakers invited" (UNESCO 2005, p. 22).

In all fields, there is a need for ongoing (and sometimes basic) training to create familiarity with ideas and practices and to effectively follow the developments. NBC members must have these opportunities; one thing that must be ensured is that they all have easy access (through the Internet, for example) to the international literature. At the simplest, parts of sessions will be given over to presentations of matters of interest, whether or not they have a direct bearing for the time being on the issues before the committee.

There is also the issue of the professionalization of bioethical activity, which was the theme of the 2007 annual meeting of the European Association of Centres of Medical Ethics (Martin, 2008).

Roles of the NBC secretariat

General points – ensuring continuity

The committee's effectiveness depends heavily on its secretariat/secretary. It is the mainspring of its operations and works closely with the chairperson (or executive committee as the case may be) and under his or her responsibility. Once again, it is important for the committee and its secretariat to be independent (practically and intellectually) of the public authority, even if it is attached to a ministry for administrative purposes. In general, the secretary is not, strictly speaking, a member of the NBC, but may be in some circumstances.

The secretariat ensures the continuity of NBC activities. It must have capabilities in the bioethical field, broadly defined – full knowledge in one of the disciplines chiefly concerned, supplementary expertise in the other disciplines and experience of interdisciplinary work – and must be able to ensure that contributions from different fields are used productively.

Administrative duties

The secretariat carries out the necessary administrative work under the supervision of the chairperson or executive committee, organizing meetings and other tasks, convening members,

preparing premises, drafting reports, liaising with public or private organizations/services and with counterparts abroad, among other activities.

It is important for it to have management skills and, in particular, in the drafting of texts (everything from routine correspondence to drafts of committee opinions). It is responsible for keeping the NBC's files and archives. It is involved in composing periodic reports, which it also produces and distributes.

Its responsibilities include overseeing the spending of the NBC's budget allocations and preparing the next budget. When outside experts are employed under particular terms of reference, the secretariat will be involved in preparing the necessary documents and overseeing proper execution of such terms of reference.

Technical/substantive duties

The secretariat prepares specific dossiers and coordinates the work of preparing recommendations or position papers (the term *avis* is used by the French CCNE and *prise de position* by the Swiss NBC). To this end, it may be responsible for gathering documents (examining the literature, searching the Internet and contacting specialists) and participating in working groups. Another requirement here is for it to be available to deal with requests from the authorities, the media and individuals or sectors concerned with bioethical issues.

The activities of the Swiss National Advisory Commission on Ethics – evaluation and outlook

Experience shows that the value of the contribution made by the NBC is closely linked to its diversity of viewpoints and the balance between them. The more its recommendations reconcile an array of relevant ethical views on a potentially controversial subject, the sounder they are as a basis for decision-making. In 2006, to mark the fifth anniversary of the NBC, debates were held in the three linguistic regions of Switzerland to analyse its record. Those discussions enabled the Commission to adapt its procedures, improve the quality of its recommendations and enhance its communication work. One striking development was the desire expressed in political circles for the Commission not only to issue opinions on topical matters but also to anticipate future issues by formulating guidelines and a basis for future decision-making. The Commission has taken note.

It has also understood that it must keep the public better informed about its way of working. It is aware that its success depends on its involvement in specialized international debates. There has been an upsurge of productive dialogue between countries and within international organizations (such as UNESCO and WHO), mainly dealing with recommendations and draft regulations. The NBC has engaged with this international logic to the extent its limited resources allow, and this is important for improving the quality of its work in Switzerland itself.

List of position papers by the Swiss National Advisory Commission on Biomedical Ethics		
No.	**Title (in English translation)**	**Date published**
16/2009	Research on children	Mar. 2009
15/2008	Introduction of diagnosis-linked fixed payments per case in Swiss hospitals (in BMS 36/2008)	Sep. 2008
14/2007	Pre-implantation diagnosis II. Specific issues with legal norms and HLA typing	Oct. 2007
13/2006	Due diligence criteria for assisted suicide	Oct. 2006
12/2006	"Ethical waiver declarations" imperil the principle of health insurance solidarity	May 2006
11/2006	Research on human embryos and foetuses	Jan. 2006
10/2005	Pre-implantation diagnosis	Dec. 2005
9/2005	Assisted suicide	Jul. 2005
8/2005	Medical care: a duty	May 2005
7/2004	Sterilization of people incapable of discernment	May 2004
6/2003	Regulation of organ and tissue donation by living people in the law on transplantation	Dec. 2003
5/2003	Transplantation of liver lobes from living donors: the issue of financing	Jun. 2003
4/2003	Reproductive cloning of human beings	Apr. 2003
3/2002	Research on embryonic stem cells	Jun. 2002
2/2002	Abortion time limits	May 2002
1/2001	Research on imported embryonic stem cells	Sep. 2001

Over the years and after thorough debate, the NBC has drafted position papers on subjects such as embryo and stem cell research, assisted suicide and pre-implantation diagnosis (see www.nek-cne.ch). When its membership was renewed for the first time, it undertook a stock-taking exercise with the assistance of eminent persons such as parliamentarians, senior officials and chief editors. The Commission was applauded for engaging with political and socially topical issues. It was requested to be more proactive and forward-looking and to map bioethical issues. Media coverage of its work – including interviews with members – was fairly full. Reservations were however expressed about its interaction with the public at large: more work was needed to popularize its activities, in the positive sense of the term, by deciphering the issues. When dealing with a given subject, the Commission should give a better idea of the consequences of different options: "If we take position A, what will happen in practice is this, if we take position B, the effects will be such and such…"

On subjects that are inevitably complex, its reports have been criticized by representatives of particular schools of philosophy or spirituality. In an open, pluralist society, the Commission is very careful to listen to different opinions. It strives to reach positions acceptable to the majority, but unanimity would only be attainable at the cost of blandness. It is perhaps remarkable that on an issue like assisted suicide, for example, 11 of its 12 positions/theses were accepted unanimously by its members. As a Member of Parliament has pointed out, furthermore, certain bioethical issues fall within the category of the "undecidable". Ethics often produces more questions than answers, and everyone must ultimately find the latter themselves, given that the aim of ethics is, in simple terms, to work out "how to act for the best".

International cooperation and networks

The Swiss NBC maintains relations with equivalent committees in a number of countries, particularly its large neighbours, namely Germany (the chairwoman of the German National Ethics Council has participated in a meeting of Swiss NBC in 2006) and France. It is represented at periodic meetings of national ethics committees from around the world and Europe (COMETH), at those of the European Association of Centres of Medical Ethics (EACME), and occasionally on the Steering Committee on Bioethics of the Council of Europe (CDBI). It keeps abreast of the work of the UNESCO International Bioethics Committee (IBC). Some of its members participate in the conferences of the International Association of Bioethics and other meetings.

In 2003, the NBC chairman travelled to New York to participate as an expert with the Swiss delegation in the work of the United Nations on a convention against reproductive cloning of human beings. He worked on a WHO working group responsible for dealing with the implications of a possible influenza pandemic (global consultation on addressing ethical issues in pandemic influenza planning) and was given responsibility for part of the report drafted at the conference held in Geneva in October 2006. In this work he incorporated the results of the studies conducted by the NBC itself on the subject, at the request of the Federal Office of Public Health.

The importance of a national bioethics committee

In a number of countries, including Switzerland, the popular "saloon bar" political feeling is often that some down-to-earth common sense is enough to provide answers to the bioethical challenges and dilemmas arising from developments in biomedicine. One feels one hears those who guillotined Lavoisier during the French Revolution on the ground that "the Republic does not need scholars". In addition, nationalist circles argue that international relations and cooperation do not serve any great purpose. This gives cause for concern. The Swiss so-called "militia model" (expecting people from civil society to come forward and engage in public duties such as participation in the NBC for practically no financial reward) has its virtues but also its limitations. Such a frugal approach cannot be expected to give results comparable to what could be achieved if there were a willingness to devote adequate resources (human and material) to the task. Here, it is important to be discriminating – in the positive sense of the term – about which areas have a great, even urgent, need for reflection and action and which do not. It would be very unfortunate if drastic constraints prevented a national committee from discharging its duties properly; this is a concern for the Swiss NBC just as it surely is for its counterparts in other countries.

The fact is that such a body, charged with advising the authorities on major and potentially explosive issues, now has an indispensable role as a source of independent, soundly based advice informed by a broad overview of developments in society. It works to the standards of, and in close contact with, the international debate. It cannot provide ready-made answers, its aim is not to lay down politically and morally correct positions for the country, but it does make a substantial contribution to the discussion among the public and the authorities, particularly the legislature. Examining controversial situations and their ethical implications, studying possible alternative approaches and coming up with draft regulations, that is, the descriptive and analytical part, forms the bulk of the committee's work and is perhaps even more important than its final recommendations themselves, which may not be accepted unanimously by its members or the population at large. What the national committee gives policy-makers is a developed, differentiated basis from which they can draw their own conclusions. The Swiss National Ethics Commission believes that its work is an aide to visualizing, perceiving and evaluating the issues; it is by no means a matter, obviously, of allowing the public authorities to evade their responsibilities by transferring them to a group of State-approved "moral experts". On complex issues, both political opinions favouring an option and those opposing it can gain in robustness when they draw upon substantive independent thinking (this paragraph has been translated and adapted, with the author's permission, from Rehmann-Sutter, 2009).

Conclusion

What place should people – and politicians in particular – be giving to ethical thinking/work in the early twenty-first century? Ethical thinking is of course needed not only in the biomedical sciences, but more broadly in the areas of climate change, global water supply issues, food security, and generally, in the efforts to achieve progress towards a sustainable and equitable world.

This is a major societal and political issue. Although the record of the Swiss NBC since its establishment in 2001 can be viewed with some satisfaction, vigilance is still necessary to ensure that it has the resources to continue and, if possible, extend its activities. Every country, however modest in size and importance, must have a public system capable of contributing effectively to the national and, as far as possible, the international debate. It cannot be overestimated how important it is for the authorities to examine attentively, and indeed urgently, the ethical basis of our actions and our societies, including some of the doctrines that are leading us, and actually have led us in the recent past, into environmental and financial crises. Paradigm shifts seem essential and national ethics committees should help to prepare the ground for them. It is important to have proper systems in place with clear missions, guarantee their independence and provide them with the human and material resources required to do their work.

REFERENCES

Martin, J. 2008. Professionnaliser la bioéthique – Comment ? *Revue médicale suisse* 4 : 484-486. Also in: EACME Newsletter (European Association of Centres of Medical Ethics, Maastricht, Netherlands) under the title: Après la conférence annuelle de l'EACME de Zurich, March 2008, No. 18.

Rehmann-Sutter, C. 2009. Wie weit reicht die öffentliche Verantwortung für Gesundheit? *Bulletin des médecins suisses* 90: 1300-1303.

UNESCO. 2005. *Guide No. 1. Establishing Bioethics Committees.* Paris, UNESCO.

UNESCO. 2006. *Guide No 2. Bioethics Committees at Work: Procedures and Policies.* Paris, UNESCO.

UNESCO. 2007. *Guide no 3. Educating Bioethics Committees.* Paris, UNESCO.

The National Medical Ethics Committee of Slovenia

Božidar Voljc

Introduction: the origins of National Medical Ethics Committee

The University of Ljubljana's Faculty of Medicine has a 90-year-long history, and medical ethics has been its particular concern during almost one-half of this period. In 1965, one year after the adoption of the Helsinki Declaration, one of the university faculty members, Professor Janez Mil inski, helped establish a Board for medical ethics at the Faculty of Medicine and introduce a formal system for ethical review of research related to D.Sc. degree theses and other scientific projects. The members of the Board were nominated by the Faculty Council. In 1995 the Ministry of Health Care issued a Decree on the Constitution, Terms of Reference and Procedures of the National Medical Ethics Committee (hereinafter Committee), defining among other things the scope of its powers and the way to nominate its members. By the same ministerial decree, major health institutions were allowed to establish Regional Ethical Committees responsible to the National Committee.

The powers and duties of the Committee were broadened and defined in greater detail following the 1997 Oviedo Convention and its Additional Protocols, the July 2000 Slovenian Directive on Clinical Drug Trials, and the European Directive 2001/20/EC on the application of good clinical practice in the conduct of clinical trials on medicinal products for human use. The range of the Committee's work was extended further when the Ministry of Education, Science and Sport introduced a regulation that all research on human subjects funded by public money should be reviewed for ethical acceptability by the Committee. Although all its administrative and other costs are covered by the Ministry of Health Care, the Committee is an independent body, not formally accountable to any supervising authority.

The scope of Committee's work

The Committee deals with ethical and deontological questions related to medicine and gives statements and explanations about ethical issues arising from health care practice, research on human beings, and the rights and safety of the individual while receiving health care. The scope of the Committee's work includes:

- protection of privileged information including the personal data of patients, health workers and their co-workers;
- testing of new methods of prevention, detection, and treatment of illnesses and injuries and of methods of rehabilitation;
- pharmaceutical trials; and
- biomedical research in general.

The Committee must also give its consent in cases of research involving personal data and human tissues. It may also offer advice in a broad range of medical ethical issues. Questions are submitted to the Committee through or by the Ministry of Health, its National Health Council, the Slovenian Medical Chamber, health institutions and individuals. The Committee can also produce opinions about bioethical

questions on its own initiative. If a researcher has failed to submit the project for ethics review, wrongly assuming that a review is not required, a careful retrograde review is obtained. If there is no ethical problem, consent is normally given. However, cases of intentional non-compliance lead to disciplinary action with potentially serious consequences for the researcher, including a revocation of the licence to practice. In practice, no such cases have yet been recorded. The decisions of the Committee cannot be appealed. Only in cases where the Council of Europe or the World Health Organization would have adopted a different stand is the Committee obliged to reconsider its decision.

Not everything that is ethically unacceptable is prohibited by law; therefore the Committee may reject or advise against activities that are lawful. On the other hand, if legislation lags behind the development in science or medical practice, the Committee may authorize research or treatment even in certain cases where this would not be in accordance with the existing law.

In sensitive cases where rights of the human subjects are concerned, the Committee enforces standards of protection that are higher than defined by minimum requirements of the law. Even though the Committee takes great care to ensure patients' autonomy, it may exempt the researcher from the requirement to seek consent to the research use of their personal medical data if certain conditions are met, for example, if the research is in public interest, if unreasonable efforts would be necessary to contact the data subjects, if the study is expected to provide important new scientific information, and if the potential risk of harm to data subjects appears to be remote. Exemptions from the data protection requirements are also allowed where research identifies potentially serious and preventable risks to the health of the data subject. In such cases, the individual's identity may be uncoded and appropriate action taken to initiate the necessary preventive measures or treatment.

Composition of the Committee

The Health Minister appoints members of the Committee from a shortlist of reputed experts nominated by the Faculty of Medicine, the National Health Council and the Slovenian Medical Chamber.

The Committee has a president, vice president and members. Apart from eight experienced and reputed medical doctors of different specialties, it also includes a clinical psychologist, a sociologist, a lawyer, a theologian and a lay person. For twelve years the Committee has been chaired by the current president of the Slovenian Academy of Sciences and Arts, and the lay person has held the position of the vice-president. This composition allows for a multi-disciplinary approach to ethical issues. Occasionally it is necessary to include the expertise and knowledge of external experts in order to reach a decision. For more detailed management of particular issues the president may appoint a task group consisting of Committee members and/or experts from the relevant field.

Meetings of the Committee

The Committee meets monthly. It reviews proposed research projects and reacts to events, views and new ways of treatment which raise ethical and other questions in the society or among professionals. The Committee enjoys great reputation in the public, in the government and in its professional environment. Its statements and decisions have always been final. It has been successful

in responding to periodic sensationalist reports on bioethical topics in the media with its ponderous, professionally founded and moderate analysis. There is a high level of consensus among members during debates and decision-making; voting is a very rare exception. No legal actions have as yet been taken against the Committee's decisions, a fact which reflects the high legitimacy of its work.

Engagement on the international arena

The work of the Committee has earned it an international reputation as well. Its president, Dr. Trontelj has been a member of the Steering Committee on Bioethics of the Council of Europe since 1995, and has had two mandates as a member of its Bureau. He participated in drafting the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, also known as the Convention on Human Rights and Biomedicine or the Oviedo Convention, and was a member of the working party drafting the Protocol on biomedical research to this convention. He is also a member of a working group preparing a Guide for research ethics committees. The members of the Committee actively participate in various international conferences on medical ethics. In 2008, the president of the Committee and a co-worker organized the 11th National Ethics Council (NEC) Forum.

Conclusion

Today, there is evidence that the work of the Slovenian Medical Ethics Committee has gained national confidence; obtaining its consent has become a precondition to all biomedical research projects, and the ethical principles guiding the Committee's work have achieved a wide recognition. The Committee has acquired ample experience which could be translated into recommendations for the national ethics committees that have recently started their operation.

Since medical ethics and deontology touch upon a number of fields, the composition of the ethics committee should cover a wide range of disciplines, and its work and decisions should be as transparent as possible. However, the experience of the Slovenian Committee suggests that fair representation of medical doctors among the membership is an important advantage. The reason is that in medical ethics and deontology most questions originate in medical activities. In Slovenia we do not agree with the view that physicians should tend to their own profession and research while the ethical questions are handled by professionals from other fields. Since the time of Hippocrates, medical ethics has been an inseparable part of the physicians' professional life, as well as of the overall health care and medical fields. Since it is impossible to imagine a doctor's career without ethics, medical doctors should remain a key partner in discussions and decisions on bioethics.

National Ethics Advisory Bodies and Committees in Norway: history, lessons learnt, and common challenges ahead

Jan Helge Solbakk

Introduction

The present paper represents an overview of the developments in the field of research ethics and bioethics in the northernmost part of Europe during the last 30 years. Although the story in this case is Norwegian (and partly Nordic), I shall argue that it contains elements that may be of relevance to countries in other allegedly remote parts of the world in the process of setting up National Bioethics Committees and systems of research ethics committees.

As in drug studies, it is useful to divide this story into three different phases. Accordingly, phase I deals with the initial introduction of academic medical ethics into Norwegian medicine; phase II concerns the effectiveness and relative safety of early initiatives; phase III represents an account of the period after effectiveness has been established and additional evidence of effectiveness has begun to accumulate for specific indications and of possible adverse effects.

Phase I – the academic emergence of research ethics and bioethics

The official academic story may be dated back to 1966, when a young Norwegian physician named Erik Enger was awarded his PhD in medicine on a dissertation dealing with medical, ethical and legal aspects of randomized clinical trials (Enger 1966). The empirical part of his dissertation consisted of two huge randomized clinical trials, one dealing with patients having suffered a brain stroke and a second study dealing with heart infarction patients. The studies had been performed in the late 1950s and early 1960s, i.e. before the first *Declaration of Helsinki* had been adopted in 1964. In contrast to the *Nuremberg Code,* the *Declaration of Helsinki* did not only deal with medical experiments on healthy subjects but also contained ethical guidelines for clinical research involving *sick* people. The patients participating in the studies had been informed about the purpose and scope of the studies, but no information had been given to them about the randomization procedures or about the use of placebo, nor had formal consent from each patient been procured. The Helsinki guidelines challenged the young physician to include in his dissertation an ethical analysis of this type of research design. Dr. Enger's doctoral dissertation represents one of the very first academic treatises in modern medical ethics - in Europe as well as worldwide. His dissertation was published the year Henry K. Beecher's famous article "Ethics and Clinical Research" sent shock waves through the American medical research establishment (Beecher 1966).

The reason for telling this story in such a detail is not only due to the particularly early date of Enger's work: the story also illustrates two features which could be said to be "pathognomonic" of the emergence of academic medical ethics and bioethics in Europe. First, the story illustrates the role

of physicians as academic initiators of the field. Theologians, philosophers and lawyers entered the academic field of medical ethics later. Second, it draws attention to medical research as the original object of ethical concern. That medical research became the main focus of interest in the early years of modern medical ethics in Europe is quite evidently related to the atrocities and medical crimes having been committed by Nazi physicians and researchers during World War II and the prompted development of the *Nuremberg Code*. As stated by Annas and Grodin "...all contemporary debate on human experimentation is grounded in Nuremberg" (Annas and Grodin, 1992, p. 3).

I think, however, that one should also keep a second possible factor of World War II in mind, namely the creation and detonation of the first atomic bomb. This endeavor - and the scientific contribution to it - made it painfully clear to everyone taking part in the aftermath of critical self-reflection that the research community had built its scientific ethos on at least two fallacious assumptions: the assumption that the sum of the positive effects of scientific research and technological development always outweigh *the adverse effects* of the same activities, and the assumption that the adverse effects of scientific research and technological development are always reversible. Such factors should not be excluded from this part of the story because of their important role in making medical research ethics such a central object of academic concern from the very outset.

Phase II – the bureaucratic emergence of research ethics and bioethics

Already in 1953 the World Medical Association's Committee on Medical Ethics had "begun grappling with the issue of human experimentation" (Annas and Grodin, 1992, p. 157), and at that time a need for professional guidelines was recognized, i.e. guidelines designed by physicians for physicians as opposed to the 10 commandments of the *Nuremberg Code*, which had been formed by jurists for use in legal trials. Although the 8th General Assembly of the WMA in 1954 adopted a *Resolution on Human Experimentation: Principles for Those in Research and Experimentation*, it was not until the final adoption of the Committee's draft *Code* of ethics for human experimentation at the 18th World Medical Assembly in Helsinki in 1964, that research ethics as a bureaucratic enterprise within the medical communities really could start to evolve.

Besides the physician-origin of the *Declaration of Helsinki*, the main difference between these guidelines and the *Nuremberg Code* is that in the original version of the *Declaration* (Helsinki I) an explicit distinction is made between clinical research combined with professional care involving sick persons and clinical research carried out on healthy subjects for the advancement of scientific knowledge.

It is worth noting, though, that *Helsinki I* did not make any mention of peer review or of a system of ethics committees. This indicates that the welfare and security of the research subjects were still considered to be the full responsibility of the individual investigator. In spite of this lack of reference in the *Declaration* to any system of extra-individual peer review, a discussion had started in Sweden in the early 1960s about setting up Regional Ethics Review Committees that addressed medical research involving human subjects. The first committee was established in 1965 at the Karolinska Hospital in Stockholm. The process of establishing ethics review committees in all the medical faculties was prompted by the 1966 US federal policy statement on protection of human subjects issued by the

Surgeon General of the United States Public Health Service (USPHS), which required that all medical research projects involving human subjects which received USPHS grants should undergo review by a research ethics committee.

Although the need for revising *Helsinki I* in order to cope with the rapid advances in medical research and technology was suggested on several occasions, it took several years before WMA appointed a special committee for that purpose. The Committee was made up of three young Nordic physicians, who had provided the academic field of medical ethics with substantial contributions: the Swedish psychiatrist Clarence Blomquist, the Danish gastro-enterologist Povl Riis and Erik Enger from Norway, whom I have already referred to. Curiously enough, as the Committee's draft proposal was finally presented to the 29th World Medical Assembly in Tokyo in 1975, no delegates - except for the Finnish delegates - voted against the proposal. One delegation abstained from expressing their vote.

As the transmission of the experimental protocols to "a specially appointed independent committee for consideration, comment and guidance" (Helsinki II, Basic Principles I.2) now finally had become an international requirement, the process of setting up research ethics committees could proceed. I shall again limit my account to the Norwegian part of the story; not because this story is necessarily more interesting than narratives from other European countries, but because the Norwegian story illustrates particularly well how medical research became not only a driving force in setting up a bureaucracy of ethics committees in Europe but also in establishing research centers in medical ethics.

MRC's Research Ethics Committee

The first committee in Norway was set up by the Norwegian Medical Research Council (MRC) in 1978. Since the establishment of the system of *Regional Ethics Review Committees* in 1984 the MRC's Committee acted as a coordinating and advisory body in medical research ethics. A working committee consisting of one member from each of the RECs and headed by the chair of the MRC's Ethics Committee used to meet three to four times a year.

The MRC Committee (since 1990, the National Committee for Medical Research Ethics) has throughout the years published a number of recommendations and reports on various topics in the field of medical ethics, such as: Informed consent; Research on children; In vitro fertilization and artificial insemination; Ethical questions connected with registration of genetic disorders; Treatment of sensitive personal data; Research on fetuses; Ethical considerations relating to prioritization and resource allocation in medical research; Research on persons with impaired informed consent capacity; Ethical aspects of population studies (epidemiological research); and Ethical evaluation of post-marketing studies.

The system of three national research ethics committees

In June 1989 the Norwegian Parliament (Stortinget) endorsed the recommendation of a 1988 White Paper from the Ministry of Education and Research for the establishment of national research ethics committees within the following three subject areas of research and development:

- medicine in a broad sense ("health and life sciences")
- the social and behavioral sciences and the humanities, including law and theology

- natural science/technology including those parts of biotechnology and genetic technology that do not fall under medicine.

Great importance was placed on securing representation in the national committees from the fields of ethics and law, as well as on the adequate membership of lay persons.

The members of the three national committees of research ethics are appointed by the Ministry of Education and Research on recommendations from the National Research Councils (in 1993 the five existing discipline specific research councils were merged into one council and named the Norwegian Research Council). The secretariats of the national committees are administered by the Norwegian Research Council. It should be noted that the directors of the secretariats are required to have background training in ethics and are expected to do their own research in ethics in addition to their administrative responsibilities.

For the subject area of medicine the Government in 1990 gave the Norwegian MRC's Committee for Medical Research Ethics the status of the *National Committee for Medical and Health Research Ethics*. The committee has 12 members with different professional backgrounds, including ethics and law. Besides, there are lay representatives in the committee. Traditionally, the committee has been chaired by a physician, but is at present chaired by a female theologian. The members of the Committee are appointed for terms of four years and no member may sit on the Committee for more than two terms. The Committee meets 5-6 times a year.

According to the mandate laid down by the Ministry of Education and Research on 16 May 1990, the main assignments of the National Committee for Medical and Health Research Ethics are the following:

- to keep itself continually informed of current and potential questions of research ethics in the field of medicine,
- to act as a coordinating and advisory body for the RECs,
- to inform researchers, the administration and the public of current and potential questions of research ethics in the field of medicine,
- to submit reports on matters of principle relating to medical research ethics, and comment on specific matters of special significance relating to research ethics,
- to report on its activities at an open meeting at least once a year, and in whatever ways it finds suitable promote informed discussion in society of ethical questions relating to medical science and knowledge, and
- to keep other national and international research ethics committees informed of its activities, and in cooperation with them seek to establish a platform of principles of research ethics which extends beyond the boundaries of the respective research subjects.

Similar charges are given in the mandates of the two national research ethics committees.

Since 2008, the National Committee for Medical and Health Research Ethics has also functioned as an appeal body for the seven regional committees for medical research ethics. These committees evaluate all individual medical research projects, while the the National Committee for Medical and Health Research Ethics gives its opinion on issues that are more a matter of principle. Biannual meetings attended by the chairs and secretaries of all the councils deal with issues on which the committees need

to collaborate. Furthermore, all members of the National Committee and the regional committees attend a two-day joint meeting in the autumn, for professional replenishment and discussion (Information in this paragraph has been accessed at: http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/).

One additional - and indeed a very notable - charge given to the National Committee for Medical and Health Research Ethics was to take initiatives to promote training and research in medical ethics. The latter charge explains why the Committee found it natural to locate its secretariat together with the first Center for Medical Ethics (CME) in Norway as well as assist in the establishment of a National Research Program in medical ethics located in the Center and funded by the Medical Research Council.

The Norwegian Biotechnology Advisory Board

During the parliamentary debate discussing the proposal of establishing the system of three National Research Ethics Committees, a group of MP's from the opposition parties proposed in addition the establishment of a *National Advisory Board in Biotechnology*. This proposal was also endorsed by the Parliament.

The Norwegian Biotechnology Advisory Board is an independent body consisting of 21 members appointed by the Norwegian government. Each member has a relevant background and/or education to competently discuss questions regarding modern biotechnology. Eight members of the board represent different public organizations. The main task of the Norwegian Biotechnology Advisory Board is to evaluate the social and ethical consequences of modern biotechnology and to discuss usage which promotes sustainable development. The Norwegian Biotechnology Advisory Board has approximately ten regular board meetings and organizes two to three public conferences annually. The secretariat of the Board has five employees assisting and coordinating the board. It publishes a free, quarterly journal "Genialt" in Norwegian. In addition it makes information pamphlets on various topics regarding modern biotechnology (source: http://www.bion.no/index_eng.shtml).

This implies that since 1990, Norway has in fact had four national bodies dealing with the ethics of scientific research and development.

Phase III – the proliferation of research ethics and bioethics

During the last 11 years there has been a further growth in the number of national bodies dealing with the ethics of scientific research and development, through the establishment of four additional institutions: the Norwegian Board of Technology (1999), the Norwegian Advisory Board on Ethical Aspects of Patenting (2004), the National Commission for the Investigation of Scientific Misconduct (2007) and the National Committee for Research Ethics on Human Remains (2008):

The Norwegian Board of Technology works in the interface of science and technology. It aims to assess impacts and options of technology in all areas of society; to stimulate public debate on technology; and to support the political decision-making process and shaping of technological change. The Board furthermore monitors international technological trends and methods for technology assessment. The results of its activities are communicated to the Parliament, governmental bodies and the public at large. The Norwegian Board of Technology has 14 members appointed by the Government.

The members have a broad insight in different areas of technology, innovation and societal issues. The secretariat is situated close to the parliament building and government offices in Oslo, co-located with the National Committees for Research Ethics. The work is organized in projects, and the Board sets its own agenda. The secretariat manages the projects and reports to the Board. The Norwegian Research Council acts as the supervising authority (source: http://www.teknologiradet.no/FullStory.aspx?m=5).

The Norwegian Advisory Board on Ethical Aspects of Patenting was established by parliamentary decree and appointed in Royal Council ("Statsråd") in 2004, basically as a reaction to the need to adapt to the European Patent Directive. The Board is to be advisory for the Norwegian Industrial Property Office in cases where there is doubt whether § 1b applies. Up to this date, the council of the Board has been required only once. This was the case of a patent on a genetically modified salmon with enhanced growth. After in-depth discussions within the Board, it was concluded to advise negatively because of presumed sufferings of the animal and negative environmental effects. The Norwegian Industrial Property Office did not follow this advice, even though it first modified some of the patent claims on the basis of animal welfare issues. However, when the company claimed that no such negative effects where observed, the patent was eventually granted. In view of the paucity of cases sent to the Board, the Board wrote a report on the ethics of patenting (2008), where it suggested that the mandate of the Board be changed so that it could take a more pro-active role and include a closer collaboration with the Norwegian Industrial Property Office, as well as a role in public debate. In the light of this report, efforts are currently underway to improve the modus operandi of the Board (source: http://www.etikkom.no/en/In-English/Patent-Board/).

The National Commission for the Investigation of Scientific Misconduct is responsible for assessing allegations of serious research misconduct and issue a statement on whether any scientific misconduct has occurred or not. The commission covers all research fields and deals with research carried out by Norwegian research institutions private or public. It can also investigate cases abroad, if the research has been carried out by researchers employed by a Norwegian institution or if a substantial part of the funding stems from Norway. The commission is composed of seven members and four substitutes who all are nominated for a period of four years (renewable not more than once). The members cover different fields of research. The commission is independent but the members are appointed by the Ministry of Education and Research following the proposition of the Norwegian Research Council. The commission is expected to give advice to individuals and/or research institutes and to be a kind of a knowledge base for questions and experience concerning research misconduct in Norway and other countries. The commission is cooperating with similar organizations abroad (source: http://www.etikkom.no/en/In-English/Scientific-Misconduct/).

The National Committee for Research Ethics on Human Remains was established in 2008 by the Norwegian Ministry of Education and Research. The Committee consists of ten members: two lay representatives and members with different professional backgrounds. The committee evaluates the ethical aspects of research where the source material consists of human remains which are in public museums and collections, or which will be found in future archeological and other surveys (i.e. complete skeletons, parts of skeletons, and other human remains). These are often human bones

found in archeological excavations, but may also include human remains which have never been in the ground, for example parts of bodies used in artifacts, bodies contained in coffins and sarcophagi (source: http://www.etikkom.no/en/In-English/Human-Remains/).

The abundant growth of national bodies dealing with the ethics of scientific research and development during the last 20 years makes it reasonable to ask whether Norway - in terms of research and technological development - has now reached a level of *ethicization* that may not only generate better research conduct and transparency but also lead to adverse effects of a kind that may hamper a genuine promotion of ethical reflection and bioethical discourse. Several such effects can be identified:

- The existence of 8 different bodies at the national level involved in assessing the ethical dimensions of scientific research and development may generate a perception among politicians and the public that scientific research and development is such a potentially dangerous and dubious enterprise that it need to be constantly controlled and monitored.
- The existence of 8 different bodies at the national level involved in assessing the ethical dimensions of scientific research and development may generate a normative landscape that is perceived as almost impenetrable by researchers and the public.
- The existence of 8 different bodies at the national level involved in assessing the ethical dimensions of scientific research and development may generate conflicts and power struggle between the different ethics bodies with regard to division of labor and division of responsibilities.
- All of the 8 different committees focus on ethics of scientific research – only one of the domains of bioethics, which does not allow for institutionalized reflection by the governments and society on broader bioethical issues.

It is due time for relevant ministerial authorities in Norway, in consultation with representatives from the ethics committees themselves and the community of researchers, to discuss ways of making the Norwegian ethics bureaucracy a simpler and more transparent one, so that it does not loose its credibility but continues to promote ethical reflection and bioethical discourse within academia as well as in the society at large.

Common challenges ahead for National Ethics Advisory Bodies and Committees

This paper started with some historical observations about the role of the *Declaration of Helsinki* in promoting the establishment of systems of ethics review committees; it would only be appropriate to end it with some reflections about the possible role that national ethics advisory bodies and committees could take on together with regard to the globalization of biomedical and health related research. As will soon become clear these reflections relate indirectly to the most recent revisions of the *Declaration of Helsinki* as well as to Article 15 on Benefit Sharing of the UNESCO *Universal Declaration on Bioethics and Human Rights*.

Since 1996 all Member States of the United Nations as well as the global community of medical researchers have been aware of the so-called 10-90 gap, which points to a monstrous inequity in the

world with respect to what diseases are favored in ongoing or planned medical and health-related research (WHO 1996). The implication of this enormous gap is that the needs of 90% of the world's population have to be met from 10% of research funding. Unfortunately, recent studies into the so-called globalization of clinical research (Chirac and Torreele 2006; Glickman et al. 2009) gives reasons to believe that this gap has not diminished, although during the last 15 years the number of people from poor and low-income countries enrolled in clinical trials has substantially increased. On the contrary, evidence from these studies suggests that during this trial period the relative availability of new drugs to populations in poor- and low income countries has *not* increased, while the gap between wealthy nations and poor- and low-income countries with regard to who benefits from the advances of clinical research and development continues to widen!

In view of this situation of international clinical research, the bioethics debate has been marked in the last decade by a much broader focus on the need for protection of developing communities. It gives reason for deep concern, however, to observe that during the last revision of the *Declaration of Helsinki* in October 2008, the permission to use placebo in clinical trials conducted in poor and low-income countries was finally included in the *Declaration*. Besides, the obligation to provide post-trial access of the tested drug was diluted. With these revisions the acceptance of applying a lower moral standard in medical and health related research in poor and low-income countries has been given legitimacy by the institution that created the *Declaration of Helsinki*, a development that will continue to favor private and public interests in affluent countries - including the interest of science and the pharmaceutical market - at the cost of the safety, well-being and needs of individual human beings and populations in poor and low-income countries.

At a congress in bioethics organized by the Latin-American and Caribbean Bioethics Network of UNESCO (Redbioética) in Cordoba, Argentina in November 2008 and with the participation of 300 scholars in bioethics from 12 Latin-American countries, the latest revision of the *Declaration of Helsinki* (Helsinki VI) was the subject of vivid debate. During the final plenary of the congress the *Declaration of Cordoba* was unanimously adopted (Declaración de Córdoba 2008), stating that:

- *Helsinki VI* can seriously affect the safety, the well-being and the rights of persons who participate as volunteers in clinical trials;
- the acceptance of different standards of medical care - due to methodological, scientific or other reasons - is ethically untenable;
- the new possibilities for using placebo, are considered ethically unacceptable practices and are contrary to the idea of human's dignity and human and social rights, and
- the lack of hard post-study obligations in relation to study subjects and host communities offends people's integrity, amplifies the social inequity and injures the *Declaration of Helsinki's* own notion of justice.

For these reasons, the *Declaration of Cordoba* advises countries, governments and institutions that dedicate their work to bioethical issues, to reject *Helsinki VI* and recommends as an ethical and normative frame of reference instead the *Universal Declaration on Bioethics and Human Rights.*

In my view the *Declaration of Cordoba* deserves serious attention not only from governments and ethics institutions in Latin-America but from *all* governments in the world that have adopted the

Universal Declaration on Bioethics and Human Rights and thereby committed themselves to follow the principles laid down in this *Declaration*. This brings me to Article 15 of the UNESCO *Declaration* where it is stated:

"Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, *in particular with developing countries*" (emphasis of the author).

The article contains important clues for establishing a fruitful north-south and south-south collaboration between national ethics advisory bodies and committees that could end the use of double standards of care in clinical trials undertaken in poor and low-income countries and thereby re-establish the original spirit of the *Declaration of Helsinki*. Besides, such collaboration could become crucial in the development of sustainable ethics of benefit sharing.

However, for a sustainable ethics of benefit sharing to become true, it will not be sufficient to develop national medical science policies and research strategies in the affluent parts of the world that take into account the particular research for health needs of poor and low-income countries. What will be needed additionally is the development of policies that include sustainable plans for how the benefits resulting from these research programs could be shared efficiently with poor and low-income countries. How could then poor and low-income countries become actively involved in the co-evolution of a fair and sustainable global policy on scientific literacy and benefit-sharing? One way would be through the establishment of north-south and south-south collaboration between national ethics advisory bodies. A forum could be created where ethics stakeholders from poor and low-income countries could work together with their counterparts from the affluent part of the world to create a global medical science policy and research for all strategy that could lay the foundation for a fairer distribution of available resources for medical and health related research in the world, as well as of the research benefits that will hopefully stem from such a re-distribution.

REFERENCES

Annas, G.J.; Grodin, M.A. 1992. *The Nazi Doctors and the Nuremberg Code. Human rights in human experimentation*, New York/Oxford: Oxford University Press.

Beecher, H. 1966. Ethics and Clinical Research. *New England Journal of Medicine*; 274:1354-60.

Chirac, P.; Toreele, E. 2006. Global framework on essential health R&D. *Lancet* 367 (9522): 1560-61.

Declaración de Córdoba sobre Ética en Investigaciones con Seres Humanos 2008. El Congreso de la Red Latino-Americana y del Caribe de Bioética/UNESCO. Córdoba, Argentina, November 2008. Accessible at: http://www.unesco.org.uy/shs/es/areas-de-trabajo/ciencias-sociales/bioetica/red-bioetica.html.

Enger, E. 1966. *Kontrollerte kliniske forsøk på mennesker* (Controlled clinical trials on humans), Oslo: Universitetsforlaget.

Glickman, S.W.; McHutchison, J., *et al.* 2009. Ethical and Scientific Implications of the Globalisation of Clinical Research. *New England Journal of Medicine* 360; 8: 816-823.

WHO. 1996. Ad Hoc Committee on Health Research Relating to Future Intervention Options. *Summary of Investing in Health Research and Development*, Geneva.

The Danish Council of Ethics

Lise Wied Kirkegaard

Introduction

Since the beginning of the 1980s, innovations as genetic engineering, assisted reproduction and fetal examination have caused ethical problems. The birth of the first child from in-vitro fertilization in Denmark in 1983 resulted in an intense media debate about reproductive technologies which captivated the general public. In order to study and evaluate the situation, the Danish Minister of Interior set up a committee in April 1984. Six month later, in October 1984, the committee submitted the report "The Price of Progress", which suggested a law establishing a central ethical council for the health services.

The Act establishing the Council

The Act on the Danish Council of Ethics was passed in Parliament in June 1987 by a large majority. The Council was established to provide the Parliament, the official authorities and the general public with ongoing advice and information about ethical problems raised by developments within the National Health Service and the field of biomedicine.

In June 2004 the scope of the Council's mandate was extended, and since January 2005 the sphere of activity has been "the ethical issues associated with the research and use of biotechnologies and genetic engineering pertaining to human beings, nature, environment and foodstuffs. The activities also include other ethical issues associated with health services and biomedical research relating to human beings."

The current act frames the following conditions for the Council:

"The Council of Ethics is an independent council. The Council's operations and activities shall be based on respect for the integrity and dignity of the human being and future generations as well as respect for nature and the environment. Respect for the integrity and dignity of the human being also encompasses the early phases of human life, including fertilized human eggs and embryos. Respect for nature and the environment are conditional on nature and the environment having a value in their own right."

The purpose of the Danish Council of Ethics

As written in the Act, the Danish Council of Ethics is an independent council. The Minister of Health and Prevention has no instructional powers in regards to the Danish Council of Ethics and likewise the Minister has no obligation to follow the recommendations of the Council.

In relation to the above mentioned ethical issues the Council has the following tasks:

- advise the Parliament, ministers and public authorities on ethical issues;

- follow developments and submit statements or reports on the general and fundamental ethical issues associated with the researching and application of biotechnologies and genetic engineering; and
- conduct information and debate-generating activities to the public, and make provisions to keep the Danish public continually informed about the developments within the sphere of activity.

The purpose is accomplished by submitting reports and statements in specified areas and by mounting debate generating activities in the form of public enquiries and debate days, publishing of debate books, anthologies, videos and teaching material, extensive lecturing activities, as well as through other means.

According to the Act, the Council also submits an annual report to the Parliament about its activities.

The Council itself gives priority to the assignments within its sphere of activity and can also deal with issues of general and fundamental ethical nature on its own initiative. The Council is neither an expert nor a layman organ, but rather "a mixture" of the two types of bodies. It is important to note that the Council does not have to reach an internal agreement in its opinions and recommendations. It is essential that the Council's work presents to the outside world the complexity of various dilemmas contained in a given ethical problem. Maintaining a space for different views is seen as strength of the Council.

The Parliamentary Committee

The Act also sets up a Parliamentary Committee on the Council of Ethics for the purpose of safeguarding the close relations between the Danish Parliament and the Council of Ethics. The Parliamentary Committee influences the composition of the Council of Ethics by selecting nine of the 17 members in the Council. The Committee is also responsible for appointing the Chairperson of the Council.

The Committee constantly monitors the work of the Council of Ethics. Joint meetings during the year are fruitful for the Committee as well as for the Council. The politicians of the Parliament can call on the Council to take up certain topics within its terms of reference. Most recently, such requests have resulted in the Council's recommendations on surrogate motherhood (spring 2008), and in the report on organ donation (December 2008).

The members of the Danish Council of Ethics

The Council of Ethics consists of 17 members, all appointed by the Minister of Health and Prevention after the following rules:

- 9 members are suggested by the Parliamentary Committee
- 4 members are suggested by the Minister of Health and Prevention
- 1 members is suggested by the Minister of Environment
- 1 member is suggested by the Minister for Food, Agriculture and Fisheries
- 1 member is suggested by the Minister for Science, Technology and Innovation

- 1 member is suggested by the Minister for Economic and Public Affairs

The 8 members suggested by the above-mentioned ministries must have insight into the ethical, cultural, social and other professional issues of importance to the Council, and both laypersons and experts are represented. Furthermore the appointments shall ensure equal representation of men and women.

The appointment of the members and the chairperson is for a term of three years, with the possibility for reappointment for another three years.

The relationship to the Biomedical Research Ethics Committee System

Since 1980, Denmark has had a system of research ethics committees with a number of regional committees and the Danish National Committee on Biomedical Research Ethics. According to Danish law, all biomedical research projects in Denmark involving human beings or any kind of human tissue, cells, etc., need permission from a regional ethics committee. It is the responsibility of the committee system on biomedical research ethics to ensure that from a research ethical point of view, biomedical research projects are carried out in a responsible manner. The system also ensures that the rights, safety and well-being of trial subjects participating in such biomedical research projects are protected, while at the same time possibilities are being created for the development of new, valuable knowledge.

According to the Act on the Council of Ethics, the Council shall operate in collaboration with the Danish National Committee on Biomedical Research Ethics. The fields of responsibility for the two institutions are in principle totally different, as the Council of Ethics does not deal with the review of research projects, but instead has the opportunity to discuss the more fundamental ethical problems associated with research and healthcare. Naturally, the mutual exchange of experiences is of great value for both the Council and the National Committee. At annual joint meetings, relevant problems are being discussed and points of view on ethical matters are exchanged.

Activities: Examples of relevant topics of engagement in recent years

Organ donation

In its report from December 2008 the Danish Council of Ethics presents recommendations regarding what the politicians should do in order to put a sound framework in place for organ donation. The aim is to offer suggestions as to how society can accommodate the needs of people with failing organs for healthy organs in an ethically defensible way, among other things by creating a proper framework for the relatives.

Organ donation as a practice in the health services involves difficult ethical considerations. This is primarily due to the dependency that exists between the recipient's need for organs and another person's death. Organ donation frameworks which are good from an ethical point of view, therefore, must entail making proper allowance for the interests of both the donors and the recipients of organs. People with an illness-related need have an interest in ensuring that it is possible to perform organ transplants, and consequently that organs are available. But it is important for everyone in society that the dead body is treated with respect and dignity. Relatives of the organ donor should be provided with

a human setting in which they can bid farewell to their next-of-kin. It is important that potential organ donors - that is to say, all citizens over the age of 18 - have a positive encounter with the relevant public service, based on respect and understanding for any doubts and questions they may have regarding the fundamentally difficult decision to become an organ donor.

The Council of Ethics' members do not agree as to what framework is actually ethically reasonable. For example, some of the Council's members think that presumed consent should be introduced for organ donation, while others think that explicit and informed consent should be maintained as it is today in Danish legislation. All members do agree, however, that it is important to create a proper setting for relatives to take a statutory leave from work and that citizens should be familiar and comfortable with the particular circumstances of the death process brought about by organ donation.

That means that the Council of Ethics' recommendations do not always point in a particular direction. Instead it can be seen as a thoroughly argued chart or catalogue of the Council members' views as to which social frameworks should exist for organ donation. This can hopefully act as a beneficial platform for reflection and decision-making by politicians and general-interest readers.

It can be said that the Danish Council of Ethics' recommendations are descriptions of different routes towards better ethical frameworks for organ donation.

Euthanasia

The Council of Ethics has repeatedly worked with the topic of euthanasia. In 2003, the Council published the statement: *Euthanasia - legalization of the killing on request?* The report deals with the question whether it should be permitted for doctors in Denmark to take the life of persons who are severely suffering and, in some cases, dying patients who request to die. In 2003, the Council of Ethics was - by consensus – an opponent of euthanasia. What the Council has been able to contribute to the debate is to clarify the ethical dilemma: the citizens' need for autonomy over their own lives and their desire to avoid suffering versus the principle of sanctity of life - that it is morally wrong to take someone's life.

In autumn 2009, this topic again has been the subject of public debate in Denmark. As more countries have introduced legal opportunities to get help for terminating the life of a person who no longer wants to live, the debate flares up again, and the proponents of euthanasia want the Danish healthcare system to offer this service. Because of the ongoing public debate, the Council will take up this topic again.

Prenatal diagnosis

In October 2009 the Danish Council of Ethics published a report entitled *The Future of Prenatal Diagnosis.* The report focuses on new methods for prenatal diagnosis that presumably will be developed within the next few years. These methods will make it possible to obtain information about the hereditary characteristics of the fetus by taking a blood sample from the woman. The new methods will not involve the increased risk of ½ -1% of miscarriage that relates to invasive testing, therefore these new methods are significantly more attractive than the existing ones and it is likely that they - if possible - may be used extensively in early pregnancy.

The application of new methods involves a range of ethical issues that are discussed in the report. A central problem is that they will make it possible for pregnant women to access information about the fetus before the 12th week of pregnancy, which in Denmark is the upper limit for having an abortion. Therefore, the women might choose to have an abortion, if the fetus has characteristics the women or couples perceive as undesirable. But the question is whether this is acceptable in all cases, for example due to less serious diseases or characteristics like physical attributes or the sex of the fetus, and where exactly the limit has to be drawn.

The report contains some other discussions related to prenatal diagnosis. One of them is whether prenatal diagnosis involves specific elements which might make it difficult for the pregnant woman to make independent and informed decisions. Another discussion is the degree to which the Danish Parliament should be involved in designing the practice of prenatal diagnostic.

Surrogate motherhood

In the spring of 2008 there was an extensive debate in the media regarding surrogate motherhood.

In Denmark, commercial agreements on surrogacy are forbidden. That means that the surrogate mother is not allowed to make money from her services. It is also forbidden for doctors to carry out assisted reproduction in connection with an agreement between two parties on surrogacy. The law only opens the way for surrogacy, where there is a close, typically familial kinship between the two women, and – in addition – where the surrogate mother has parented the child genetically.

The Council of Ethics recommendations on surrogacy state that commercial agreements on surrogacy should be banned and advertizing for surrogate motherhood therefore must not be permitted. Furthermore, a surrogate mother can not be forced to hand over her child under the terms of a surrogacy agreement. Finally, the assignment of parental custody should only takes place if deemed to be in the best interest of the child.

Chimeras – ethics and regulatory needs

Chimeras are living organisms incorporating cells from at least two different individuals. For a number of decades researchers have been developing chimaeras by moving cells –and whole organs – from one individual to another.

With the creation of human-animal chimaeras, research compels the society to pose questions of one of the conditions of life we have taken for granted so far. We normally think of animals and human beings as two distinctly discrete categories, and the borderline between humans and animals is fundamental to our culture and legislation. Human beings are covered by far more comprehensive protective considerations than animals, which among other things can be made part of medical experiments associated with certain risks, kept as pets and eaten. Virtually no country, including Denmark, has legislation covering creatures that are neither animals nor human beings.

Will parts of the chimera research presently being conducted potentially lead to the creation of individuals that are changed in morally significant ways? Will chimaera research be capable of

producing crossbreeds that cannot be classified as either animals or humans? Could we end up with individuals we would not know how to treat?

In the report *Man or Mouse? Ethical aspects of chimera research* (2007) the Danish Council of Ethics and the Danish Ethical Council for Animals urge politicians to take steps to modify current regulation to prohibit the creation of chimeras that would be difficult to place biologically, ethically and legally.

In November 2008 the Council held a public conference at the Parliament's Building in Copenhagen. The purpose of the conference was to discuss what types of research has a potential capacity to alter the identity-forming organs and thus become an ethical problem, as well as how to modify the legislation to avoid such problematic experimentation.

Genetically modified plants – utility, ethics and belief

The debate on genetically modified plants is not just about scientific risk evaluations. It also has to do with more attitudinal questions of utility, ethics and belief. These are the issues most often vital to taking a personal stance, and they form the focus of the Council's report on *Genetically modified plants – utility, ethics and belief.* The report has been drawn up at the request of the Danish Minister for the Environment, who asked for the particular issues mentioned taken on board in the deliberations in the Council.

Ethical Forum for Young People

The Danish Council of Ethics wants to improve young people's knowledge and awareness of bioethical topics, and to coach them in the art of discussing fundamental values in a democratic manner.

The Ethical Forum for Young People is a teaching and democracy project which the Danish Council of Ethics has organized for elementary schools every second year since 2001. Some 25,000 pupils between ages 14 to 16 become acquainted with the project on each occasion, which always has a topical subject within the Council of Ethics' sphere of activity. The Council develops teaching material, which is ready for use in the schools in the autumn. The classes then nominate pupils to take part in the Ethical Forum for Young People. The Council of Ethics selects 17 of the nominees, who then meet for two days to debate and take a stance on the topic.

Ethics in cyberspace

As mentioned earlier, the Council shall conduct information and debate-generating activities in the public. The website *Ethics and the Building Blocks of Life* for upper secondary schools makes it possible for the young students to get information and discuss ethics and biotechnology on the basis of thorough introductions to aspects of biology, philosophy and social sciences. The website deals with five biotechnologies from a natural-science and ethical perspective (genetic engineering, cloning, stem cells, chimaeras and nanotechnology), and is well-visited.

Another example of ethics in cyberspace is the *Ethical Challenge* on *facebook*. In 2008 the Council offered users of the social network a chance to take a position on ethical dilemmas within assisted

reproduction, biosensors, organ donation and much more. The game then provides a rough picture of the users' *ethical profile*: to what extent is the user community spirited, duty minded, a planner or a liberal? The user can compare his or her profile with friends on *facebook*, an online social network, and get the discussion going.

Newsletter

Every month the Danish Council of Ethics sends out a newsletter, in Danish, about biotechnology and bioethics. The newsletter contains digests of the most essential news from the world of research, legislation, policy-making and ethical discussions, internationally and in Denmark. The newsletter contains a good assortment based on professionally accredited sources, making it well suited to the reader wishing for reliable, objective information on biotechnology and bioethics.

Debates

The Danish Council of Ethics subsidizes the holding of debate-generating events on ethics. Across the country in 2008, 46 lectures and talks on ethical topics were held with the Council's support – on everything from "Assisted life and euthanasia" to "The artificial human being". Entirely different fora and initiatives enjoy the benefit of such lecture, such as Silkeborg Folk High School, Bronderslev Amateur Dramatics Society, Gunnestrup Church and many others in 2008.

Annual reports

As mentioned earlier, the Council has a statutory duty to produce an annual report about its activities. The most recent version of the annual report covers the activities of the Council in 2008, which were characterized by ethical dilemmas connected with the human body. Consequently, it incluedes the report on organ donation, a teaching booklet on 'Marks for Life' (tattooing, piercing and circumcision) and a statement on surrogacy. The English version of the annual reports can be read at www.etiskraad.dk.

Conclusion

The establishment of the Danish Council on Ethics was a response to real and pressing ethical questions arising from developments in life and health sciences. Since its establishment, the Council has consistently served as an imporant platform to debate and to address an ever-expanding scope of emerging bioethical issues. In the process, the Council has itself undergone an evolution into a broad-based body that formulates recommendations in order to provide ethical guidance for policy-makers and to raise awareness about bioethical issues among the general public.

Newly Established National Bioethics Committees:
prospects and challenges

The Jamaica National Bioethics Committee

Anthony Mullings

Introduction

Jamaica is a participant in UNESCO's Assisting Bioethics Committees (ABC) initiative for the establishment and capacity-building of a National Bioethics Committee (NBC). The process commenced in June of 2007 under the auspices of the Jamaica National Commission for UNESCO (JNATCOM), which is a governmental agency. The appointment of members was confirmed on September 27, 2008 and a formal launch ceremony was held on October 1, 2009.

The establishment of a National Bioethics Committee in any country, especially with the full cooperation of the government, is a difficult step in the right direction. By taking this step, the government recognizes the value and the importance of the reflection, from an ethical perspective, on questions arising from the application of modern technologies and practices in bio and life sciences. To date, Jamaica is the first English-speaking Caribbean Territory to do so.

The creation of a NBC is a significant achievement by any society and can be put in perspective by a quotation from the Bioethics section of the European Commission's website: "As the life sciences and biotechnology develop, they contribute considerably to securing personal and social welfare, as well as to creating new opportunities for our economies. At the same time, the general public is increasingly concerned about the social and ethical consequences of these advances in knowledge and techniques, as well as about the conditions forming the choices made in these fields" (European Commission, 2009). In order to address these social and ethical consequences, the development of channels for dialogue is necessary to ensure respect for agreed fundamental values. One such channel is a National Bioethics Committee, defined as "an independent platform for public debate and policy advice in bioethics" (ten Have, 2009).

Public debate and policy advice: choice of topics to consider

According to Article 19 of the *Universal Declaration on Bioethics and Human Rights:* , "Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) Assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) Provide advice on ethical problems in clinical settings;

(c) Assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) Foster debate, education and public awareness of, and engagement in, bioethics." (UNESCO, 2005).

The European Union believes that "an effective societal scrutiny, an ongoing public dialogue, and an integration of ethical and social aspects into the early phases of research, before the technology is

ready for use by society, are key preconditions for harvesting the potential of biotechnology" (European Commission, 2009). The European Union has made it clear that states, in addressing their developmental needs, "cannot afford to focus exclusively on the scientific and research aspects to the detriment of social dialogue so as to ensure that science delivers what people need and complies with an acceptable ethical consensus". (European Commission, 2009)

In an evaluation of the National Bioethics Committee of Taiwan, the authors indicate that in a democratic and pluralistic society, national bioethics committees, when properly constituted, are institutions creating an opportunity for the reaching of a "moral consensus" through "dialogue and deliberation," thus promoting "public consensus" (Rei and Yeh, 2002). These views seem to support the idea associated with Noam Chomsky that people, and not the states, are moral agents, and can impose moral standards on powerful institutions.

Bioethics in Jamaica

Jamaica is a small island state with a land mass of 4,244 square miles and an estimated population in 2009 of approximately 2.84 million. The island lies 90 miles (145 km) south of Cuba and 100 miles (161 km) west of Haiti. The population is diverse and multiethnic with a majority of African ancestry as a result of slavery, but with a healthy mix of European, Indian, Chinese and Middle Eastern peoples. Its history dates back over 600 years when it was occupied by the Taino people who spoke the Arawak language. Subsequently, it was occupied by the Spanish until 1655 and then by the British, from whom the country gained independence in 1962. Under British rule, the island was dominated by the slave economy which ended in 1838. During the Second World War a refugee camp for evacuees of Gibraltar was established in Jamaica. The population therefore constitutes a multiracial, multiethnic society with significant cultural and religious pluralism. The political system is the Westminster style democracy and the motto is "Out of many one people".

The society is in transition from a largely agricultural to a more industrialized one, with all the trappings of modern technology. There are several well-established institutions with research capabilities, the oldest being the University of the West Indies established in 1948. Great interest has developed in researching areas such as the use of botanicals in medical treatment; developing alternative energy sources; and improving agricultural output both on land and in water. There is an established National Bio-safety Committee with special interest in Genetically Modified Foods. The government itself facilitates research through several agencies such as the Scientific Research Council and Ministry of Agriculture. If an NBC, as characterized previously, is to be of benefit to Jamaica it would have to reflect the characteristics of the population in the context of the past, the present and the future growth and development.

In the establishment of the National Bioethics Committee of Jamaica (NBCJ), the preparatory committee attempted to reflect the reality of the Jamaican social landscape by adopting a specific definition of Bioethics as "a field of critical reflection on, and examination of, ethical issues of life and human existence". The committee then proceeded to identify fields of importance to the society which would be of relevance to a bioethics committee within the adopted definition. The twenty-two fields identified included such standard fields as science and technology and health care, but also covered

the humanities, information technology, education, the environment, law, and human rights. Having identified the fields to be covered, the challenge was the identification of the best process for selecting Committee members in order to ensure the broadest social representation possible. It was agreed that a committee of not less than 15 persons would be recommended and that persons would be selected not to represent an organization or an interest group. Although such entities would be asked to nominate persons for ratification by the relevant government authority, it was stipulated that once appointed, the member would be expected to act independently.

But can a Committee within the architecture of a government agency, such as JNATCOM in case of Jamaica, really act independently? For Jamaica, the answer lies in the constitution and the rules of procedure of the NBC which are designed to create the space for an independently functioning committee. They grant the Committee the rights to determine its own work agenda, to have its own secretariat, and to recall members for cause. They also set term limits on chairmanship and membership of the committee, and identify the process for electing members for the executive officers, as well as an evaluation process.

The decision by JNATCOM to nominate the members of the preparatory committee based solely on their expertise and demonstrated interest, without considerations of political or ideological allegiances, was a commendable first step towards ensuring independence. Indeed, the preparatory committee recommended a continuation of that process in selecting the members of the NBCJ.

Conclusion: what of the future?

A committee such as an NBC has to be conscious of the need to promote the public good within the context of the need for development. Development, especially spawned through or fostered by science and technology, will be dependent on the adoption and use of new and emerging technologies and the reengineering of past technology. In order to "ensure that science delivers what people need and complies with an acceptable ethical consensus (European Commission, 2009)," it will be the NBC's challenge to seek ways and means to determine the acceptable ethical consensus within the reality of the competing interests of the democratic pluralist society. This consensus must have public support – a "public consensus" as described by Rei and Yeh, and therefore strategies will have to be developed to encourage the public's involvement. The NBCJ is well attuned to these issues and intends to pursue strategies to meet these needs.

References

ten Have, H. 2009. Establishing and reinforcing bioethics infrastructure – the challenge of national bioethics committees. Presentation at Summer School Health law and ethics, Erasmus University Rotterdam, July 2009. http://www.erasmusobservatoryonhealthlaw.nl/lectures (accessed 5 September 2009)

UNESCO. 2005. *The Universal Declaration on Bioethics and Human Rights*. Paris. Accessible online at http://www.unesco.org

European Commission. 2009. Bioethics: integrating the ethical, legal, social, and wider cultural aspects into life science and biotechnology research. http://ec.europa.eu/research/biosociety/bioethics/bioethics_en.htm (accessed 28 September 2009)

Rey, W.; Yeh, J. 2009. Steering in the tides: National Bioethics Committee as an institutional solution to bio-politics? http://www.eubios.info/ABC4/abc4363.htm (accessed 8 October 2009)

The Spanish Bioethics Committee (SBC)

Yolanda Gómez Sánchez

Introduction

The Spanish Bioethics Committee (SBC) was set up by the Law of Biomedical Research (LBR) (14/2007, 3 July 2007). Article 1.1 of the Law establishes that its aim is to regulate biomedical research, with full respect to human dignity, human identity and the inviolable and inalienable human rights. Dignity is a classical reference in the laws and international documents on biomedical and biotechnological matters. The reference in Article 1 of LBR has to be interpreted as an adhesion to other national and international documents which also demand that actions and policies in the field of biomedicine and health sciences be based on human dignity and on other rights and liberties which nowadays are regarded as necessary elements of dignity. States with very different legal systems and social values have alleged dignity as the basis to regulate biomedical problems and consolidate a minimum standard to protect freedom and equality of the human being.

Currently, biomedical research and its applications constitute a fundamental tool to improve quality and expectancy of life for the citizens. But it is also true that some of these techniques could endanger freedom, equality and dignity of the individual. For this reason, without renouncing the progress that they can bring, the States and civil society must strictly control these activities and establish measures to protect human beings. One of the tools that can be useful to protect human beings in the field of biomedical research and applications is the creation of independent, multidisciplinary and pluralist committees that foster debate and provide valuable guidance to policymakers on bioethical issues.

The Law of Biomedical Research cited above meets the need to promote bioethical reflection through creating an appropriate consultative platform by setting up a number of institutions. These organs are committed to specific qualified functions based on the impartiality, independence, technical capacity and professional competence required from their members. On the one hand, the Law regulates the Research Ethics Committees which shall guarantee in each research center the appropriateness of the methodological, ethical and legal aspects of the research activities that affect human beings or the use of human tissue. On the other hand, the Law designates the Committee to Guarantee the Donation and Use of Human Cells and Tissues to evaluate and report on every research project in which cells and tissue of human embryonic origin are obtained and used, or other similar cells are obtained by means of different techniques of cellular manipulation which already exist or which may be discovered in the future. The Committees shall also develop other functions on scientific, ethical and legal aspects. In addition, the Law of Biomedical Research sets up, for the first time in Spain, a national committee called the Spanish Bioethics Committee (www.comitedebioetica.es). This Committee shall be consulted on ethical and social implications of medicine and biology and on guidelines and general principles for the elaboration of codes of good practices in scientific research to be followed by the research ethics committees.

The Law tries to respond to the need of establishing a national consultative institution on issues related to life sciences which also stands for Spain at the supranational and international level in the institutions dedicated to bioethics. The Committee shall cooperate with other national committees and committees of the Autonomous Communities with advice functions on this matter.

As we all know, the origin of the first bioethics committees is linked to the abuses detected in scientific research on human beings during the past century. Nuremberg processes made public the atrocities performed in the name of science. The Code of Nuremberg of 1946 enumerates the necessary principles to protect human beings involved in a clinical research project or experiment: the principle of informed consent, the right of the individual to reject the process at any stage and the accountability of the researcher. The Code does not expressly mention the existence of a committee, but the need of controlling the respect to the principles of the Code undoubtedly contributed to the creation of committees as we know them today. Some authors affirm that a committee controlled a research project in 1953 for the first time. The Declaration of Helsinki adopted in 1964 by the World Medical Association confirmed the need of establishing committees of ethical review, independent from the researcher, to promote scientific integrity and to protect human beings.

The development of a committee-based ethical review moved forward with the emergence of clinical ethics committees, linked to the principle of autonomy and operating in the field of biomedical applications. Since the creation of the first committees until today, the idea of the committee as a collective organ has gained wide acceptance, recognizing that a collective effort of ethical review is more useful and efficient than the opinion of individual experts in ethics or law. The dialogue between experts of different scientific disciplines and social fields constitutes an essential tool for bioethical analysis. Interdisciplinary approaches allow the analysis of a problem from a perspective that can never be obtained from the analysis of a single branch of knowledge.

In 2007, when the Law of Biomedical Research established the Spanish Bioethics Committee, other bioethics committees set up by a number of Autonomous Communities had already been operating in the country (Spain is divided into seventeen Autonomous Communities and two Autonomous Cities). The scope of action of these committees is limited to the territory of the respective Autonomous Community. In contrast to this, the importance of the Spanish Bioethics Committee is based on its geographical coverage – which is the entire national territory, its plural composition and the scope of operation that the Law has assigned to the Committee. All this factors make this organ unprecedented in Spain but similar to the national bioethics committees in other countries.

A sign of the independent character of the Committee, among other aspects, is the ability to formulate independently its own statutory regulation. The Statutory Regulation of the Bioethics Committee was drafted and approved by the Committee in its meeting of 15 December 2008.

Composition and selection of the members

The Law of Biomedical Research defines the Spanish Bioethics Committee as a collective, independent and advisory organ, which is composed by a maximum number of twelve members, elected among scientific, legal and bioethical experts. The composition of the Committee shall reflect

in a well-balanced manner the different disciplines involved in bioethics. This aim has been achieved by the election of experts in biology, law, pharmacy, philosophy and medicine.

The pluralist composition of the Committee is also reflected in the way of election of its members. All the members were appointed by the Ministry of Health and Consumption (since 2009, Ministry of Health and Social Policy), published in the State Official Gazette No. 3, 3 January 2008, but were proposed by several Ministries and Autonomous Communities through the Inter-regional Council of the National Heath System (which is a collective organ where the autonomous territories of Spain are represented).

The members of the Committee act independently from the authorities that proposed or appointed them, and cannot be neither members of the governmental institutions of the State, the Autonomous Communities or of the local governments, nor be members of the national Parliament or of the Parliaments of the Autonomous Communities. Furthermore, the Statutory Regulation passed by the Committee regulates the potential conflicts of interest by establishing the duty of the members to abstain from intervening in the analysis, discussion and decision on affairs which can affect their independence, impartiality or objectivity and in any case when required by the current legislation or by the Plenary of the Committee.

The members of the Committee shall not make the working documents public before publishing them and shall not give any partial or total information on the issues dealt with by the Committee until their publication by the Committee. The members of the Committee are appointed for a period of four years and can be re-elected just once, except in case of replacing, before the end of the term of office, of another member, in which case the term of office of the new member will last until the end of the four years. The new member can also be re-elected.

The renewal of members will take place every two years, renewing each time half of the members. The first renewal will be by drawing lots. Members of the Committee cannot be removed from office, except in case of permanent incapacity to fulfill their duties, non-fulfillment of their duties, incompatibility or penal prosecution. Members leave their post at the expiry of the term of office or when they resign.

The Committee is organized in two collective organs: the Plenary and the Permanent Commission, which is composed of the President, the Vice-President and four members.

The functions of the Plenary are, among others, the constitution of boards or working groups to study and prepare different questions. These groups can be formed by members of the Committee only or by members of the Committee and external experts. Both the members of the Committee and the external experts who can intervene on a certain question are obliged to preserve the confidentiality on the discussions and reports by the Committee until their publicity.

The individual organs of the Committee are the President and the Vice-President. The Law of Biomedical Research establishes that the President of the Committee shall be appointed among its members by the Minister of Health and Consumption (currently, this competence is exercised by the Minister of Science and Research), once proposed by the Plenary of the Committee in a voting session which requires a two thirds majority and for a term of two years. The President can be reelected for two more years.

The Vice-President is appointed by the Plenary among the members of the permanent Commission. There is also a Secretary of the Committee, who is a high-ranking public servant (with rank of general deputy director), allowed to speak but not to vote in the Committee.

Functions of the Committee

According to the Law of Biomedical Research and the Statutory Regulation, the Bioethics Committee has a number of very different functions, amongst them:

(a) To make reports, proposals and recommendations on behalf of national and autonomous public institutions in fields with ethical implications. The Committee can also act on its own initiative when there is an issue related to biomedicine or life sciences which imply relevant ethical and social aspects. The reports, proposals, recommendations and other documents drafted by the Committee will be published on its website with respect to the fundamental rights of any persons involved. Specially, the Committee shall protect the right to honor personal and familiar intimacy, image and personal data protection.

(b) The Committee also takes over the mission of establishing the general principles to be followed by the elaboration of codes of good practices in scientific research, which will be developed by the Research Ethics Committees.

(c) The Spanish Bioethics Committee also has the important function of collaborating with other national and autonomous committees with advisory functions on the ethical and social implications of biomedicine and of life sciences. For the accomplishment of this function, the Committee shall promote the communication with other committees and shall establish cooperation relations and ways for the exchange of information, regardless of the competences of each body. This function is especially important in a quasi-federal State, as is Spain, where most of the competences regarding health correspond to the Autonomous Communities. A number of Autonomous Communities have also set up advisory Committees on bioethics.

The relationship between the Spanish Bioethics Committee and other Committees and Commissions takes place at several levels. On the one hand, the Bioethics Committee publishes all its reports and sends them to the Committees of the Autonomous Communities. In addition to this, there is the possibility of holding joint sessions between the Spanish Bioethics Committee and the Committees of the Autonomous Communities to exchange information and to analyze subjects of common interest. At any time, the Committees of the Autonomous Communities can address the President of the Spanish Bioethics Committee requesting information or cooperation in the drafting of a report, proposal or recommendation.

(d) Another important function of the Bioethics Committee is the representation of Spain at international meetings or institutions on bioethics. Since the creation of this new Committee, the official representation of Spain in meetings dealing with bioethics shall be assumed by the Committee. The representation can be assumed by the President, the Vice-president or by any member of the Committee.

(e) The Committee is obliged to elaborate an annual report on its activities and to present it to the public authorities. Thus, the Committee respects a principle of transparency and offers an important amount of information to researchers and in general to civil society.

In addition to the functions established in the Law of Biomedical Research and in its Statutory Regulation, other functions can be conferred to the Committee by law. Thus, the functions of the Committee, if needed, could be further elaborated in the future. Neither the Law nor the Regulation stipulate that the Bioethics Committee can produce reports on behalf of private enterprises or individuals. Undoubtedly, the Committee is an institution which gives advice to the public authorities and has no competence to receive complaints or to settle disputes between citizens or between a public power or administration and a citizen. However, the Committee can issue reports, present proposals or make recommendations on its own initiative. Thus, while citizens cannot directly address the Committee, the Committee can take interest in a socially relevant problem and draft a report. This way the Committee can establish a connection with society and does not remain isolated in the sphere of public powers.

The Statutory Regulation which has been approved by the Committee establishes that the Committee is allowed to hold ordinary and extraordinary sessions, Plenary or Permanent Committee sessions, and working group sessions outside its official headquarters in Madrid. The aim of this norm is that the Committee convenes sessions in different Autonomous Communities upon request of the authorities of the Autonomous Communities, and/or of the public and private organs and institutions of the different territories, or upon request of any member of the Committee. During the first eleven months of effective functioning of the Committee, two working sessions have taken place out of its official headquarters, the first one in the Autonomous Community of Asturias and the second one in the Autonomous Community of Catalonia.

Nature of the Spanish Bioethics Committee

The Law of Biomedical Research defines the Bioethics Committee of Spain as a collective, independent and advisory body, whose members have to be elected among experts in science, law and bioethics. The Spanish legislator has designed the Bioethics Committee of Spain as an interdisciplinary organ in which bioethical problems which affect the life of people can be freely discussed. The incorporation by the Committee of experts from different experimental and applied sciences, as well as legal and bioethics experts, reflects the need to approach bioethics questions from different perspectives and constitutes one of the most positive aspects of the Spanish Bioethics Committee. The complexity of current conflicts related to life sciences also demands global solutions in which very different factors are taken into account. Only an interdisciplinary Committee is prepared to face this challenge.

Bioethics is ethics applied to biology, medicine and in general to the so-called life sciences. It is important to point out that bioethics has always intended to contribute not only to the academic discussion and the creation of intellectual standards, but also directly to the decision making process to address real problems and conflicts. The emerging bioethical norms of the 1970s and the following years allowed many doctors and other related professionals to make decisions on human life and to solve concrete problems in their professional field according to values and principles founded on

reason and justice. This way, bioethics contributed to establishing an ethical framework which could be accepted by a broad number of people in different societies on questions and problems emerging from new biomedical and biotechnological knowledge.

But the object of the study of bioethics – life and life conditions – is a changing reality, which influences its meaning and its development. New discoveries will continue to be made that improve living conditions but also raise new threats for liberty and dignity of the individual. Similarly, legal systems change and modify their principles according to the new problems emerging from life and health sciences. Among the factors contributing to the development of new norms regarding life and biomedical and biotechnological applications, we have to point out the progressive acknowledgement of freedom of the individual to make his or her own decisions concerning health, physical integrity and well-being. This progressive acknowledgement and valuation of individual freedom has changed the departure point of the whole conception of bioethics, which emerged as a method of the professional to make decisions. Currently, it demands a new conception which takes into account the will of the individual and of each individual taking part in the bioethical decision. In many countries – still with important exceptions – it is already the individual affected who legally decides, and not any more the professionals.

On the other hand, the need of legally regulating biotechnological progress constitutes a decisive element in the increasing importance of law on this field. When law extends its field of action, bioethics becomes less important because there is already a binding norm on aspects which at an earlier stage required a discretional decision of the biomedical or the biotechnological expert or the decision was made according to bioethical principles. The progressive possibility of establishing a series of norms on life and health sciences has allowed the use of a new term, biolaw, which we could define as a body of norms of any nature, hierarchy, competence and origin on life and its development.

In this sense, we can further distinguish between a biolaw of national origin (from the different States) and a biolaw of international origin, which already represents an important body of norms. The relationship between bioethics and biolaw has not always been clear but today the need to foster the linkages between these fields is evident in both theory and practice. Bioethics shall find in law its best friend.

The Spanish Bioethics Committee follows this aim. The different scientific background of its members and the fact that the Committee advises public powers show the need that bioethics develops into a field of analysis of problems in society. Solutions to these problems shall not remain alone in the field of reflection, but shall contribute to the intervention of States, international organizations and other public and private bodies in policies and measures which offer guarantees to citizens. The legal norm is the instrument to achieve this aim.

Work Program for 2009-2010

The Spanish Bioethics Committee started its work with a first Plenary meeting on 22 October 2008, by constituting the Committee and adopting an agreement to elaborate its own Statutory Regulation. The Committee also discussed and approved its Work Program for the period 2009-2010,

which includes the elaboration of eight reports on important current problems for Spain and for other countries and international organizations:

1) Banks of cellular lines.
2) Benefits for patients deriving from clinical research. Patents and rights of the patient.
3) Biometrics and data protection.
4) Codes of good clinical and research practices
5) Research on practical surgery and informed consent
6) Conscientious objection in the field of sanitary issues
7) Placebos
8) Chimeras and biological hybrids in research

Two members of the Committee will be in charge of drawing a draft report on each of these topics. The draft report will be studied in a number of meetings of the Committee, where it can be amended.

In addition to this ordinary work program, the Committee can draw other reports on new problems. This was the case of the Report by the Spanish Bioethics Committee, approved in the plenary session of 7 October 2009, on the bill of the organic law on sexual and reproduction health and abortion (http://www.comitedebioetica.es/documentacion/index.php). In this report, the Committee establishes that its aim was to offer institutions and public opinion arguments and considerations to contribute to the reflection on the regulation of abortion contained in the bill of law presented to the Parliament by the Government.

Conclusions

The creation in Spain of a permanent and independent Bioethics Committee is a very positive development. The broad functions given by the Law on Biomedical Research and the internal Statutory Regulation to the Committee will allow the Committee to develop its mission in a wide field of applications and technologies related to medicine and biology. Both the elaboration of its First Work Plan 2009-2010 and the elaboration of the important Report on the non-criminalization of abortion show the vitality of the Committee and the usefulness of its reports. With the creation of the Bioethics Committee, Spain joins the group of countries which already have such a collective organ.

The Challenges of a New National Bioethics Committee: the Ghanaian Experience

Alfred A. Oteng-Yeboah
and
Apollonius O. A. Asare

Introduction

The Ghana National Bioethics Committee was formally inaugurated on 29 January 2009 after several months of deliberation. The need for this followed from UNESCO's call to its Member States to set up National Bioethics Committees to discuss, inform and offer useful suggestions to opinion leaders, the general public and other practitioners in the area of bioethics on the ethical challenges emerging due to developments in medical, biological and life sciences.

The Ghana National Commission for UNESCO took note of an earlier General Conference decision in 2005 and brought together people from selected institutions, civil society and research institutions to form the core of the Ghana National Bioethics Committee (GNBC). This core group explored possibilities of participating in the Assisting Bioethics Committees (ABC) project of UNESCO.

Mr. Henk ten Have, the Director of the Division of Ethics of Science and Technology of UNESCO, led a panel of experts visiting Ghana to hold discussions with the core Bioethics Committee in Accra on 22nd – 23rd March, 2007. The meeting produced an agreement to continue working in several directions, including developing Statutes that would guide the Committee, drafting a Memorandum of Understanding together with UNESCO that stipulates three year long capacity-building assistance provided in the framework of the Assisting Bioethics Committees (ABC) project, and preparing for a training programme for members of the Committee, organized by UNESCO.

The first activity of the ABC project was held in January 2009 after the National Bioethics Committee has been inaugurated. The activity was in the form of a workshop on developing working methods for the Committee. The objectives of the Workshop were to:

- Clarify the role and mission of the Committee
- Develop clear working methods
- Draft rules of procedures
- Develop policy for record management
- Develop policy for public information
- Develop policies for networking

The statutes of the Committee

The statutes of the Ghana NBC contain 12 articles which define the composition, mandate, functions and working methods of the committee and establish a secretariat. There are articles on confidentiality, use of external expert advice and the selection and tenure of officers of the committee.

The challenges of the Committee

Among the many challenges faced by the committee, the one involving its identity and legal status appears to be most pressing. Being placed within the Ghana National Commission for UNESCO which is hosted by the Ministry of Education, the obvious role of the committee is that of advocacy and policy advice. This means that awareness-raising, through communication and public education must form a major area of operation.

Like many other national bioethics committees, the Ghana Committee cannot use any legal means to get redress on perceived "bad" ethical issues which may affect the public. Fortunately for Ghana, the medical research institutions have their own ethical boards which screen research activities that involve human subjects. But other organizations engaged in scientific and agricultural research, including in traditional medicine research, lack these ethical codes and will need the services of the NBC. It is expected that the NBC, when it assesses its full potentials, will use bioethics principles to develop guidelines for all stakeholders whose activities have a potential to create ethical dilemmas in the society.

As a committee which is expected to play advisory and advocacy roles, the nomination and selection of representatives from identifiable institutions or groups will need very careful consideration. The nominating institutions and groups will need exposure to the Statutes of the Committee to enable them to select the most appropriate and able representatives.

Additionally, there will be the need to carefully assess the nature of the committee's outputs in annual reports, but more specifically its bioethical pronouncements on societal issues, to generate and to court public confidence.

Conclusion: future steps

The committee has vowed to look carefully at many of the questions that may conflict with its role and to address them. For example, the NBC will consider and reflect on the existing developmental frameworks in Ghana and ensure that bioethical issues considered as necessities are given a "conscience". In so doing the NBC will ensure that:

- The government of Ghana is adequately informed about the Universal Declaration on Bioethics and Human Rights and its implication for national development;
- The functions of NBC do not duplicate functions of statutory Human Rights Organization like the Commission for Human Rights and Administrative Justice (CHRAJ) in Ghana;
- The NBC will play roles to support the Ghana Government's view on the concept of sustainable development.

Concerning issues of nomination to the committee and other functions, the NBC will ensure that:

- The NBC composition adequately reflects the balance among stakeholders in the field of ethics;
- The NBC compliments existing national efforts
- The NBC is poised as a new mechanism to protect human dignity and social well-being.

Moreover, for the unhindered operations of the NBC, the Committee will work towards convincing the Government of Ghana through its Ministry of Education to see the need to support its activities, especially in setting-up the national secretariat and securing an appropriate budget for its effective operation.

As part of its campaign to provide proper foundations for bioethics, the NBC will be forward looking and consider making inputs into the tertiary education curriculum by introducing the teaching of bioethics, especially in the medical schools and other bio-related fields of study.

Establishment of the National Bioethics Commission of El Salvador

Walter Orlando Lara

Introduction

As a UNESCO Member State that has adopted the Universal Declaration on Bioethics and Human Rights, in accordance with Article 19(d) of the Declaration, El Salvador has established the National Bioethics Commission under the organizational structure of the Ministry of Health in order to "foster debate, education and public awareness of, and engagement in, bioethics".

The establishment of the committee was based on the current interest of the authorities in advancing the field of bioethics in the country, and a convergence of political and social will on the part of the Ministry of Health, Ministry of Education, some universities and the Salvadorian National Commission for cooperation with UNESCO. Interest in the subject has similarly been shown by health and human science professionals and by others who work directly or indirectly with people.

A new ministerial resolution, dated 11 September 2009, restructured the National Bioethics Commission to ensure that it is guided by principles of integrated planning and implementation, and represents a technically structured organization with clearly defined responsibilities and members whose activities bear the stamp of credibility, transparency, inclusion, growth and honesty, along with multidisciplinary participation.

The sustainability of this Commission rests on its incorporation into the country's political system, with due respect for the technical autonomy that it requires to develop the role of impartial advisory body to tackle the requirements and issues relating to bioethics.

The various factors taken into account in establishing the Commission are therefore detailed below and are consistent with the principles established by major organizations, countries and experts at the regional and international levels in regard to the establishment of national bioethics commissions.

The state of Bioethics in El Salvador

In 2004, the Pan-American Health Organization (PAHO) produced a research document on bioethics in El Salvador, with an aim to create an information resource on the state of bioethics in the country, which could then be used as an input when considering its future prospects.

The research found that endeavors in bioethics-related discussions, training and practice were confined to health matters with only two active hospital committees: one research ethics committee at the Rosales Hospital and a medical bioethics committee at the Benjamin Bloom Children's Hospital. Four universities teach bioethics as part of the curriculum of specific courses and some tutors have therefore been trained in the subject.

At that time, universities, medical associations and other entities identified with the development of bioethics began to come together. However, knowledge in this area remained confined to a select

group of persons and professionals. A few articles relating to bioethics have been published in the medical journals of two universities.

In coordination with the Higher Council for Public Health (CSSP) and the Pan-American Health Organization (PAHO), the Ministry of Health issued a Ministerial Decree in 2005 establishing the National Bioethics Committee, to be composed of multidisciplinary members, with the purpose of assessing, from the standpoint of ethics, health research protocols involving human subjects and implemented mainly in the institutions providing health services. On the basis of the stated objectives, the five-year Strategic Plan drawn up that year and the Committee's rules of procedure, the members submitted a request to the relevant authorities for the name to be changed to the National Clinical Research Ethics Committee in 2006, in order to collaborate on the introduction of research ethics and bioethics into formal education, in partnership with UNESCO and the Latin American Faculty of Social Sciences (FLACSO). This took the form of virtual courses aimed at the members of various existing committees in national hospitals. This Committee is still active and its mandate ends in May 2010. After this date, the Committee's head will call for a new proposal to structure the new Committee on the basis of the national health policy.

Moreover, in 1999, the Ministry of Health established the National Health Research Committee (CONAIS), whose purpose was to regulate health research and to form the National Ethics Committee. CONAIS became inactive in 2001.

Establishment of the Bioethics Commission with a broad mandate

The Commission was established on the basis of UNESCO's recommendation and the identified need for an advisory body to analyze bioethics issues in El Salvador. On 18 May 2009, the National Bioethics Commission of El Salvador (CONABES) was established by ministerial resolution. In September 2009 the Commission was restructured.

The Commission must be an advisory body and its composition must be multisectoral and interdisciplinary, comprising representatives who are interested in learning about universally established bioethical values that emphasize respect for human rights and human dignity.

It is required to systematically analyze the ethical aspects of medical and health sciences, biological sciences, human sciences, health policies and all other aspects directly or indirectly related to people. In order to carry out its duty and achieve nationwide coverage, the Commission may form departmental, municipal or local committees, depending on the problems and the population's needs.

It is vital to stress the Commission's advisory role, not only in relation to the Ministry of Health but also to other Ministries or government bodies that deal with people, the environment, biotechnology, food and education.

Objectives

What to advise, to whom and why? Such questions will be answered through a process of analysis, communication and social participation. The process will be open for consultations and will not be construed as an exclusive group of experts dictating what should be done.

The goals are to promote bioethical reflection without using sophisticated terminology in order to interest all levels of society, and to encourage debate, through dialogue and consultation and coordination. All opinions are valued. Imposed criteria do not yield the desired results, especially in an area about which little is known in the country. This applies not only to training organizations but also to the general public.

Duties

The organizational and operational handbook, to be produced by the Commission, must state its vision, mission, objectives and scope, as set out clearly in the resolution of its establishment. The participation of the various stakeholders is of the utmost importance. It is not enough merely to publish a plan or timetable without taking into account the people's opinion, endorsement or consent. Information must be clear, accurate and concise. Otherwise, it may lead to speculation, misunderstanding or even rejection of the Commission's activities or programmes arising from the discharge of its functions.

In regards to the review of research activities, a very specific statement is required on what will be researched, by whom, with what resources and in which geographical area, the topic for consideration and the duration. This implies a coordinated action of the National Research Committee and the newly established National Bioethics Commission.

Promotion of the development of the legal framework regulating various aspects of bioethics in the country is another major aim of the Commission. Although the country's legislation is silent on the issue, proposals must be analyzed and submitted to the relevant authorities so that they can be included in ethical review process. This is the only means of putting the Commission's operations on a sound footing.

Coordination is the central feature of all of the above-mentioned responsibilities. If the Commission does not act in coordination with public and private bodies, sectors, associations and institutions, all of its efforts to promote bioethics will not yield the expected results.

According to the experts, members are not necessarily required to have experience in bioethics, the overriding factors being the individual desire to serve, the availability, impartiality, objectivity and ability not to act under any ideological pressure. A Commission requires a physical space, logistic support and human resource training in order to function.

Conclusion

The Commission must establish such processes clearly and through consensus among its members, once the parameters that will guide the activities have been set. It is therefore very important for the members of the Commission to have a clear understanding of the role that they will play, the implications of their decisions, the commitment undertaken by the country in appointing them and, above all, their commitment towards the population, as it is the latter who will ultimately evaluate their performance.

The National Bioethics Council: The Brazilian Initiative

Volnei Garrafa

Introduction

In many countries around the world, the establishment of national bioethics commissions or councils (NBCs) has provided effective spaces for dialogue and negotiation between people and groups that think differently. At the same time, these bodies have fulfilled a fundamental role in establishing limits, whether through supporting actions of the executive branch, guiding the legislature or providing precepts on which decisions by the judiciary have been grounded. Because they are constituted as *parastatal* structures, NBCs may also represent a solid interlocution space within which social movements can act. Although linked to the state, they are independent in their decisions, pluralistic in their composition and have a non-normative nature. Such characteristics greatly favour participation by organisations within civil society.

In Brazil, there have been three recent initiatives towards creating forums of this nature. The first was an entity within the executive branch of government – the "Bioethics Commission" created at the Ministry of Health, through a Ministerial Ordinance in 2002. This commission was essentially technical in nature, but it was not received well and was annulled soon after its creation. The second initiative was undertaken by the Legislature, that considered a Bill of Law presented in May 2004 by two congressional representatives. Because of "flawed initiative", a legal term used in legislative circles to describe an action for which the agent does not have "regulatory jurisdiction", the bill did not move forward through the legislative process. However, this bill remained registered in the House of Representatives and opened the way for a third initiative along these lines. This time, the initiative came from the Executive, which has explicit jurisdiction to make such proposals.

The Bill of Law No. 6032, which was sent to the National Congress as a Presidential Message on October 7, 2005, was an outcome of activities of a Work Group (GTBioética) that had been instituted by the Ministry of Health, through delegation from the Civil Office of the Presidency of the Republic. The mission of the Working Group was to analyse current models of national bioethics committees internationally and to formulate a proposal for creating a level of jurisdiction that would be able, at national level, to discuss ethical issues arising from the advances in science and technology in Brazilian society. This was subsequently named the National Bioethics Council (CNBioética). GTBioética was composed of two representatives from the Ministry of Health (Coordinator and Secretary), three representatives from the Brazilian Society of Bioethics and one representative from each of the following institutions: National Health Council, Brazilian Society for the Progress of Science, Brazilian Academy of Sciences, Federal Public Attorney's Office, Ministry of Science and Technology, Ministry of Justice and Ministry of the Environment. The Ministry of Health was considered to be the appropriate locus for coordinating this work, because of the large interface of bioethics (in the Brazilian case) with the field of healthcare.

The process of constructing the draft for the Bill of Law

GTBioética worked briefly but intensely since the commencement of its activities in July 2004 in order prepare the Bill of Law for introduction in the National Congress. The initial basic document called the "Proposal for a Draft Bill of Law to create the National Bioethics Council" was produced after three meetings of the group with full attendance of members, and nine meetings of operating and executive subgroups.

The document was formulated in a way that invites participation of the Brazilian society, through a wide-ranging and democratic process of public consultation. This included three stages:

(a) Publication of an initial basic document in the Federal Official Gazette;

(b) Promotion of public sessions to discuss this document with Brazilian civil society, in strategic cities in the country's five geographical regions: Porto Alegre (southern); São Paulo and Rio de Janeiro (south-eastern — the most heavily populated region); Recife (north-eastern); Manaus (northern); and Brasília (central-western). The methodology adopted in conducting the meetings consisted of summaries of the antecedents of Councils already operating in other countries (Brasil, 2004), the general characteristics of GTBioética (composition, mission and work process) and presentation of the document itself;

(c) Publication of a new document that was drafted following the regional discussions and the receipt of independent suggestions from the public, sent in through an internet-based public consultation over a two-month period (Corrêa and Garrafa, 2005).

Aimed at promoting broader dissemination and discussion of the draft bill, as well as gathering and organising specific contributions from the civil society, public consultations took place during October and November 2004. Prior to the meetings, specially prepared supporting bibliographic material was distributed to the participants in order to better direct the discussions (Garrafa, 2004). The meetings sought to gauge the reception from civil society, in order to ensure a democratic, participative and co-responsible process leading to the final output. Although GTBioética was self-sufficient and had the powers to fulfil the delegated mission, it deemed absolutely essential to broaden the consultation to include people working in this field, general public and private institutions. Public consultations gave voice to the stakeholders that were not represented within the group and enhanced the commitment of the group towards the process. After systematisation, the suggestions were grouped according to topic and correlated with the articles to which they referred, in order to reveal the essence of the contributions.

The final stage in the public consultation was the consolidation of all the materials obtained through the different consultation strategies. After systematisation, classification and critical analysis by the working subgroup, the final report of public consultations was submitted to the final and decisive meeting of GTBioética, on December 8, 2004 (Corrêa and Garrafa, 2005).

The final version of the document "Bill of Law for Creating the National Bioethics Council" was handed over to the Presidency of the Republic in September 2005 and was sent to the National Congress by the President himself on October 7 of the same year.

Conditions proposed for the NBC in the draft Bill of Law

From analysis of initiatives in other countries aimed at implementing different models for bioethics commissions – particularly in Germany, Belgium, Denmark, the United States of America, France, Italy, Portugal and the United Kingdom – certain implementation strategies and functional characteristics were identified as success factors. (Brasil, 2004; Garrafa, 2004; Tapajós, 2004). With the aim to take advantage of good practices and lessons learned by various NBCs internationally, a set of required conditions was drawn up as a basis for the Brazilian proposal.

The first condition was to make sure that society is able to participate in the process of drafting the proposal. Since the national bioethics committees allow society to be represented in its political, intellectual, social, corporate, religious and specific-group diversity, it is natural that the creation of a body that delves into the ethical questions of biological and life sciences be informed by debates involving the scientific community, the philosophical and religious schools, and the social movements (Fernandes, 2002). Maintaining a participative and democratic process in formulating proposals ensures the complementary and interdependent social control that is desirable for addressing collective issues. This is significant because other common forms of social control – self-control (achieved by the parties involved) and legal control – are not enough in themselves to fulfil social interests. Self-control may appear accommodative, given that it brings together the community of specifically interested parties. In turn, legal control – even though it is essential within a democratic context, is often too slow in its application; laws are shaped as society's responses to historical events that have already transpired (Garrafa, 2004).

The second condition, along the same lines, relates to ensuring society's representation in the composition of the Council. Since bioethics, like ethics and morals in general, is not reserved exclusively for people who are specialists in the subject, every human being should have the opportunity to participate in the related reflections and decisions.

The third condition is a pluralistic and multidisciplinary composition of the Council, which mitigates the risks of elitism and corporatism in this collegiate body. With regard to elitism, it must be stressed that the members of the Council often have to consider material of high scientific and technological density, and of great philosophical depth, highlighting the need to have the adequate technical capacity to evaluate the issues raised. With regard to corporatism, the requirements for participating in the council cannot exclusively favour academic qualification, since this will not necessarily be representative of all social segments (Garrafa, 2004). Likewise, the risk of professional corporatism needs to be averted because of the potential distortions and damage resulting from its application within an NBC (Garrafa, 2004).

The fourth proposed condition concerns legitimacy. The opinions of a National Bioethics Council must not be understood as the final word on the topic of the consultation, but rather as an important contribution to advancing the public debate that is ongoing around the issue. The recommendations and proposals that come from the Council are always of consultative nature, as happens in the countries where the notion of the popular mandate has been consolidated. Thus, the council gives opinions, makes suggestions, provides analysis and gives recommendations regarding alternative measures that

could be taken in the light of specific problems that are brought to its attention (Fernandes, 2002). However, the decisions are made by the parties that have the right to do so: in other words, by those who have political power that has been democratically conferred on them. For a Brazilian NBC to act in an institutionally stable manner, in accordance with the country's constitutional order, and following the best practices elaborated above, it must be set up by a legislative action. In this respect, the linkage of the Council to the State's apparatus is desirable. The Council would benefit by appearing as an advisory body to the head of the executive, relating administratively to the Presidential or Prime-Ministerial (in the case of parliamentary system) office.

The fifth and last condition concerns the capacity to benefit from specific technical advice within different fields that feed the discipline of bioethics, as a supplement to the existing expertise within the Council. Since the debates often involve technical questions of high complexity, it is important to have ad hoc participation from organisations, universities, researchers and specialists in the subject, thereby forming the element of technical contribution (Fernandes, 2002).

After defining these five conditions, it was necessary to obtain a common understanding regarding the basic concepts within the text. Of these, the most important was the term "bioethics", which permeated all the discussions, given that it defines the scope of the NBC's actions. This is a new area of knowledge that was not seen as independent from the fields of biomedicine and biotechnology up until the early 1990s. Starting with the adoption of UNESCO's *Universal Declaration on Bioethics and Human Rights*, by acclamation by the191 Member States of UNESCO in Paris, in October 2005, this term has expanded to a concept that has come to incorporate not only the abovementioned characteristics but also social, sanitary and environmental questions (UNESCO, 2005). Since the concept of bioethics continues to evolve, the Working Group advised against incorporating its definition in the law. In fact, the NBC itself would be in the best position to elaborate on such definitions in the future. This position was in line with the decision by the United Nations Educational, Scientific and Cultural Organisation not to incorporate a universal definition of bioethics in the Declaration (UNESCO, 2005).

The conceptual differences between the terms "council" and "commission" were also a matter for discussion. From the legal point of view, although there are no differences between them, there is an understanding that the word "council" brings the tone of a consultative body, whereas a "commission" alludes to the idea of linkage with the institutional authority that created it. Since the Brazilian Federal Constitution has created several councils, adoption of this term deemed more appropriate for maintaining consistency in the terminology. Since a certain level of institutional linkage is inevitable, there will be a continued discussion on the legal mechanisms that would ensure the financial autonomy for the NBC to function properly.

The major points of the draft Bill of Law presented to the Presidency of the Republic

The draft for the bill of law to create CNBioética was structured around four principal points: mission, formality of the institution, operating principles, and composition. The proposal defined CNBioética as a consultative collegiate body of national coverage, aimed at dealing with ethical questions resulting from healthcare practices, from scientific and technological advances within the fields of biology, medicine and health, and from situations that put human life and environmental

balance at risk (Fernandes, 2002). With these characteristics, the fundamental function of the council is to issue opinions, from a moral point of view, to delineate issues that may have different interpretations. Thus, it is a reference level for analysing and discussing situations involving ethics and morals.

After defining the fundamental elements for the council, the next step was to discuss its operating principles, translated as substantive criteria to function while fulfilling its basic mission. In establishing these principles, the preservation of the fundamental values enshrined in the Federal Constitution was ensured by a kind of "declaration of values".

Achieving balanced composition of CNBioética was considered a fundamental determinant of the success or failure of the initiative, given that the final result should reflect a combination of the major societal forces. In formally instituting the Council as a State body, its proposed composition was multidisciplinary (regarding the training of its members) and pluralist (regarding political-ideological orientation), with broad societal representation covering the whole social and cultural diversity of the country. Therefore, it was advocated that the council should be composed of 21 members nominated by the President of the Republic, taking into account the need for gender, ethnic and multidisciplinary balance, from among individuals of notable knowledge and irreproachable reputation, on the recommendation of institutions representing their specific fields (Garrafa and ten Have, 2010).

According to the proposal, the composition of 21 titular members (with further 21 substitutes) includes: six representatives of civil society; three experts from the field of biological and health sciences; three persons from the field of philosophy and human and social sciences; three persons from the exact and earth sciences; three bioethics specialists; and three personal nominations by the President of the Republic, from among individuals of notable knowledge. These names would be sent to the government by the different social and scientific entities in the country, and the decision and responsibility for the choices would fall on the President of the Republic, the greatest holder of popular votes and therefore the principal democratic authority of the nation.

Given the important mission of the Council, which requires taking an unprecedented position within national experience, it needs to focus on topics of national importance. Otherwise, it could become immobilised with insurmountable demands regarding a wide variety of requests. For this reason, it was decided to limit the number of people eligible to consult CNBioética to prominent figures representing the people and the State: the President of the Republic; the President of the National Congress; and the President of the Federal Supreme Court. With regard to the possibility of formal direct consultation by the public, the possibility of popular representation by means of gathering the signatures of at least 0.1% of the voters regularly registered through the country's Supreme Electoral Court was retained. In the Brazilian case, approximately 120,000 signatures of eligible voters would be needed for CNBioética to have the legal obligation to accept a request for a public opinion on the specific topic of interest of the population in question (abortion or the used of embryonic stem cells in research, for example). This would be a difficult but not impossible task, and would require organisation and dedication from the interested party.

The mechanisms that promote the stability and credibility of the Council were considered fundamental for the success of the initiative. The stability of the institution, which is an essential element to effectively carry out the mandate, is a function of optimal institutional attachment and the

provision of relative financial autonomy. Despite the possibility of creating CNBioética as an advisory commission directly subordinated to certain authorities, the analysis of how the current models from other countries function showed that creating the council as an independent body was the best option. This would make it unavoidable for the initiative to be submitted for consideration by the Legislature, in the form of a Bill of Law, based on article 84 of the Brazilian Federal Constitution, item IV.

The legislative process opens the possibility to determine both the coverage of the Council's actions and the stability it needs to effectively join the state structure. In discussing the autonomy of the Council, it should be noted that political and technical autonomy is essential for issuing credible and sound opinions on ethical questions, while administrative and financial autonomy is desirable to avoid any risks of undue external influence. Considering that an institutional linkage is unavoidable, since the proposed Council is a State body, the Bill of Law proposed a direct link to the Presidency of the Republic (or to the Presidency of the Council of Ministers), which represents the highest agent of the Executive.

Ensuring the credibility of CNBioética is a subtle and difficult question, since it is conditional on the credibility of its individual members. Nevertheless, certain mechanisms to promote credibility were foreseen, such as stipulating conditions under which it may be appropriate for a Council member to abstain from participation in discussion due to conflict of interest or other reasons. One discussed mechanism for promoting credibility was submitting the candidate for the presidency of the Council, nominated by the President of the Republic, to public hearings and an approval process in the Senate. This strategy would enhance the visibility of the process, assess the suitability of the nominated person for the post, as well as seek the approval of the Legislature. Through ratifying the President's choice, the Legislature would demonstrate its acceptance of and commitment towards the implementation of this new consultative body.

Civil society's contributions towards the draft for the Bill of Law

Submission of the draft Bill of Law for civil society's scrutiny provided the best opportunity for identifying strengths and weaknesses of the proposal and, at the same time, consolidating basic arguments for ensuring the sustainability of the Council that has a difficult mandate to engage in issues for which no moral consensus exists. The main topics that were discussed with the civil society were the functions, links, principles, guidelines and composition of the proposed Council.

With regard to its function and links, ensuring technical and political autonomy for a body that will have close relationships with the state structure was a primary issue that permeated the process of public consultation. In fact, as a body that cannot be ideologically subordinated to any authority, the Council's links to the state should only be administrative, so that it has an independent budget to sustain its operations.

In relation to the principles and guidelines that should govern the actions of the council, there was much discussion regarding the possibility of replacing the text of the specific article dealing with this matter, with the full text of principles, rights and fundamental guarantees laid down in the country's Federal Constitution. Furthermore, it was considered correct to make some of its principles

explicit, so that a code of conduct to be followed by members of the Council could be elaborated in a more evident manner.

The requirements for the public to make direct consultations with the Council were greatly questioned by civil society. Even though the National Congress provides formal popular representation, in the form of consultation through the President of the National Congress, it was decided to incorporate the suggestion to add flexibility to the Brazilian constitutional formula for popular representation. It needs to be noted that the country's Constitution provides for an obligatory response to consultations by the public to the National Congress that are undertaken through requests bearing the signatures of 1% of all voters. This number would be excessive (in the Brazilian case, more than 1.2 million signatures) for a body like CNBioética. On the other hand, it was not considered possible to create a specific ombudsman's office to receive direct requests from citizens, because this would severely distort the Council's ability to discuss macro-issues of absolute collective relevance. Moreover, it would also require a more robust administrative structure to deal with the weight of separate demands. Proposals to expand the number of Council members were also rejected, following the same logic.

Another hotly debated point was the balance of the social representations. Despite various suggestions, the existing allocation of Membership among various segments of society was not modified, based on the understanding that there can not be sufficient places for all of the groups that might be considered eligible for this forum, and that very large membership risks to dilute the weight of the members in the Council. In this respect, two main demands were considered: an increase in the participation of civil society (from three representatives in the work group's initial proposal to six in the final document, with decreases from four to three for the numbers of representatives for each of the three scientific fields, thus maintaining the total number of 21 members); and insertion of mechanisms to ensure cultural, ethnic and gender balance, thereby reflecting the country's plurality.

Other contributions, although important, related to topics that subsequently were deemed to be matters for regulatory decrees, to be implemented after the council had been installed. Although the argument that the Councils created for consultative purposes do not receive remuneration was noted, it was observed that society accepted the terms of the article of the draft of the Bill of Law stipulating fees for the titular members, with only one proposed exception in cases of accumulation of several public positions, as laid down in the Federal Constitution.

Clarifications on the final format of Bill of Law No. 6032/05

Some changes were introduced into the original proposal when the draft of the Bill of Law reached the Presidency of the Republic. The first and most important was a redefinition of the function of the Council, which went from "consultations regarding matters of bioethics, linked to the Presidency of the Republic" to "advice to the President of the Republic regarding ethical issues...". This modification changes the status and role of CNBioética that were originally proposed in the draft Bill of Law – as providing council to the various segments of government with priority for the executive, to a new role of advising the President. This measure, combined with the removal of the provision for commitment of a budgetary allocation from the Presidency of the Republic, diminished the possibility that the Council

would be guaranteed relative financial autonomy, in order to maintain it as a body within the State and not just within the Government.

The new text also expanded the council's activities and commitments, so that it would compile studies and reports, along with promoting forums for national discussion. This requirement expansion carries a risk to overload the Council with a requirement to produce documents and thereby to bring the core activities relating to its fundamental mission to a standstill. Considering the quantity of current topics that qualify for examination by the Council, it is fundamentally important to preserve both the mission and the paths along which the Council can be asked to give opinions.

The composition of the Council, which was a topic most vigorously debated by civil society during the drafting process of the Bill of Law, was retained mostly intact. It only underwent one change, which was to remove the provision for submission of the name put forward by the President of the Republic to preside over the council, to a public review in the Federal Senate.

Three final changes were made to the text before it was sent for consideration and adoption to the National Congress: suppression of the provision that the Council itself would elect its vice-president; limiting the power to convene the Council exclusively to the President of the Republic (in the original proposal, this could be done by the President of CNBioética himself or even by a call from two thirds of the members of the Council itself); and removal of the chapter dealing with remuneration of the Council members in the form of attendance fees for providing services to the council.

Unless these matters are reviewed again by the various political parties in the Legislature, in discussing the regulations for the law, the first of these measures will remove the possibility of the members to influence the presidency of the Council. In turn, the second measure would remove some of the authority and function of the president of the council by transferring the power to directly convene the council exclusively over to the President of the Republic. Regarding the suppression of the article on remuneration for members of the Council, the proposal followed Brazilian direct public administrative practices. On this point, it is important to ensure that all expenses of Members, arising from performing their functions can be properly covered by the budget allocated to the Council.

Final considerations

The Bill of Law for creating the National Bioethics Council in Brazil has not exhausted all of the avenues that could be explored, which makes it possible for the final result to be obtained through a process of collective construction, given that the topic goes beyond formal legal characteristics (Garrafa and ten Have, 2010). However, the discussion currently underway in the Legislature is decisive. Articles in the original draft for the Bill of Law that had sought to construct the essence of the Council but which were suppressed or modified may be analysed politically and reviewed within the Legislature. In any event, what is expected ultimately is that the Council will be fully able to act as a moral delineator both for society and authorities, understood within the context of the autonomy of the various powers and the mechanisms for ensuring the credibility of the Council itself.

It is evident that the installation of a National Bioethics Council in Brazil has just to begin, given that the path chosen for creating it was the longest but the safest and most stable one: by means of an ordinary law that needs to be considered and approved by both legislative houses of the National

Congress: the House of Representatives and the Senate – instead of creating it through a simple and fragile decree, which would result in the great weaknesses already observed in some Latin American countries and in other countries around the world. Despite the long onward process that can be discerned, the fact that this topic has been given priority on the Government's agenda and by the President of the Congress himself (who has given it priority on the agenda for future legislative discussions), and that it has been widely discussed within society, demonstrates the undeniable development of bioethical reflection in Brazil. It also reveals the convergent understanding that it is necessary to set up a permanent and stable structure for discussing polemical issues that cannot be left unanalysed, in the light of respect for moral pluralism and ethics.

REFERENCES

Brasil, Ministério da Saúde. 2004. *Sistematização das contribuições da consulta pública sobre a proposta de anteprojeto de lei ordinária para a criação do Conselho Nacional de Bioética*. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Documento técnico, mimeo. Brasília.

Corrêa, A.P.R.; Garrafa, V. 2005. Conselho Nacional de Bioética - A iniciativa brasileira. *Revista Brasileira de Bioética* 1(4): 401-16.

Fernandes, H. 2002. *Bioética e Comissões Nacionais no Estado Brasileiro.* Dissertação de Mestrado, Programa de Pós-Graduação em Ciências da Saúde - Área de concentração em Bioética, Universidade de Brasília (orientação: prof. Volnei Garrafa).

Garrafa, V. 2004. *Texto de apoio para a consulta pública do Anteprojeto de Lei para criação do Conselho Nacional de Bioética*. Sociedade Brasileira de Bioética, documento técnico, mimeo. Brasília.

Garrafa, V.; ten Have, H. 2010. National Bioethics Council: a Brazilian proposal. *Journal of Medical Ethics* Vol. 36:. pp. 99-102.

Tapajós, A.M. 2004. *Contribuições às discussões para uma Comissão Nacional de Bioética no Brasil*. Sociedade Brasileira de Bioética, documento técnico, mimeo. Brasília.

UNESCO. 2005. *The Universal Declaration on Bioethics and Human Rights*. Paris: Accessible online at http://www.unesco.org

The Guinean National Bioethics Committee

Ibrahima Boiro

Introduction

At the end of the last century, several major discoveries in the field of life sciences helped to decipher the fundamental mechanisms of life itself. But these major achievements did not come about without raising some profound questions. While these scientific findings indeed hold a great potential for the welfare of humankind, they also pose significant threats to human dignity and human rights if applied indiscriminately.

Bioethics, which deals with the ethical and normative, as well as social and cultural aspects of these developments, plays an indispensible role in protecting human dignity and fundamental human freedoms vis-à-vis technological advances in life sciences.

Bioethics now covers a vast area that poses many challenges. Initially, bioethics was largely a reactive approach to situations that were already at hand; today, it has a significant anticipatory role. It is essential to know well not only the development of scientific research in progress, but also its potential impacts and its future directions and applications. This necessity of anticipating requires integration of bioethics in the research process from the beginning. Bioethics has a trans-disciplinary nature that lies at the interface between different disciplines, and is continuously sustained by public debate. This can involve all components of society, and take place in various social and cultural contexts.

It is clear that the citizens across the world are showing increasing willingness to be more informed about the ethical questions arising in the areas of health research and biotechnology, and to participate more responsibly in making decisions. But this participation must be informed, meaning that it must be based on scientific information that is thorough and balanced, and presents various points of view, even if contradictory, as well as uncertainties. Consideration should be given to the most appropriate means to deploy for a public debate, with the support of the means for mass communication, while making sure that all actors take part in it (scientists, policy-makers, representatives of civil society, industry, trade unions, and religious denominations). In this regard, the national ethics committees have a major role to play, especially in regards to awareness-raising, dissemination of information, and organizing events on education, training, and public debate.

Background to the establishment of the Guinean National Bioethics Committee

The Minister of Higher Education and Scientific Research, as a prelude to the General Conference of UNESCO held in October 2005 which adopted by acclamation the Universal Declaration on Bioethics and Human Rights, signed Decree No. 2004/342/MESRS/CAB/DRH, creating the Guinean National Committee for Bioethics (CNGB).

Thus the government acquired a working tool for structuring and utilizing the reflections which have been ongoing within academic and religious establishments and even in the civil society, relating

to ethical issues in medicine, life sciences and technology as applied to human beings, as well as certain cultural practices related to ancestral traditions.

Several needs appeared on the National Committee's agenda from the very outset, namely:

- To formulate Guinean legislation and policy in bioethics;
- To carry out programs of information, training, awareness-raising, education and knowledge dissemination about bioethics;
- To monitor the International Bioethics Committee's activities in connection with the UNESCO Ethics of Science and Technology Division.

In accordance with the clauses of the Universal Declaration on Bioethics and Human Rights, the due care was taken to ensure that the Guinean National Bioethics Committee is independent, multidisciplinary and pluralist. In its functioning it can be decentralized to the regional, local or institutional scale depending on its own needs.

Composition of the National Bioethics Committee of Guinea

To create a multidisciplinary and pluralist dialogue on bioethics within the National Committee, as well as at various levels of the Guinean State and society, the committee is composed of scientists, policy-makers, representatives of the civil society and some religious figures (Muslim and Christian). The total number of Committee members is 19.

Some activities undertaken by the CNGB since its creation

In order to enable the CNGB to facilitate the establishment of regional networks of bioethics with a purpose of sharing experiences and capabilities, the Committee members have drawn up a project of "Draft Agreement of collaboration between the CNGB and the Division of Ethics of Science and Technology of UNESCO". The protocol was signed on 7 April 2009, in Conakry, during a ceremony attended by the Minister of Higher Education and Scientific Research and the Director of the Division of Ethics of Science and Technology of UNESCO.

The CNGB offered conferences and discussions to provide information about Bioethics issues at Conakry University and at the Pasteur Institute of Guinea. The CNGB also lead awareness sessions in some mosques and churches on the role of the Committee and on the bioethical approaches to some traditional practices in the country.

Work Program for 2010

In 2010, the CNGB plans to carry out the following activities:

- Organize a national training workshop in bioethics, in Conakry, with the support of the Division of Ethics of Science and Technology of UNESCO;
- Develop a "course in Environmental Ethics", dedicated to students in the Master in Environmental Sciences;
- Create four Committees in the regions of Guinea, namely Kindia, Labé, Kankan et N'Zérékoré;

- Develop three training modules for students of Conakry and Sonfonia Universities on the following topics:
  - **a)** What is Ethic and Bioethics?
  - **b)** The protection of the environment, biosphere and biodiversity in a sustainable development dynamic;
  - **c)** The protection of future generations and intergenerational equity.

References

UNESCO. 2001. Bioethics: International Implications; proceedings of the Round Table of Ministers of Science, UNESCO, Paris.

UNESCO. 2005. Universal Declaration on Bioethics and Human Rights.

UNESCO. 2003. International Declaration on Human Genetic Data.

UNESCO. 1999. The Universal Declaration on the Human Genome and Human Rights: from theory to practice.

Likinda Bafonda, E. 2006. *Bioethics Terminology from A to Z.* Bioethics National Committee, Kinshasa.

The National Bioethics Committee of the Democratic Republic of the Congo

Evariste Likinda Bofonda

Introduction

In the Democratic Republic of the Congo (DRC), the last two decades have been marked by indescribable and multifaceted socio-economic, politico-military and humanitarian crises. All energies have focused on re-establishing the minimum conditions for a secure life in society, leaving the public authorities very little opportunity to consider some emerging issues such as bioethics, let alone to legislate on those matters. It is not so long since the country was trying to finalize the content of its new post-war constitution.

Specifically in the medical field, the country is faced with the fact that people are still dying from hunger, unsafe drinking water, malaria and other infectious diseases that would be perfectly curable if the resources of science were available. The entire country is badly under-medicalized: although it has been divided up into health districts in accordance with the primary health-care policy, there are places where, for example, expectant mothers have no access whatsoever to prenatal care and give birth without medical assistance because there are no adequate medical facilities or competent medical personnel in their area. There is an alarming resurgence of the great endemic diseases of the past, such as trypanosomiasis, that were once controlled but have now returned to compound the AIDS epidemic.

The country is in fact struggling with poverty-related problems that require resolute policies if they are to be solved. They are problems into which basic research could certainly be carried out in order to improve scientific understanding, but in practice all that is sometimes needed to enhance the people's well-being and promote human dignity are some logistics and a modicum of organization. The country is still in the elementary phase of its search for solutions in the struggle for survival. How to improve the conditions of human beings in this situation is surely the first ethical question that must be raised.

The case for bioethics in DRC

Given these dismal living conditions for many in the country, some may question the propriety, the relevance, and the urgency of bioethical debate. Indeed, to delve here into the issues raised by technical and scientific progress, from organ transplants to genetic engineering to conception outside the womb, might seem like mere intellectual indulgence that is very far from offering any prospect of practical solutions to the real problems of society. Yet, in the seven years that a national bioethics committee has been operating in the Democratic Republic of the Congo, this debate has proved gradually to be not only necessary but most urgent for the populations of poor countries aspiring to development.

A number of factors show the relevance of this debate, and some of them may be noted here.

Globalization

As communications have become increasingly powerful, no-one can remain unaffected by what happens elsewhere on the planet; geographical and national borders are being broken down and problems are becoming universal. Furthermore, since the matters dealt with by bioethics concern the protection and promotion of human dignity, solidarity among all human beings is at stake, wherever they are in the world.

Cross-border research

A great deal of multicentre and cross-border research is now being conducted; initiated in the developed world, it is being conducted at any given time in a number of countries, particularly in Africa. Population groups there are thus affected as human subjects in clinical or other trials. Vigilance is therefore required: it would be unacceptable for research institutions or pharmaceutical firms to carry out clinical experiments on human subjects without applying the same rules of ethics and risk evaluation as in developed countries.

Poverty-linked vulnerability

It is to be feared that, in a situation of widespread deprivation, poor people may easily be turned into guinea-pigs, with ethically unacceptable experiments being performed on them for a small payment. Media reports have revealed, for example, that human organs are being traded illegally in various places.

Experiments that have already yielded conclusive results

Without involving true genetic engineering, there have already been some cases where procreation has taken place outside the womb (test tube babies in Kinshasa since 2002). This also reveals the ease of technology transfer in our times.

The need for legislation

Legislation must be passed on all of these issues. In the Democratic Republic of the Congo, work is under way in the field of medically assisted procreation, in particular, which currently takes place in a complete legal vacuum. Legislators must understand what is at stake and, with the benefit of informed advice, turn their attention to the issue.

Participation in the world debate

Any situation will be perceived by different observers from their own particular vantage points, with each focusing on what they consider important. Where poor countries such as the Democratic Republic of the Congo are concerned, it would make sense for their participation in what is now supposedly a global debate, to emphasize issues of justice and equity in the world. Enormous planetary resources have been invested in all types of research projects, and we know that only a privileged minority can eventually derive some health benefits from them, while the vast majority of the earth's inhabitants will have no benefit at all, even though they could well experience some negative side-effects. Ethics, it would seem, is also equity.

To participate in this global debate and have something relevant to say about these matters, experts from each country first need to think long and hard about them, particularly at a time when documents of universal scope are being drafted to provide guidance to all the world's inhabitants. This is why the work being done by UNESCO, as part of its Assisting Bioethics

Committees (ABC) project, to support the establishment of national bioethics committees that could later operate as a network is of such interest and relevance.

National Bioethics Committee of the Democratic Republic of the Congo

Right from the start, before it could even begin to issue opinions, the National Bioethics Committee of the Democratic Republic of the Congo had to engage in a major training operation, with Committee members striving to obtain information on the issues involved in a fairly new paradigm. The aim was to obtain as much knowledge as possible on bioethics and enhance capacity to grasp the essence of the ethical matters raised. Even though the resources and infrastructure are not currently available to undertake biotechnological engineering, the experts on ethics committees must be able to keep abreast of the outcomes of scientific work and give them their proper place among global concerns – concerns for policy-makers and concerns for public opinion. It is important for them to strive not only to understand the issues involved in technical and scientific progress, but to anticipate its future directions. Where clinical trials are concerned, they must not only look out for the well-being and safety of their subjects but also, and vitally, ensure that the research undertaken is truly relevant to the priorities of the populations concerned.

Particular emphasis is being placed on ethical education in universities, but also in secondary and primary schools. With UNESCO support, the National Bioethics Committee of the Democratic Republic of the Congo organized a workshop bringing together the experts who lecture on ethics at French-speaking universities in Central Africa and Madagascar so that they could jointly review the different teaching programmes with a view to mutual enrichment and possible harmonization. The hope has been expressed that a documentation centre and a UNESCO bioethics chair can be established in Kinshasa.

Conclusion

Running a bioethics committee involves all sorts of expenditures. It is necessary, for example, to organize and equip the secretariat, hold committee meetings, train members, hold seminars, conferences and public debates and publish opinions for public information and awareness purposes. Different sources of revenue therefore need to be sought, which is not always easy in countries with small budgets. Any new initiative on establishing national bioethics committee should be based on the political will of the government and should seek resources from appropriate sources that are adequate to ensure effective functioning of the consultative body.

Bioethics Networks: Collaborating Across National Boundaries

Bioethics and shared values of Europe

Pēteris Zilgalvis

Introduction

The JACOB Conference brings together members of National Bioethics Committees from all parts of the world, representing a rich diversity of backgrounds, histories and specific challenges, and sharing the commitment to promote ethical norms in biological and medical sciences. This commitment begins with protecting the fundamental human right of access to health care, as well as protecting those who participate in and those who could benefit from research. It is clear that already on this fundamental level, the challenges for national bioethics committees are very diverse. Besides differences in access, the disparity in the quality of health care may lead to fundamentally different perspectives between countries in regard to the same phenomenon.

More generally, socio-economic and cultural differences give rise to a wide range of perspectives on what is acceptable in health care, research, and science. Such diverse perspectives can coexist side by side, but more and more often they confront each other in a globalised world. Examples of this are clinical trials that are carried out in developing countries but sponsored by a western country or organisation. What is then the responsibility of the sponsors vis-à-vis the patients in developing countries? Should the ethical standards of the "sponsor country" or of the "local country" apply? The European Commission also has to deal with this issue, as it funds research that involves clinical trials carried out in developing countries. Our policy is that for such trials no "double standards" in ethics are allowed; for protection of persons in research, the same standards as in Europe should apply.

Research, ethics and Europe

The importance of ethics for science and technology cannot easily be underestimated. There are many developments in science and technology that give rise to ethical questions in society – stem cell research, genetically modified food, human enhancement, to name just a few. The intense social debate triggered by such developments highlights the importance of high ethics standards for science and technology. This importance has long been recognised by the European Commission, which has stimulated bioethics research and ethics review since the early 1990s, via funding numerous international bioethics research projects, networks, conferences and capacity building actions. In doing so, the Commission has been instrumental in establishing a robust bioethics research community, as well as furthering a comprehensive infrastructure for ethics review in Europe.

The primary focus of European Commission's activities is on the Member States of the European Union, but it also tries to engage countries and international networks outside Europe, with an understanding that the European Research Area must be open and outward looking. Under the Commission's funding programme for research, the so-called *Framework* programme, funding has been provided for research and capacity building projects in ethics throughout the world. Just two examples of such projects are:

- EULABOR, which deals with European and Latin America Ethical Regulations Systems of Biomedical Research; and
- NEBRA, which focuses on Networking for Ethics on Biomedical Research in Africa.

It is important to note that the idea of the JACOB Conference was engendered as the result of discussions at another important European Commission conference held in May 2007 in Brussels –"Ethics, Research and Globalisation," which addressed capacity building on research ethics in developing countries and emerging economies.

Bioethics and globalization

For years now we have heard about globalisation as the free flow of persons, capital, goods and services across borders. After the recent global financial crisis, we hear of the shift of global economic power to the East. But the bioethics community has been globalised in a spirit of equality for years. Furthermore, the European Commission has recently placed an emphasis on a "fifth freedom" of knowledge to be added to the four original principles of free movement, and has pledged to boost cross-border mobility of researchers, students, scientists and university teachers, as well as labour markets and work conditions for European researchers and further reforms in higher education. In this light, bioethics becomes an essential component of the efforts to cross national boundaries and promote a global approach.

The Lisbon Agenda and the Lisbon Treaty

Science and technology are rightly subject to social debate, but we should also make sure there is a balance between this and other needs, such as the need to promote scientific progress to make economic activities sustainable in order to be able to ensure the provision of healthcare and other social programmes. In this light, the transition to a competitive, knowledge economy is a key policy of the European Union, also known as the Lisbon Agenda.

In Europe, Lisbon is a famous city for many reasons, but also because it now bears the name of a new European treaty – the Lisbon Treaty, which has been ratified after long national consultative processes. The Lisbon Treaty brings important changes to the functioning of the European Union, but it also reaffirms the European Union as a Union based on shared values, such as human dignity, freedom, democracy, human rights protection, pluralism, inclusion, social justice, gender equality, freedom of science, and sustainability. These values are stated in the European Charter of fundamental rights, which forms part of the Lisbon Treaty.

The importance of a "Europe of values" has also recently been stressed by the President of the European Commission, José Manuel Barroso, in the political guidelines he presented for the mandate

of the next European Commission that has started its five-year term in 2010. In President Barroso's words:

> "I will redouble my efforts to make an ambitious Europe happen. A Europe that puts people at the heart of the policy agenda and projects European values and interests in the world."

The need for international cooperation

The emphasis on values in European Union policy is also reflected in its policies to attain the highest ethical standards with regard to health care, science and research.

For ethical considerations to be able to have a real, substantial impact on medical practise or on the trajectory of science and technology, however, there is a pressing need for a more global dialogue and collaboration on ethics in science. In the current age of globalisation, research itself has very much become an international and multinational collaboration, with partners from across the globe.

Moreover, national health care systems are exposed to the impacts of globalisation, with increasing medical tourism for fertility and even stem cell treatments, organ transplantation and a number of other challenges.

As a result, the impact of national decisions on health care, but most importantly on science and ethics in science, has also become more influential internationally and, at the same time, more limited nationally. In a pessimistic viewpoint, national decisions are prone to lead to displacement of activities to less regulated countries. Undoubtedly, the globalization of science has made the need for global cooperation on bioethics ever more pressing. The European Commission will continue to actively encourage international cooperation, and is extending its commitment to new fields that are beyond the realm of classical bioethics, such as nanotechnology and Information and Communication Technologies. An example of this is the "Code of Conduct for responsible nanosciences and nanotechnologies research" and the Expert Group on the Global Governance of Science. Furthermore, it aims to involve civil society in decision-making at the earliest stage about new technological developments.

Conclusion

The JACOB conference provides an excellent opportunity to plant the seeds of further international cooperation in ethics. National bioethics committees are important national focal points for reflection and dialogue in a society. Through their networking and exchange of best practice, national policy-makers, parliamentarians and stakeholders can be made aware of international developments in a timely manner.

Bioethics in the CIS Countries: engaging in ethical discourse

Olga Kubar

Introduction

The countries that comprise the Commonwealth of Independent States (CIS) have contributed significantly to the formation of the modern concept of protection of human rights and dignity in medicine and biology, through a long history of emphasizing a moral approach to the medical profession and medical care. Such conclusion is a direct result of analysis of the cultural and historical unity of the nation-states in the CIS region, and confirms a concept of humanitarian unity of human development (Kubar, 2001, 2007).

This historical reality serves as the platform for promoting the principles of the *Universal Declaration on Bioethics and Human Rights* (UNESCO, 2005), and, especially, article 14 of the Declaration on "Social Responsibility and Health," in the CIS countries. Another extremely important condition is the reality of historical, socio-cultural and economic collaboration among the CIS countries which is grounded in the mutual historical inheritance, geographical closeness, the shared political history of the pre-Soviet and Soviet periods, formation of deep ethnical, cultural and religious heterogeneity within the countries, and the use of Russian as a common language. These factors have contributed to the existence of differences among the countries in the region, but also to the existence of high degree of tolerance and respect towards these differences.

Bioethics legislation in the CIS countries

It should not come as a surprise, therefore, that the principles of the *Universal Declaration on Bioethics and Human Rights* have been enshrined in national and regional documents. General principles such as respect for autonomy and individual dignity of a patient, as well as a principle of justice, are included in the Constitutions of all CIS countries. They all proclaim a person as a basic value (Art. 4, Constitution of the Republic of Armenia; Art. 13, Constitution of Azerbaijan Republic; Art. 2, Constitution the Republic of Belarus, Art. 3, Constitution of the Ukraine, Art. 2, Constitution of Russia; P.1, Art. 36, Constitution the Republic of Moldova, etc.). A free development of a person is protected by law and independent courts. Personal dignity is acknowledged as having a special value to be protected by the State in all CIS countries, and all forms of medical, scientific or other experiments involving human subjects are prohibited without their voluntary consent.

The legal protection is extended to cover persons' privacy and confidentiality, as evidenced by constitutional provisions declaring the right of personal security, the right to personal and family secrets, the right to confidentiality of correspondence, phone communications, mail, telegraph messages and information transmitted via other communication means. In most countries, it is prohibited to collect, store, use and distribute information about individual life without such person's consent. Unique response for the acceptance of the Declaration's principles is the commitment to non-discrimination and

non-stigmatization, which guarantees equality of all persons independently of gender, race, nationality, language, origin, property and position, place of residence, denomination, political and religious beliefs, membership to public organisations, or other considerations.

The right to health and the state's duties in the context of the Article 14 of the Declaration (on 'Social Responsibility and Health') are legally fixed not only in the Constitutions of the all Commonwealth countries but have also been adopted as specific laws related to issues of health care and patient rights. Some examples include:

- Republic of Armenia's law "On Medical Care and on Services for Population" (1996);
- Azerbaijan Republic's law "On Protection of Population Health" (1997);
- Republic of Belarus law "On Health Care" (1999);
- Georgia's law " On Health Care" (1997);
- Republic of Kazakhstan's law "On Protection of Population Health of the Republic of Kazakhstan" (1991);
- Kyrgyz Republic's law "On Protection of Population Health of the Kyrgyz Republic" (2005);
- Republic of Moldova's law "On Rights and Responsibility of Patient" (2005);
- Russian Federation's law "On Protection of Citizen Health" (1993);
- Republic of Tajikistan's law "On Protection of Population Health" (1997);
- Ukraine's law "On Health Care" (1992); and
- Republic of Uzbekistan's law "On Protection of Citizen Health" (1996).

Respect for human vulnerability specifically relates to protection of vulnerable groups of patients in the CIS. All constitutions of the CIS countries contain the prohibition of medical, scientific or other experiments involving human subjects without their voluntary consent: Kyrgyz Republic also mentions psychological tests in this list (Art.18). All countries adopted separate laws on psychiatric assistance to the population, counteraction to HIV infection, organ donation, transplantation, and protection of children rights. This legislation reflects the specificity of informed consent and patient confidentiality in some situations of biomedical interventions, and stipulates additional guarantees of rights of dependent groups of patients. In many CIS countries laws and by-laws regulate various issues in the area of auxiliary methods of reproduction and genetic assistance to the population (Russian Federation & Ukraine have adopted laws prohibiting human cloning).

Legal regulation of reproduction and genetic assistance to the population in the CIS countries is a sign of the implementation the Article 16 of the Declaration on "Protecting future generation." In fact, the principle has been reflected in a myriad of national laws:

- law of the Republic of Armenia "On Reproductive Health and Reproductive Rights of Person" (12.09.02);
- law of the Republic of Belarus "On Safety of Gene Engineering Activities" (09.01.06);
- law of the Republic of Kazakhstan "On Reproductive Rights of Citizens and Guarantees of Implementation Thereof" (16.06.04, N 565-2);
- laws of the Russian Federation "On Reproductive Rights of Citizens" (26.02.03, N 67); "On Utilization of Assisting Reproductive Technologies for Treatment of Female and Male

Infertility", (05.06.96; N 86-FZ); "On State Regulation in the Field of Gene-Engineering Activities" (30.12.93, N 316);

- laws of the Republic of Tajikistan "On Reproductive Health and Reproductive Rights" (02.12.02; No.72) and "On Measures for Further Development of Medical and Genetic Assistance to the Population" (01.10.85, No.974)
- law of Ukraine "On Further Development of Medical Genetics and Bioethics in the Ukraine" (01.12.00, No.313/59).

Regional cooperation in the framework of the Inter–Parliamentary Assembly of the Commonwealth of Independent States

The scale of legal regulation in these areas attests of an explicit desire among the CIS member states to be in tune with the international norms and standards in their domestic legislation and to directly introduce international standards as an instrument for legal regulation in the field of biomedical studies and ethical examination. In this respect, the fact of mutual interests of parties seems to be symbolical. The CIS countries have become members of international organizations and structures at various levels that directly impacts establishing of universal standards for protection of human rights.

Within the framework of the Inter–Parliamentary Assembly of the Commonwealth of the Independent States (IPA CIS), the CIS member states practice collective law development in the form of model laws that provide reference points for national legislation.

Attractiveness of the CIS countries for carrying out multicenter cross-border biomedical research increases the mutual responsibility of both international organizations and governments of the Commonwealth countries for providing adequate regulatory frameworks for human rights protection that comply with universal standards. This sphere has multiple components of collaboration: counseling, joint law development, adaptation and ratification, international system of legal responsibility for violations and interstate appeal options.

An especially advantageous atmosphere for cooperation is created by the establishment of the system of ethical review. The establishment of the Forum for Ethics Committees in the Commonwealth of Independent States (FECCIS) and inclusion of this region as a single constituent of the global WHO Project "Strategic Initiative for Developing Capacity in Ethical Review" (SIDCER) provided permanent international dialogue on key issues of research ethics with international agencies leading in this sphere – such as WHO, the European Commission, the Council of Europe, the European Forum for Good Clinical Practice, the World Medical Association, as well as authoritative national agencies (Ethical committees of countries around the world).

Cooperation within the framework of FECCIS is developed with the purpose to facilitate creation of systems of good ethical evaluation and development of ethical responsibility in researchers, sponsors, authorized regulatory agencies and the society as a whole. Inclusion of the CIS countries in the process of establishment of good practices of ethical evaluation at international level is focused on understanding the necessity of reaching independence, competence, openness and responsibility in the field of human rights protection when conducting biomedical studies. Development of cooperation

facilitates free discussion among colleagues, exchange of experiences, challenges and successes, and formation of collective recognition of role of ethics in research. The main result in the frame of the legislative initiatives of FECCIS in the cooperation with IPA CIS is the creation of the Model Law "On the Protection of Human Rights and Dignity in Biomedical Research in the Member States of the Commonwealth of Independent States, 2005".

The success of implementing the principles of the Declaration in the CIS countries can be greatly aided by promotion of bioethics teaching as a subject (mandatory or optional) in medical colleges and universities, as well as at the departments of philosophy in some of state universities. Similarly, the promotion of bioethics norms and principles in the domestic realms of the CIS countries depends on the level of interest in ethical issues among the legislators that make policies in the field of science and health care, on the development of corporate ethics and national associations on ethics, and on stimulating wider public interest in bioethics through mass media.

There is a well-established system of interregional cooperation in the development of bioethical education and training for members of ethical committees. Significant contributions are made by the UNESCO National Commissions in the region's countries, which pursue common policies aimed at the following priorities:

- access to information and intellectual exchange;
- development of educational programs and approaches;
- strengthening of capacities of national agencies working on ethical issues;
- implementation of ethical norms aimed at protection of human rights in the sphere of biomedicine;
- improvement of information awareness and training in the sphere of bioethics;
- distribution of knowledge in bioethics among professional and public groups, including via mass media;
- counseling and education on bioethics issues among the social services;
- extension of availability of information about regulatory documents;
- human rights and procedures of their protection; and
- development of training programs on ethics and their integration into educational process.

It is noteworthy that cooperation in this sphere is becoming both bilateral and multilateral. This is made easier by the possibility to communicate between the CIS countries in the same language and the existence of traditional cultural and societal ties.

Conclusion

Objective and open knowledge of the status of bioethics in the Commonwealth countries unveils a whole range of opportunities for all stakeholders to search for ways to improve regional collaboration in this sphere, based on adherence to universal values and ethical principles. In general, harmonization of standards is based upon respect to human dignity, right and freedoms; recognition of achievements of scientific and technical progress; facilitation of equal access to scientific achievements through free flow and exchange of knowledge; and the protection of interests of existing and future human generations.

CIS states have duties of social responsibility, which are now applicable to the parliaments, governments, public institutions and corporations. This is an important novelty, which presents new and important problems, as well as the impulse for future work in the field of bioethics, based on regional cooperation among the countries.

REFERENCES

Kubar, O.I. 2001. Research involving human subjects: ethics and law in early 20th century Russia, *Bulletin of Medical Ethics*. October 2001, pp. 13- 17.

Kubar, O.I. (ed). 2007. Ethical Review of Biomedical Research in the CIS Countries: social and cultural aspects. Saint – Petersburg: Fenix.

Bioethical Sustainability: Towards a Value-Based Epistemic Community in the Life Sciences and Healthcare

Fernando Lolas

Introduction: moral strangers, epistemic strangers

One of the most pervasive features of contemporary societies is the coexistence of groups and communities that do not share the same values, language, or culture. In addition to human diversity and plurality of worldviews, societies also tend to create clusters or subsystems with their own codes of conduct that attempt at gaining hegemony or control over other sectors of society. "Expertocracies" are formed, since almost any activity is regulated and demands expert or evidence-based knowledge. Communities are thus formed which compete for prestige, power, and money, leading to a fragmentary "social mosaicism" in which people tend to form clusters based on language, ethnicity, religion, profession or other affinities.

We not only live in societies of "moral strangers" but also in societies of "epistemic strangers". The exact use and meaning of different concepts is not replicable or even understandable in all sectors of society. There is a great need for some form of social hermeneutics or interpretive ability, allowing for tolerant dialogue between groups, the inclination to feel and think the way others do and the social skills and competencies necessary for the construction of solidarity and social capital in the form of cooperating networks.

Since the establishment of the Bioethics Program of the Pan American Health Organization (PAHO) in 1994, through an agreement with the Chilean government and the University of Chile, capacity building in bioethics has been one of its most important aims. The definition of bioethics employed in its different activities pertains to the use of dialogue for formulating principles, for defining dilemmas and conflicts, and for applying rational and reasonable decision-making procedures for the solution of discrepancies and antagonisms (Lolas, 2006). It amounts to what Fritz Jahr defined as the "bioethical imperative", the protection and enhancement of life in all its varieties and manifestations (Lolas, 2008).

Social systems and their interrelation

The social systems related to research in all its forms (understood as creation of knowledge or organized information) and to health care (understood as the expression of *therapeia* or help in all its various forms for the needy, the helpless and the distressed) interact at critical points. The "know-do gap", that is, the distance between information and its uses and applications, is as deleterious as the so called "10/90 gap", which indicates that most spending in health research and care benefits only a minority of humankind. The know-do gap demonstrates an unfair distribution of potentialities and

emphasizes the asymmetries in the uses of knowledge, depriving many people from access to the benefits of science and technology.

Main problems of contemporary societies have simplistically been formulated as the clash between ideologies, religions or economies. The political agendas of groups pretending to fight poverty and underdevelopment are sometimes monotonous repetition of slogans without any real intellectual contribution to the debates arising from global climate change, vested interests of industry and military powers, separation between ethics and economy. The idea of justice has been formulated in the context of hostile repudiation of some forms of economic practices or even against the scientific enterprise, as if it were confused with political hegemony.

The concept of bioethical sustainability

In the approach taken by PAHO Bioethics Program capacity building in bioethics is related to the development of dialogical competencies that permit people to establish communities where communication and dialogue are possible and to enrich evidence-based public health and medicine with a value-based practice (Lolas, 2009). The Program targets experts and policymakers to share with them the direct experience of poverty, disease, and frustration. In short, the Program seeks to supplement the economic and political sustainability of scientific action with bioethical sustainability, thereby enhancing the legitimacy of policies and actions and the association of human knowledge with human values, diversity, and dignity.

Bioethical sustainability, as a concept, involves educating lay people and experts alike in the use of dialogue, based on the understanding that beyond the respect for diversity, there should be respect for persons and attention to the consequences of social action. Dialogical consequentialism is the position most amenable to help develop bioethically sustainable policies and activities.

This form of sustainability also involves a value-based confrontation with value-laden fanaticism and one-sided worldviews. Among the bioethical competencies that PAHO's programs across the region of the Americas and the Caribbean have tried to emphasize, implicitly or explicitly, is the recognition that the social institutions created by the bioethical discourse – committees, commissions, expert groups, communities of practice – need to be examined in terms of their true capacity to represent social interests of diverse groups. *Representing* people is different from *being representative* of people. A sustainable science from the moral point of view is a science legitimately accepted by the people concerned and everyone is a stakeholder in those areas of science that relate to health and human well-being.

International bioethics: a view from the health field

Bioethics, as we understand it, is more than ethical reflection applied to the health field. It encompasses different ethical traditions in Western thought and challenges us to go beyond deontology and teleology to a synthesis in which both individuals and organized groups can find common ground for reflection and joint action.

Health care and research are, however, exemplary fields where bioethical principles can be studied and developed easily. They constitute, in fact, areas of human interest which nobody can ignore. Within

a framework of appropriate priority setting and reasonable resource allocation, the fundamentals of bioethically sustainable health diplomacy are to treat people equally, to favor the worst-off, to maximize total benefits and to promote and reward social usefulness. A commonsense approach, so neglected by experts, has always been in the background of bioethical thinking in health matters. There, several problematic areas appear, such as the role of nation-states in an era of globalization, the role and strategic objectives of international organizations such as UNESCO, WHO, UNDP and others, the interaction between academia, industries, and government. A "shared health governance" between governments and international organizations is needed to ensure knowledge generation, dissemination and application in an equitable and sustainable manner.

Conclusion: resources for capacity building

PAHO pioneered the introduction of bioethical discourse in the Americas and the Caribbean by creating the Bioethics Program in 1994. Through the establishment of training programs at different institutions, the development of monographic courses, the assistance in the establishment of training opportunities for scientists, caregivers and members of ethics committees, the carrying out and publication of surveys and studies, and the permanent advice to policymakers, politicians, and opinion leaders, the Program has created a network of people conversant with dialogical practices and willing to contribute to the furtherance of knowledge and the improvement of the health of the peoples in the region of the Americas and the Caribbean.

Most materials and publications can be found online (www.paho.org/bioetica), among them the journal Acta Bioethica (ISSN 0717-5906), which first came out in 2000 as a continuation of *Cuadernos del Programa Regional de Bioética*. Currently, the journal is indexed in the main world databases and is highly quoted. Several books produced by experts from all over the world are freely accessible to scholars. A series of monographs and special publications have been used as teaching material in different countries. Associated with many public and private institutions, the main objective of the Program has been to contribute to initiatives that may result in an improvement of the quality of research and the delivery of accessible healthcare.

REFERENCES

Lolas, F. 2006. Bioethics at the Pan American Health Organization. Origins, developments, and challenges. *Acta Bioethica* Vol. 12, pp. 113-119.

Lolas, F. 2008. Bioethics and animal research. A personal perspective and a note on the contribution of Fritz Jahr. *Biological Research* (Santiago) Vol. 41:, pp.119-123.

Lolas, F. 2009. Towards a value-based public health in Latin America and the Caribbean. The work of PAHO Bioethics Program. In Lolas, F. (editor) Dimensiones éticas de las regulaciones en salud. *Monografías de Acta Bioethica N°3, CIEB*, Santiago de Chile, pp. 389-401.

Division of Ethics of Science and Technology of UNESCO

This publication is the result of collaboration between UNESCO and the European Commission to reinforce bioethics capacities of countries that have recently established, or are planning to establish bioethics bodies at the national level. It is an important contribution towards creating a common platform for sharing knowledge, resources and experiences between the long-standing and the nascent national bioethics committees, and should be a valuable resource for all the stakeholders who are concerned with strengthening the national bioethics infrastructure.

The articles brought together in this book draw a multicolored picture of national bioethics committees as they tackle various ethical issues in countries across the world. Through a constructive, informative and balanced debate, these committees provide space for free and open expression of different, often opposing viewpoints existing in different segments of society on critical bioethical questions. Such debates inevitably spill over beyond the confines of the committee meeting rooms, and enrich the knowledge on a given issue among the experts, policymakers, and the general public.

UNESCO
Division of Ethics of Science and Technology
Social and Human Sciences Sector
1, rue Miollis
75732 Paris Cedex 15
France
http://www.unesco.org/shs/ethics

9 789231 041839