



Brief Report on the 8th Global Summit of National Bioethics Advisory Bodies

Singapore, 26 & 27 July 2010

The 8th Global Summit of National Bioethics Advisory Bodies was hosted by Singapore's Bioethics Advisory Committee and the Ministry of Health. The Ethics & Health Unit of the Department of Ethics, Equity, Trade and Human Rights, World Health Organization (WHO), which provides the permanent secretariat for these Global Summits, and the European Commission (Science, Economy and Society - Governance and Ethics Unit - L3, Directorate-General for Research) were actively involved in planning the meeting. The programme for the 8th Global Summit is set out in the Annex (below) for reference.

Delegates representing the WHO, the Council of Europe, and the European Commission were present together with delegates from National Ethics Committees (NECs) in 33 countries.¹ A report on the 7th Global Summit (Paris, 2008) was presented by Dr Patrick Gaudray on behalf of the French National Consultative Ethics Committee on Health and Life Sciences. In addition, the Tunisian candidacy for hosting the 9th Global Summit in Tunis in 2012, was unanimously approved.

Delegates were welcomed by the Director of Medical Services, Ministry of Health, Singapore, who stressed the increasing importance of bioethics in the decisions government agencies have to make. He illustrated this approach in Singapore with reference to human embryo research and living donor organ transplantation. He was followed by Dr Ruediger Krech, Director, Department of Ethics, Equity, Trade and Human Rights, WHO. Dr Krech highlighted the presence at the Global Summit of more than 30 NECs worldwide. This gave the event some credibility in terms of being able to formulate directions for development. He also stressed that WHO expected opinions and feedback from countries on some major topics, specifically:

1. Organ transplantation and compliance with the guiding principles endorsed by all WHO Member States, during the last World Health Assembly in May 2010;
2. Functioning of Ethics Review Committees;
3. Ethical issues in tuberculosis (TB) treatment and prevention;
4. Biobanking and research on stored human biological materials; and
5. Synthetic biology and its implications.

He urged the delegates to debate these topics and to try to agree on a common way forward. He viewed it as important to establish mechanisms, such as working groups, to maintain continuity across Global Summits.

¹ Australia, Austria, Belgium, Brunei Darussalam, Burkina Faso, Cambodia, China, Denmark, France, Germany, Ghana, Greece, India, Indonesia, Ireland, Jamaica, Japan, Republic of Korea, Lebanon, Lithuania, Malaysia, Mexico, Netherlands, Philippines, Portugal, Russian Federation, Sweden, Saudi Arabia, Singapore, Switzerland, Uganda, United Kingdom of Great Britain and Northern Ireland, United States of America.

Topics Discussed on the First Day of the 8th Global Summit: 26 July 2010

Ethical Issues in Transplantation of Cells, Tissues and Organs

The session focussed on the *Guiding Principles on Human Cell, Tissue and Organ Transplantation* endorsed by the World Health Assembly in May 2010. It was agreed that the emphasis needs to be on follow-up given that a framework has been established in the form of the WHO guiding principles. Important remaining issues that need to be considered by participating countries within the framework include:

1. The drawbacks and risks of rewarding donors, in any guise;
2. The need to shift emphasis to more consideration of the long term welfare of donors;
3. The importance of establishing public awareness and acceptance of organ donation, in order to facilitate better use of all resources, including cadaveric donation, with equitable non-exploitative arrangements; and
4. Avoiding over-reliance on living donors at the expense of cadaveric donation.

For the next Global Summit, reports would be sought from NECs on the interpretation and implementation of the WHO guiding principles, and on problems in giving effect to them.

Research Ethics Committees

The session focussed on the WHO draft *Guidance for Research Ethics Committees* and issues in harmonising review processes. Clarification was felt to be needed of the roles of ethics review committees, as they have come to encompass diverse duties, including research review, clinical ethics review, and advisory or regulatory powers. Clarification was also needed on issues of process, and the problems created by over-regulation and the existence of private research institutes or ethics bodies. Of further concern was the need to encourage cross-border cooperation without exploitation, which touches on a debate as to whether multiple separate review bodies are more appropriate than single regional or national ones. Concern was also raised over the implementation of suitable systems of consent, since the autonomy of consenting participants was not a given in all cultures or situations. Therefore, there was a general feeling that issues of harmonisation and accreditation needed to be addressed as a matter of some urgency in view of the increasingly international character of research. For the next Global Summit it was proposed that reports should be sought on the roles and implementation of ethics governance via the various national ethics review committees.

Ethical Issues in TB Control

Discussion largely revolved around the WHO's *Guidance on Ethical Issues in TB Prevention, Care and Control*. The presentations and the discussion clearly highlighted the tension between patient autonomy and public health considerations. Interventions driven by the latter tend to downplay the right to privacy, the right to treatment non-compliance, the right not to know, or the right to preventive steps (the latter as exemplified by prisoners or others with enforced limits on autonomy and hence possible added infectious hazard). This is an emerging issue, without established guidelines (unlike transplant ethics). However, with the spread of extensively drug resistant strains, an integrated approach is essential. How the tension is resolved might have implications for other domains with similar tensions. For the next Global Summit, it was proposed for a working group to follow-up with a forum session on the ethics of public health driven research and the limits of autonomy, together with a review of how TB control and prevention has been implemented, and what involvement ethics bodies should have. A good guidance document on TB control could set a template for similar guidance documents which might need to address similar ethical dilemmas.

Bioethical Developments

Country-specific presentations on the establishment and nature of bioethics governance were given by Jamaica and Saudi Arabia. It was clear from them and the discussions following, that there was a range of approaches. A fact-gathering approach covering a much greater range of inputs might be a pre-requisite to determining the limits to common approaches. There were also several suggestions relating to the use of the internet to facilitate better communication and updating, such as having an online repository of opinions or decisions that could be accessed. Accordingly, for the next Global Summit it was agreed that a compilation of information on national ethics bodies should be sought, which could ideally be updated annually based on national websites.

Topics Discussed on the Second Day of the 8th Global Summit: 27 July 2010

Ethical Issues in Synthetic Biology (session organised jointly with the European Commission)

Chair of the Presidential Commission for the Study of Bioethical Issues, USA, indicated that reviewing the ethical issues arising in Synthetic Biology (SB) had become a US priority following Craig Venter's claim to have created a synthetic cell, and that the Commission's recommendations were due by the end of 2010.² Delegates were encouraged to visit the Commission's website and to give their views. Some salient concerns included:

1. Respect for the intricacy of the natural world;
2. Biological safety and security. Synthetic organisms once released might not be recapturable or 'recallable';
3. Ascertaining true benefits in such fields as synthetic vaccines, synthetic agricultural products, or biofuels, since newly synthesised genomes may not be easily or immediately determined as harmful or benevolent; and
4. Determining the challenges of a widespread dispersed technology versus the advantages of central regulation.

It was recognised that there is a need for regulation to encompass synthetic biology as it is important to ensure that there is a culture of responsibility in the scientific community. In addition, public safety should be recognised as a research concern. In addition, a summary of the views of the European Group on Ethics in Science and New Technologies was presented, as well as the considerations of the Swiss Ethics Committee on Non-Human Biotechnology on the ethical acceptability of synthetic biology. These and other views were extensively discussed, and the meeting clearly felt that issues arising from synthetic biology needed to be discussed before the next Summit, and agreed that important themes should be made known and further pursued. Safety concerns arising from the dispersion of the technology and its potential for private ventures were two prominently featured themes.

Ethical Issues in Biobanks and Research Using Stored Human Tissue

The ethical aspects of biobanking in France and Austria, and of umbilical cord blood collections in Greece were presented and discussed. There was a general consensus that the principles of solidarity and autonomy were most relevant, and that the focus needed to be on ways of protecting donor privacy while not limiting research by unreasonably insisting on specific consent or other methods of enabling donor control. The need for regulation was particularly clear for international research, or the potentially exploitative use of samples, or when claimed benefits were debated.

² *New Directions - The Ethics of Synthetic Biology and Emerging Technologies*, Dec 2010. Available at <http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf>

Ethical Issues in Stem Cell Research and Therapy

Ethical issues in stem cell research and therapy in China and Japan were considered, along with discussions in Denmark on the ethical issues in human-animal combinations. Stem cell research is increasingly moving into clinical applications in many parts of the world, and there were shared concerns over under-regulation of clinical stem cell trials, as well as over the substance of transnational regulatory process. However, the stem cell research enterprise in its entirety was not fundamentally questioned.

Medical Ethics

Three presentations were made, on disclosing genetic information to one's genetic relatives in Australia, medical profiling and online medicine in the UK, and current debates on end-of-life ethics in Switzerland. Three dilemmas that could not be resolved unambiguously were highlighted. Firstly it seemed doubtful if the traditional medical model could survive the ethical challenges presented by easier access to medical knowledge, especially from online sources, which would entail procedures outside medical control. Secondly, an inherent conflict between autonomy and justice arising from the disclosure of genetic information did not seem to lend itself to any obvious resolution. Thirdly, it was increasingly felt that end-of-life issues had a substantial social component, taking them beyond the limits of normative medical ethics. These issues need to be monitored and considered further.

Bioethical Developments (International Organisations)

Discussions led by a panel comprising the European Commission, the Council of Europe and the WHO highlighted a need for clarification on the role of the WHO and its relationship with other bioethics organisations. The meeting also recognised the need to avoid an excessively narrow interpretation of bioethics, since the latter goes far beyond health matters.

Conclusion

The participants of the 8th Global Summit reaffirmed the Summit as a valuable forum for information exchange and collaboration on bioethical issues of global importance, with the aim of advancing understanding of such issues, fostering international debate and building global consensus. They agreed to establish virtual working groups to facilitate the exploration of topics discussed during the 8th Global Summit, which might include:

1. The ethics of organ and tissue transplantation, drawing attention to the *Guiding Principles on Human Cell, Tissue and Organ Transplantation* that were endorsed by the World Health Assembly in May 2010;
2. The ethical aspects of the control of TB and related public health activities;
3. The ethics of research involving human beings, including harmonisation of review processes for research ethics committees;
4. Biobanking and research on stored human biological materials;
5. New biotechnologies such as synthetic biology; and
6. Other topics of common concern.

They requested for the WHO, as the Permanent Secretariat:

1. To collect and make available opinions and reports published by national bioethics advisory bodies, on a regular basis (at least annually);
2. To facilitate communication and exchange between these bodies, particularly to support the virtual working groups; and
3. To collaborate with these bodies in organising and hosting the Summit.

NECs will explore new ways to provide financial support to NECs in Low and Middle-Income countries to enable their participation in the Summit.

The Tunisian National Committee of Medical Ethics will host the 9th Global Summit, which will be held in October 2012 in Tunis, Tunisia.

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Programme for 8th Global Summit of National Bioethics Advisory Bodies

Day 1: 26 July 2010 (Monday)

Time	Programme
8.00 – 9.00 am	Registration
9.00 – 9.05 am	Welcome Address Judge (ret.) Richard Magnus <i>Chairman of the 8th Global Summit Organising Committee</i>
9.05 – 9.20 am	Opening Address Professor Kandiah Satkunanantham <i>Director of Medical Services, Ministry of Health, Singapore</i>
9.20 – 9.50 am	WHO Strategy on Ethics – Collaboration with National Ethics Committees Dr Ruediger Krech <i>Director, Ethics, Equity, Trade and Human Rights Department, World Health Organization</i>
9.50 – 10.05 am	Report on 7th Global Summit of National Bioethics Advisory Bodies Dr Patrick Gaudray <i>Member, Comité Consultatif National d’Ethique pour les Sciences de la Vie et de la Santé, France</i>
10.05 – 10.35 am	Tea
10.35 am – 12.00 pm	Ethical Issues in Transplantation of Organs, Tissues and Cells Chairman: Professor Leonardo de Castro, Chair, Philippines Health Research Ethics Board <ul style="list-style-type: none"> • <i>Twenty-Five Years of Progress: WHO and the Promotion of Ethical Transplantation</i> Professor Alexander Capron, University Professor, Distinguished Professor of Law and Medicine, University of Southern California, USA • <i>The Declaration of Istanbul: Where did it come from? What is it? Where are we going with it?</i> Professor Jeremy Chapman, President, The Transplantation Society • <i>Organs, Tissues and Cells Trafficking: A joint Council of Europe and UN study</i> Dr Laurence Lwoff, Secretariat, Steering Committee on Bioethics, Council of Europe • <i>Ethical Issues in Human Organ Donation: the Singapore experience</i> Associate Professor Roy Joseph, Chairman, National Medical Ethics Committee, Ministry of Health, Singapore
12.00 – 1.30 pm	Lunch

Time	Programme
1.30 – 3.00 pm	<p>Research Ethics Committees</p> <p>Chairman: Professor Lee Hin Peng, Deputy Chairman, Bioethics Advisory Committee, Singapore</p> <ul style="list-style-type: none"> • <i>WHO Standards and Guidance for Research Ethics Committees that Review Health Related Research with Human Beings</i> Dr Tikki Pang, Director, Department of Research Policy & Cooperation, World Health Organization • <i>Standards and Guidance for Research Ethics Committees</i> Dr Julius Ecuru, Assistant Executive Secretary, Uganda National Council for Science and Technology • <i>Biomedical Research Ethics Governance in India</i> Professor PN Tandon, Chairman, Central Ethics Committee on Human Research, Indian Council of Medical Research
3.00 – 3.30 pm	<p>Tea</p>
3.30 – 5.00 pm	<p>Ethical Issues in TB Control</p> <p>Chairman: Dr Arthur Chern, Group Director (Health Regulation), Ministry of Health, Singapore</p> <ul style="list-style-type: none"> • <i>WHO Guidance on Ethical Issues in TB Prevention, Care and Control</i> Dr Andreas Reis, Department of Ethics, Equity, Trade and Human Rights, World Health Organization • <i>Comments on WHO Guidance on Ethical Issues in TB Prevention, Care and Control</i> Professor Qi Guoming, Chairman, Ethics Committee, Ministry of Health, China • <i>TB as a Test Case for Bioethics</i> Professor Eugenijus Gefenas, Chairman, Lithuanian Bioethics Committee
5.00 – 6.00 pm	<p>Bioethical Developments</p> <p>Chairman: Professor Boris Yudin, Vice-Chairman, Russian Committee on Bioethics, Russian Academy of Sciences</p> <ul style="list-style-type: none"> • <i>Experience Sharing – Jamaica National Bioethics Committee</i> Dr Anthony Mullings, Chair, Jamaica National Bioethics Committee • <i>National Regulation of Biomedical Ethics – how responsive to our needs?</i> Professor Abdulaziz MA AlSwaiem, Chairman, National Committee of Medical and Bioethics, Saudi Arabia
7.00 – 9.45 pm	<p>Welcome Dinner at Arts House</p> <p>Host: Professor Lim Pin, Chairman, Bioethics Advisory Committee, Singapore</p>

Day 2: 27 July 2010 (Tuesday)

Time	Programme
8.30 – 10.15 am	<p>Ethical Issues in Synthetic Biology</p> <p>Chairman: Professor Daniel Tarschys, Chair, Swedish Council on Medical Ethics</p> <ul style="list-style-type: none"> • Dr Lino Paula, Science, Economy and Society - Governance and Ethics Unit - L3, Directorate-General for Research, European Commission • <i>Review of Advances in Synthetic Biology</i> Dr Amy Gutmann, Chair of the US Presidential Commission for the Study of Bioethical Issues • <i>Ethics of Synthetic Biology – An EGE Opinion</i> Professor Julian Kinderlerer, Member, European Group on Ethics in Science and New Technologies • <i>Synthetic Biology: The Public Debate in Germany</i> Dr Joachim Vetter, Head of Office, Ethikrat, Germany • <i>Synthetic Biology: Ethical Considerations</i> Professor Martine Jotterand, Member, Federal Ethics Committee on Non-Human Biotechnology, Switzerland
10.15 – 10.45 am	<p>Tea</p>
10.45 am – 12.00 pm	<p>Ethical Issues in Biobanks</p> <p>Chairperson: Professor Sigrid Sterkx, Member, Belgian Advisory Committee on Bioethics</p> <ul style="list-style-type: none"> • <i>BioBanks or BioLibraries: To protect and serve...Whom?</i> Dr Patrick Gaudray, Member, Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé, France • <i>Ethical Aspects in Biobanking</i> Dr Christiane Druml, President, Austrian Bioethics Commission • <i>Umbilical Cord Blood Collections</i> Professor George Maniatis, Deputy Chairman, Hellenic National Bioethics Commission, Greece
12.00 – 1.00 pm	<p>Lunch</p>
1.00 – 2.30 pm	<p>Ethical issues in Stem Cell Research and Therapy</p> <p>Chairman: Dr Vijay Kumar, Member & Secretary, Central Ethics Committee on Human Research, Indian Council of Medical Research</p> <ul style="list-style-type: none"> • <i>Putting the Medical Ethics Principles into Medical Practice: Stem Cell Research and Application</i> Professor Qi Guoming, Chairman, Expert Committee of Medical Ethics, Ministry of Health, China • <i>Japan's Stem Cell Policy and Regulations: from the Viewpoint of Bioethics</i> Professor Ryuichi Ida, Member, Expert Panel on Bioethics, Council for Science and Technology Policy, Cabinet Office, Japan

Time	Programme
	<ul style="list-style-type: none"> • <i>Man or Mouse? Ethical issues in crossing the human-animal barrier</i> Professor Peder Agger, Chairman, Danish Council of Ethics
2.30 – 4.00 pm	<p>Medical Ethics</p> <p>Chairman: Professor Sadek Beloucif, Chairman, Bioethics Committee, Agence de la Biomedecine, France</p> <ul style="list-style-type: none"> • <i>Disclosing Genetic Information to a Person’s Genetic Relatives: The Australian Experience</i> Dr Sandra Hacker, Chair, Australian Health Ethics Committee • <i>Medical Profiling and Online Medicine: the ethics of ‘personalised’ health care in a consumer age</i> Mr Hugh Whittall, Director, Nuffield Council on Bioethics, UK • <i>End-of-Life Ethics: Current debate in Switzerland</i> Dr Magrit Leuthold, Member, National Advisory Commission on Biomedical Ethics, Switzerland
4.00 – 4.15 pm	Tea
4.15 – 5.15 pm	<p>Bioethical Developments (International Organisations)</p> <p>Chairman: Dr Manuel Ruiz-de-Chávez, President, National Commission of Bioethics, Mexico</p> <p>Panel of International Organisations working with National Ethics Committees:</p> <ul style="list-style-type: none"> • Dr Lino Paula, Science, Economy and Society - Governance and Ethics Unit - L3, Directorate-General for Research, European Commission • Dr Laurence Lwoff, Secretariat, Steering Committee on Bioethics, Council of Europe • Dr Marie-Charlotte Bouësseau, Ethics, Equity, Trade and Human Rights, World Health Organization
5.15 – 5.50 pm	<p>Closing / Planning for the Next Global Summit of National Bioethics Advisory Bodies</p> <p>Chairman: Judge (ret.) Richard Magnus, Chairman of the 8th Global Summit Organising Committee, Singapore</p> <ul style="list-style-type: none"> • Tunisian Candidacy for the Organisation of the 9th Global Summit of National Bioethics Advisory Bodies (2012) • Final Statement of the 8th Global Summit
5.50 – 6.00 pm	Closing Remarks
6.00 – 6.30 pm	Press Conference