

10th GLOBAL SUMMIT OF NATIONAL ETHICS/BIOETHICS COMMITTEES

FINDING PATHS THROUGH THE WORLD



10th Global Summit of National
Ethics/Bioethics Committees

June 22-24

Mexico City 2014





...Bioethics has become an institutional fact in almost every country in the world. The existence and increasingly intense activity of committees is a tangible proof of the expansion and vitality of bioethics...

...The National Ethics/Bioethics Committees (NECs) are key elements to understand the development of the ethical reflection on public affairs particularly in health and life science. Analyzing and discussing how they work, their main challenges, strengths and achievements will help to portrait the state of the art of NECs around the world...



**10th GLOBAL SUMMIT
OF NATIONAL
ETHICS/BIOETHICS
COMMITTEES**

FINDING PATHS THROUGH THE WORLD

10th GLOBAL SUMMIT OF NATIONAL ETHICS/BIOETHICS COMMITTEES

FINDING PATHS THROUGH THE WORLD



10th Global Summit of National
Ethics/Bioethics Committees

June 22-24

Mexico City 2014



**10th Global Summit of National Ethics/Bioethics Committees,
Finding Paths Through The World**

First edition 2015

2015 Comisión Nacional de Bioética/Secretaría de Salud

Calzada Arenal No. 134, col. Arenal Tepepan,

C.P. 14610, Deleg. Tlalpan, México, D.F.

Phone: +52 55 54872760

<http://conbioetica-mexico.salud.gob.mx>

ISBN: 978-607-460-473-3

Edited by:

Manuel Hugo Ruiz de Chávez Guerrero

Raúl Jiménez Piña

Proofreading coordinator:

José Manuel Lozoya Pacheco

Proofreading:

Aidée Orozco Pérez, América Nelly Pérez Manjarrez, Ángeles Marina Adame Gayoso,

Edén González Roldán, Gabriela Pineda Hernández, Gustavo Oláiz Barragán, Karla

Gabriela Sánchez Villanueva, Mario Patricio Silva Schütte, Marisa Valdés Fernández,

Miguel Ángel Morales Gutiérrez, Sandra Lizbeth Carrizosa Guzmán.

Design: EDITARTE

www.editarte.com.mx

Printed and made in Mexico

Editor's note:

The views expressed on this publication are those of the authors and do not necessarily reflect the point of view of the National Bioethics Commission of Mexico. All images and pictures were taken from the authors' presentations.

It was considered best to keep the original sense of the lectures. Consequently, these are published in the language they were delivered, which is also why some of them appear in English, Spanish or French, and only a style review was made -barely correcting slip-ups in the spoken discourse.

CONTENT

Presentation	11
Foreword	13
Acknowledgments	15
Preface	17
Opening session	21
• Manuel H Ruiz de Chávez, President of the 10th Global Summit of National Ethics/Bioethics Committees	21
• Issac Morales Tenorio, Secretary of Foreign Affairs representative	25
• Maureen Birmingham Panamerican/World Health Organization representative	27
Inauguration ceremony	31
Key note speeches	33
• The 9th Global Summit of National Ethics Committees. Review and discussion	33
• Evolution and prospects of the National Bioethics Commission of Mexico	36
• Introduction to the 10th Global Summit: Outline and expectations	41

Session 1: National Bioethics Committees: profile, role and function	51
• Presentation	51
• Introduction	52
• NECS questionnaire: overview and presentation	55
• L'indépendance la CNE, indispensable dans une démocratie directe	61
• Gaps between ethical deliberation and reality	65
• The role of international organizations	73
Session 2: Emerging Health Technologies	79
• Presentation	79
• Introduction	81
• Ethics of new and emerging health technology	83
• Assessment of new health technologies	87
• Ethical issues in information and communication technology for health	91
• La télésanté clinique au Québec: un regard éthique	97
• Novel neurotechnologies: intervening in the brain	101
• Regenerative Medicine using pluri-potential stem cells	107
Session 3: Universal Health Coverage (UHC)	113
• Presentation	113
• Introduction	114
• Ethical priority-setting for a progressive realization of universal health coverage/Making fair choices on the path to universal health coverage	116
• Challenges in the system of social protection in health	124
• Institucionalización de la salud	127
• Universalidad: Responsabilidad del Estado	132
• The Paradox of Sri Lanka's Health Achievements	134
• Good quality well accessed medical care: dream or ethical imperative	138

- Co-payment: a challenge to priority-setting and universal health coverage? A Swedish NEC perspective 141

Session 4: Research involving Vulnerable populations with focus on children 145

- Presentation 145
- Introduction 147
- On the concept of vulnerability in research150
- Towards an ethical framework for the involvement of children in research 154
- Informed Consent in Research Involving Children with Cancer160
- Safeguarding Children: Pediatric Medical Countermeasure Research 164

Bioethics on the Global Level: Issues and Challenges 173

Role and Function of Steering Committee: Future Summits 187

- Next Venue209

Closing remarks 215

Market Place Sessions 217

CONBIOÉTICA-Mexico travel grant 221

List of participants 224

Contributors 235

PRESENTATION

Mexico is honored and proud for the great success of the 10th Global Summit of National Ethics/Bioethics Committees, which gathered representatives from more than one hundred countries from around the globe to foster open dialogue, mutual learning and exchange information about specific and priority aspects of bioethics issues, both for our country as well as the group of nations who participated.

This productive meeting, held with great enthusiasm and expectation, laid the ground work for discussing and analyzing national and global public policy on ethics in health. The Summit was meant not only as an opportunity for Mexico to highlight its efforts in bioethics, but as a way of consolidating Mexico's leadership in the Americas, a key aim of the National Bioethics Commission's work in recent years. It was an ideal platform for all of the Americas to become aware of the wide-ranging and complex projects, work and advances that have been carried out in this field.

The issue is of utmost importance for our government, as the President of the Republic, Enrique Peña Nieto, has made a call to build a society of rights, within the framework of a more egalitarian and inclusive Mexico. This has, on one hand, strengthened the National Bioethics Commission, and, on the other, promoted the creation of bioethics committees in each of the states. The stage and the areas of opportunity for advancing a bioethical culture in our country, thus, are favorable for the promotion of projects and programs aimed at developing knowledge in the field, such as the organization of this great event.



The realization of the 10th Global Summit of National Ethics/Bioethics Committees is a reflection of the commitment of our nation to the best causes of Humanity. I would like to thank all participants for their valuable contributions and for making this such a memorable occasion. ●

Mercedes Juan
Secretary of Health, Mexico

FOREWORD

The Global Summit of National Ethics/Bioethics Committees (GSNEBC), held once in every two years, brings together National Ethics Committees, i.e., bodies with a recognised national role in providing bioethics advice or decision regardless of their names, such as Ethics/Bioethics Committees/ Commissions/ Advisory Bodies, from around the world to share their thoughts and experiences in relation to bioethical issues. It serves as an international forum for exchange of views and debate on bioethical issues of common global interest, therefore contributing both to common understanding and consensus building between nations as well as assisting those nations developing their national bioethical framework and guidelines. It is an independent initiative by and for the NECS. WHO and UNESCO offer their assistance and cooperation for the effective functioning of the GSNEBC, while WHO has agreed to serve as the Secretariat.

From June 22-24, 2014, Mexico City had the honor of receiving official representatives from various nations as host for the 10th GSNEBC.

As an outcome of this meeting, this book is issued. It contains the analysis and discussions that took place during the Summit, which will be helpful, for National Ethics Committees all over the world, national governments, international organizations, and all those interested on issues related to ethics and health. •

*The Steering Committee for 10th the Global Summit
of National Ethics/Bioethics Committees*



ACKNOWLEDGMENTS

The organizing committee of the 10th Global Summit of National Ethics/Bioethics Committees wishes to thank the many organizations and individuals from Mexico and abroad whose work made possible this publication, particularly Dr. Mercedes Juan, *Secretary of Health*, Dr. José Antonio Meade Kuribreña, *Secretary of Foreign Affairs*, Dr. Enrique Cabrero, *Director at the Council for Science and Technology (CONACYT)*, Dr. Julia Tagüeña, *Deputy Director of Scientific Development* and Msc. Lorena Archundia, *Director of Science Planning* also at CONACYT, the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO), Armando Ahued, *Secretary of Health of Mexico City*, and the Panamerican Health Organization (PAHO).

In addition, the Organizing Committee is very grateful to the **Global Summit Permanent Secretariat** at the **World Health Organization**, headed by Najeeb Al-Shorbaji, Abha Saxena, and Andreas Reis, and to all members of the 10th Global Summit Steering Committee: Nicole Beaudry, Ramesh Kant Adhikar, Michel Daer, Julius Ecuru, Hele Everaus, Javier Luna Orosco, Manuel H Ruiz de Chávez, Ida Ryuichi, Mohamed Salah Ben Ammar, Sambacor Sarr, Hugh Whittall, Christiane Wopen, Nik Zeps, Mohammed Zuhair Al-Kawi and UNESCO.

The advice from, Jim Dratwa (BEPA), Laurence Lwoff (DH-BIO), Dafna Feinholz (UNESCO), Hilda Dávila and Marie-Charlotte Bouësseau was essential to accomplish such a great meeting.



Without the assistance of all our national and international partners, who have offered exemplary financial and organizational support, the 10th Global Summit and this report could not have been possible.

The excellent work made by the members of the National Bioethics Commission of Mexico (CONBIOÉTICA) deserves a special remark. •

*The Organizing Committee for 10th Global Summit
of National Ethics/Bioethics Committees*

PREFACE

Every human behavior encompasses an ethical dimension, especially those affecting not only individuals but also large populations. It is clear that when such actions, such as those taken by governments, are related to public health and health care, ethical examination and possible ethical dilemmas arise.

In order to face these dilemmas, thoughtful and multidisciplinary analysis based on sound evidence and inclusive dialogue is required; in this regard, National Ethics Committees represent a valuable resource to identify and generate concrete proposals to solve ethical issues raised in health.

Conferences like the Global Summit, where this kind of topics are discussed and analyzed, are becoming increasingly important. It is noteworthy, that the number of National Ethics Committees that participated in this event has been steadily growing with an increasing participation of low and middle income countries.

For the 10th Global Summit of National Ethics/Bioethics Committees more than 130 specialists in ethics/bioethics and health, from 57 countries gathered in Mexico City, most of the attendees were official delegates from National Ethics/Bioethics Committees (NEC). Representatives from international organizations, members of Local Bioethics Committees and special guests were also present.

The Summit was a space that allowed national representatives to share experiences concerning the ethical challenges around public health policies, as well as to debate on ethical issues of common global interest, and to contribute to consensus building on ethics issues of public health and health research.

The Global Summit is important not just because it provides a forum for exchange on ethical issues, the main added value is that it



focuses on ethical issues which no country could address by itself, but only through a global approach.

The working sessions provided the opportunity to listen to diverse opinions on issues of global concern, review the latest evidence, identify potential risks, and review the current discussion within the countries and regions. This provided the platform for intense debate during the Summit in Mexico City in order to identify common needs; the dialogue, nonetheless, was characterized as plural, rigorous and inclusive.

In addition, the foundation for the collaborative work between diverse National Committees and international organizations, such as the World Health Organization (WHO), the United National Educational Scientific and Cultural Organization (UNESCO), the Bureau of European Policy Advisers (BEPA), the Council of Europe, among others, was established. Correspondingly, the agenda, work method and venue for the 11th edition of the Summit were outlined.

This report features the developments of the plenary sessions related to the themes addressed on the meeting, namely: (i) The role and performance of National Ethics/Bioethics Committees, (ii) Emerging technologies and healthcare, (iii) Universal Health Coverage, and (iv) Health research and vulnerable groups. The inaugural ceremony, the plenary sessions, *Bioethics on the Global Level: Issues and Challenges and Role and Function of Steering Committee – Future Summits* are also included, as well as a brief summary of the Market Place sessions.

I wouldn't neglect pointing out the vital role played by the Steering Committee and the Summit's Permanent Secretariat in shaping the agenda and work mode of the conference, their effort is clearly reflected by this report.

We consider it best to keep the original sense of the plenary sessions' lectures. Consequently, these are published in the language they were delivered, which is also why some of them appear in English, Spanish or French, and only a style review was made –barely correcting slip-ups in the spoken discourse.

The National Bioethics Commission of Mexico (CONBIOÉTICA) believes this report will make a substantial contribution to developing

a deeper understanding of health challenges and their importance from an ethical perspective, both in Mexico and abroad, and that it will help to encourage ethical analysis in the public agenda.

CONBIOÉTICA also hopes that the 10th Global Summit's work and outcomes will be useful in organizing the 11th Global Summit. We wish the best to our colleagues of the German Ethics Council. CONBIOÉTICA is confident the next Summit will be successful and productive.

This report is the result of CONBIOÉTICA's work since 2012, when Mexico, supported by the Secretary of Health and the National Council for Science and Technology, was appointed as host for the 10th edition of this important meeting; establishing it as a benchmark for Bioethics at a regional and global scale, and strengthening Bioethics as a valuable analysis tool for decision making in public health policy. •

Manuel H Ruiz de Chávez

*President of the 10th Global Summit
of National Ethics/Bioethics Committees*

*President of the Council of the National
Bioethics Commission of Mexico*



OPENING SESSION

Manuel H Ruiz de Chávez,
*President of the 10th Global Summit of National
Ethics/Bioethics Committees*

It is a great honor to be here with you today opening the work of the 10th Global Summit of National Ethics/Bioethics Committees, in which more than fifty countries from all of the world will participate.

It is a privilege to share the stage with members of some of the most important and respected National Ethics and Bioethics Committees, and to speak on this occasion to my colleagues and friends.

I extend the most cordial welcome to you, honorable guests, leaders and delegates representing the National Ethics Committees of 70 countries, as well as our guests of honor, who belong to national and international organizations, and, of course, public servants from the Mexican government.

I'd like to extend special thanks to our national co-organizers: Dr. Mercedes Juan, Secretary of Health; Dr. Julia Tagüeña, Deputy Director of Scientific Development at the National Science and Technology Council; Isaac Morales Tenorio, Deputy General Director for Challenges to Development, of the General Department for global Issues of the Ministry of Foreign Affairs; and Dr. Armando Ahued, Secretary of Health for the Mexico City government.

I'd also like to express my recognition to the World Health Organization which, through its department of Ethics and Research, serves as permanent Secretariat of the Global Summit, particularly Dr.



Najeeb and Dr. Abha Saxena, and their excellent team, for their efforts in organizing this conference.

Gratitude is also due to the Steering Committee, made up of National Ethics Committees from the six regions of the WHO, who have worked for more than 1 year polishing the Summit agenda; and, of course, our colleagues from UNESCO.

Without the help of our national and international co-organizers, who have offered exemplary financial and organizational assistance, this 10th Global Summit could not have been carried out in this manner.

Finally, I must not neglect to recognize the excellent efforts of the work group from the National Bioethics Commission of Mexico. I must say that opening this conference represents the realization of all our expectations.

There has never before been a Summit that brought together delegates from the member countries of the WHO, academics and representatives of so many National Ethics/Bioethics Committees to discuss ethical issues in health and other fields. This is the most widely attended meeting of Ethics/Bioethics Committee ever held, and we are fortunate to be hosting it here in Mexico.

We are accompanied by more than 80 official representatives as well as special guests and observers. The Mexican government deserves special thanks for the financial support offered to representatives of 10 developing countries, which gave us the opportunity of welcoming national representatives of capital importance who would otherwise not have been able to attend and be here with us.

We have met here to continue the work undertaken in San Francisco in 1996, where, thanks to the intelligence, historical conscience and courage of the representatives of National Ethics/Bioethics Committees, an effort was made to hold this Summit every two years.

After more than 10 years since Brazil, 2002, the conference finally returns to Latin American soil. During the 9th Global Summit, held in Tunisia, in September 2012, Mexico was unanimously elected by the participating National Bioethics Committees to host the next bi-yearly

meeting, which is a great honor and responsibility. It reflects Mexico's commitment, through its National Bioethics Commission, to the promotion of bioethics and serving as a point of reference in this field.

The Global Summit is a forum for all those who seek to share opinions, information and experiences, and at the same time create agreements and consensus on the greatest ethical and bioethical problems in health and other fields, which require local, regional and global analysis.

Thanks to the participants, the issues dealt with and the results attained, the Global Summit is considered by participating governments as the most important international-level meeting in terms of its impact on ethics/bioethics and public health policy.

Those of us gathered here today come from many parts of the world, with very different ethnic origins, nationalities, ideologies, cultures, historical and social contexts. Hence the need to address health-related ethical dilemmas and to promote their deliberation in connection with public decision-making, based on an attitude of respect and a secular and inclusive vision.

The discussion will be grounded on common interest in the dignity of persons and of life in general. We must at all times bear in mind that ethical analysis is one of the most important elements for democratic, social and economic development, promoting peace among nations as well.

The current global scenario for health involves pressing ethical dilemmas. Despite the challenges, the prospects are promising thanks to the collective efforts that have been undertaken. This is a tremendous opportunity for all of us, to establish a system of participation capable of resolving issues relating to ethics, the development of science, technology and knowledge of health.

Dear guests, throughout two decades, the core ideals of this Summit have not changed: deliberation based on evidence, solidarity, an exchange of knowledge, and cooperation between National Ethics/Bioethics Committees.



We are facing a multiplicity of problems that cannot be resolved by one nation, nor by one decision-making body or advisory committee. We require a participative, plural and holistic vision of the challenges at hand, to construct a comprehensive response, as well as an informed local and global leadership, with a solid approach to science and innovation, to propose solutions to these problems. Their scale and complexity demands a new alliance among all of us, and a better handling of government resources.

The National Bioethics Commission believes that the bioethical approach is crucially important in planning public health policy, and also in the framework of international collaboration.

National Ethics/Bioethics Committees are crucial for building the future. By combining our resources and efforts, we, the members of this Summit, can create a better world for our countries and for future generations. This goal can be attained through cooperation among all of us, through a common effort, with passion and dedication. We must answer the call of our time and face an uncertain future with our present commitment.

For me –and, I assume, for all of you as well–, it is fundamental that we work at the intersection of science, health, ethics and technology.

I'd like to mention that this Summit precedes another important event in the field of bioethics: the 12th World Congress of Bioethics of the International Association of Bioethics. Both meetings will be held from today until 28 June in Mexico City.

The National Bioethics Commission is proud to mark the fact that Mexico is hosting the two most important events in the field of Bioethics worldwide.

This summit and the 12th World Congress of Bioethics were made possible thanks to the the Mexican government, through the Secretary of Health; which grants Mexico a privileged place as a nation, with global responsibility at the service of the best causes of humanity. •

Issac Morales Tenorio.
Secretary of Foreign Affairs representative

It is a real honor to be here with you, representing the Secretary of Foreign Affairs, Dr. José Antonio Meade Kuribreña, to extend to you the most cordial welcome to Mexico and to this 10th Global Summit of National Ethics/Bioethics Committees.

As we all know, the dizzying pace of technological and scientific advance in recent years has forced nations to ponder on the need to clarify problems centering around life sciences, the prolongation of life, genetic research, assisted reproduction, organ donation and many other issues.

For the Ministry of Foreign Relations, these global issues and challenges, like those that have to do most clearly with Global Health, are increasingly and more closely linked with the drafting of foreign policy, and the efforts of diplomacy as well.

Faced with these challenges, many governments from around the world have found a need and an opportunity to create National Committees or Advisory Councils to offer recommendations on how to address the dilemmas that have attracted the attention of bioethics and health. These bodies meet today with the formidable task of reflecting on and offering solutions to these and many other ethical and scientific quandaries.

I have no doubt that the work we will be doing in the next few days will bring substantial benefits to humanity. As many renowned specialists have said, bioethics points us towards the future.

There have been many international efforts made in the framework of multilateral mechanisms established by the international community



and regional forums like the European Council, for example, to create a set of global bioethical standards and rules that would allow us to guarantee the general principle of the international right of human beings, according to which the interests of science can never supersede the dignity of the human being, for example.

The Universal Declaration on the Human Genome and Human Rights, adopted in 1997 by the United Nations Organization for Education, Science and Culture (UNESCO), is proof of this.

The same is true for the work surrounding the International Declaration on Human Genetic Data, also adopted by UNESCO in 2003, which enshrines the ethical principle that should govern the use of genetic data; or the Universal Declaration on Bioethics and Human Rights of 2005, which continues and culminates the process begun by the Universal Declaration on the Human Genome.

The Summit that brings us together today offers an invaluable opportunity to identify ethical issues of global importance; to review recent evidence on these issues, and of course, to agree on common approaches.

No country on its own can resolve the challenges posed by bioethics issues today, hence the value of this Summit.

We are deeply grateful for the leadership of the Secretary of Health of Mexico, Dr. Mercedes Juan, to whom I'd like to extend the warmest regards of the Ministry of Foreign Affairs, and of course the National Bioethics Commission, represented by its Chair, Dr. Manuel H Ruiz de Chávez, for being able to hold this meeting, which places Mexico at the forefront as a globally responsible participant in these issues of paramount importance to the international community, and to the scientific community in particular.

On behalf of the Ministry of Foreign Affairs, I'd like to express my sincerest wish that the exchanges and experiences presented here contribute to the creation of national committees or the strengthening of existing ones, and clearly resolve how to best advance, all together, toward solving these issues. ●

Maureen Birmingham,
Panamerican/World Health Organization representative

Mexico City has the opportunity to become a privileged venue for dialogue on one of the most important themes of life and scientific activity.

Mexico has the honor of welcoming delegates from numerous nations to celebrate the 10th Global Summit of National Ethics/Bioethics Committees.

On behalf of the General Director of the World Health Organization, Dr. Margaret Chan, we extend a warm welcome to all the delegates and participants who have honored us with their presence today and this week.

I'd like to take this opportunity to recognize the efforts of the National Bioethics Commission of Mexico and the Permanent Secretariat of the World Health Organization, as well as all the members of the Steering Committee of the 10th Summit and members of the work group.

Thanks to your time, knowledge and dedication, we are today pleased to hold the tenth edition of this World Summit, in which participants can share opinions and experiences, debate ethical and scientific issues of common interest, and create a consensus for strengthening global cooperation in bioethics.

The foundations of the ethics of life merge with the human paths of learning and the social construction of knowledge.

It is in this process that we have gradually come to understand how morality marks our conduct, how we create laws to protect what we value, and ethics as a sphere in which we assume the paradox of freedom and responsibility for our actions.



The dilemmas of bioethics emerge at a pace with knowledge and technology, as well as the growing complexity of contemporary cities; dilemmas that caregivers encounter on a daily basis, because they are present in the relationship between the health team and the patients, in the level of attention possible compared to the inevitable limitation of resources, in the challenges of technological progress, like transplants and genetic experimentation; in understanding when a person has the right to be born, and when to die, and the problems arising from man's interaction with the environment and sustainability, among so many other challenges.

If these aspects are huge and complex today, they will be even more tomorrow. That's why it's important that as we examine and discuss current, urgent matters such as universal health coverage and vulnerability, we also consider the ethical challenges of the future, through dialogue, debate and learning.

Bioethics is a human activity that is born from the need to accept responsibility for the freedom to make choices and the consequences of those choices, and it seeks to constantly reflect on the many ethical dilemmas that arise with regard to health and life science, as in research with human subjects, the design or implementation of public health policy, and the provision of medical attention.

Bioethics should not be considered a code of precepts, but an exercise of analysis, in light of the ethical principles and criteria that guide our practice in various areas of health. This practice should aspire to a universal, autonomous freedom and accept the diversity of each context while sustaining the basic principle of respect for all human beings, as ends in and of themselves.

It is definitely not an easy task. We are certain that we all face difficult and complex problems in the sphere of bioethics, and the classical vision of doing good rather than harm is complicated by many factors, like autonomy and the emergence of political and social rights; and principles like distributive justice are affected by the need to make tough decisions about the priority of public policies and medical care.

In this Organization, we are committed to supporting member States to enable them to face the public health challenges of the present and the future with public policies grounded in a robust ethical framework and scientific evidence. To this end, National Ethics and Bioethics Committees are of crucial importance.

We therefore celebrate and support this Summit as a forum for so many representatives to meet, get to know each other, create networks and learn from each other, while sharing experiences.

You will take another step toward amassing the evidence for men and women to join in the design of public policies that affect millions, whether in the research laboratory or in the operating room. We can consider ourselves more responsible for our actions and ensure a life of greater harmony and fulfillment for future generations. •



INAUGURATION CEREMONY

Manuel H Ruiz de Chávez

The National Bioethics Commission believes that the bioethical approach is crucially important in planning public health policy, and also in the framework of international cooperation.

National Ethics and Bioethics Committees are crucial in forging the future. By combining our resources and efforts, we can create and build a better world for our countries, and especially for future generations.

This goal can be attained through shared collaboration between us. Through a common effort, with passion and dedication, we can rise to the challenge of our time.

Isaac Morales Tenorio

Today, June 23, 2014, at 9:45 in the morning, I declare this Tenth Global Summit of National Ethics/Bioethics Committees officially open, and I hope that our substantive and plural efforts, guided by best practices and evidence, leads to the best of successes.

Best wishes to you all!



KEY NOTE SPEECHES

The 9th Global Summit of National Ethics Committees. Review and discussion

Mohamed Salah Ben Ammar

As it has been said, this process started in San Francisco eighteen years ago, and after San Francisco, Tokyo, London, Brasilia, Canberra, Beijing, Paris, Singapore, Tunisia, and now, Mexico.

I would like to say that Dr. Manuel did a lot to bring this Summit to Mexico. He worked four years for that, and I really want to thank him and to say we are very happy to be here in Mexico.

In Tunisia, we were in a position to find a new way of functioning of this Global Summit, because we were facing problems, and we need a new breed. So what we decided was to invite all the six WHO Regional offices to have a representative in Tunisia. And in fact, we had from each region a representative. And I would like to underline that it was the first time that Africa and the EMRO region were represented by consistent number of delegates, and it was really one of our goals. Second, in Tunisia, UNESCO was involved; and Dafna was with us, but Stefano Simplici as the Chair of IBC and other members of UNESCO Bioethics Committee. The Council of Europe was also with us. I think in Paris and in Singapore, the Council of Europe was there too, so we were very proud to have all these organizations with us.

In Singapore, they decided some topics to treat and we had working groups in biobanking and in organ cell tissue and transplantation, and

here I would like to underline that these working groups worked hard, really, and we had now a resolution on biobanking, organ cell tissue and transplantation. Perhaps it's not a resolution, but an opinion written on infectious disease and on Research Ethics Committees. Unfortunately, I don't think that these opinions were diffused or used by the National Ethics Committees, but it's not too late. We have this very good job and I would like to thank all the people who participated in the preparation of this resolution or opinion, which is really important to read it and they can send it to you if you want it. As I said, lots of people participated, from different regions of the world and we had very, very nice two or three days, we worked hard, many of these people are now here in Mexico.

We had a presentation on infectious disease, on organ cell and transplantation, from different countries. All the presentations were made by our colleagues, and we learned a lot from them.

Third point, we took some decisions in Tunisia and this is, what I would like to say to the group and to the Steering Committee. For example, we decided in Tunisia to have dementia and self-determination as a topic for the next two years, and unfortunately, I don't know why these decisions haven't been followed or why we changed, but it's not important, the problem is that if we decide something, we have to follow it, and this is my recommendation to the Steering Committee. We had a lot of presentations and many of us considered that dementia and vulnerability of ageing people is a real problem that we will face in a few years. So, this is a sample of what we presented in Tunisia. As I said, we had a lot of presentations of a very high level from renowned speakers and it was really, at least for me, a very important moment.

In Tunisia, as we are a developing country, we considered equity the main value in ethics in our region and all the presentations were focused on it. We had discussion paper sessions, market place sessions, the issues of interest for NECS session, and regional activities. In these sessions always, equity was, as in French we say, "le fil rouge" the thread we followed. Protection of vulnerable people, elder people,

clinical trials, organ donation; all these topics were treated always considering equity.

Other topic discussed was the role of the State in health population, how the State should manage the situation of health in the population, the drugs' availability, the quality of service, what the role of the State should be, in order to ensure, again, the equity on the system of health. We saw that we need national debates in each country, and the State should not only edict laws, but also talk to the population to restore or to have the legitimacy and the confidence of people, because in our countries, health and the health system are not always well seen. Our population always complains about the quality of health services. We concluded we should not only inform, but also have to foster debates on what our choices are and why do we make them. It was a very important resolution too.

What should be the responsibility of the National Ethics Committees? It's not easy. Do the National Ethics Committees should have a normative role? In addition, what is the process to choose the topics to be addressed and how? This is one of the questions that I don't think we answered, but we talked a lot about it in Tunis.

How to apply the decisions of the National Ethics Committees and at which levels? Should their resolutions be applied on the international level, on the national level, local, or within the institution?

This was the main subject we discussed on Tunis, we also talked about the candidature of Mexico, now we are here. Thank you for hosting us.

I hope that during this meeting we will, perhaps, reinforce the process applied in Tunisia: market place, discussion papers, Steering Committee. Moreover, give a new life, more than a new life, the opportunity to the Summit to have a real efficiency on the field. ●

Evolution and prospects of the National Bioethics Commission of Mexico

Manuel H Ruiz de Chávez

I'd like to take this opportunity to share with you a succinct overview of the evolution and actions taken by the National Bioethics Commission, from the time it was created to the present, and to complement it, a series of reflections and proposals on development, the future and converging perspectives –from an international point of view– in the field of bioethics.

The origins of the Commission go back to the creation in 1989 of a study group on bioethics, within the Mexican General Health Council, an institution that brings together all the country's public and private health institutions.

Later, in 1992, thanks to the commitment and talent of Dr. Manuel Velasco Suárez –a renowned Mexican physician, founder of some highly important institutions, whom we remember today with great respect and fondness–, the Commission was formally created on March 30 of that year.

The Commission has pursued its mission of promoting a bioethical culture in Mexico through four processes that encompass its various tasks: (i) offering guidance, standards and advisory services in the field of public policies on bioethics; (ii) promoting bioethical infrastructure or capacity in the country (state committees, hospital bioethics committees and Research Ethics committees); (iii) providing a forum for the dissemination of bioethical knowledge among specialists, experts and the general public –through electronic and printed media,

as well as the free services of its physical and virtual library–; and (iv) encouraging the academic development and social discussion of bioethics.

For the Commission, in its current form, Bioethics is an essential task that demands a clear vision of its conception, means and ends, because it represents the crystallization of ethical courses of action with regard to the development of knowledge and its technological application –which affect virtually every sphere of life–, grounded on a reflection that places the highest value on the preservation of the human being, life in general and its environment.

Bioethics constitutes a space to come together and discuss issues, a space for the convergence of different fields of knowledge and know-how –humanistic, scientific, practical, specialized and general–, that responds to the objective need for collaboration between diverse cultures, with different features and origins, regarding the essential questions that concern all of society: peace, health, concerted local, national and global participation in caring for the environment and natural resources, to name just some of the core issues.

Within the Board of CONBIOÉTICA, far from adhering to a complex, rigid and clearly provisional definition of Bioethics, we thought it's best to work on the basis of our own notion, which includes the reflections of the most renowned specialists that make up –Board's and takes into account the contributions of national and international institutions: "Bioethics is a field of applied ethics that reflects, deliberates and proposes standards and public policy measures to regulate and resolve conflicts in social life, particularly in life sciences, as well as in medical practice and research, that affect life on this planet, both today and for future generations."

Following the thought of some truly committed specialists in Bioethics, we believe this is a useful approach for guiding actions not only in the conceptual and educational arena but in their practical translation, considering ethical implications in societies with different degrees of development and cultural characteristics.



The idea is to promote a responsible attitude toward the decisions made by citizens and health professionals, authorities, social organizations and governments in their various orders or spheres of action, on a secular basis, respectful of the diverse positions that derive or may derive from bioethical dilemmas, particularly those linked to human life and the protection of health for individuals and groups.

As I said before, the central purpose of CONBIOÉTICA is to promote a bioethical culture in this country, which means planning and constructing strategies and lines of action that contribute to the ethical development of society as a whole, to shape and stimulate a reflexive awareness, both among individuals and in society at large, regarding situations of uncertainty that come with technical and scientific progress, and to seek out broader participation in a plural and respectful discussion that incorporates differing criteria and normative actions to benefit society, without harming social groups in vulnerable situations.

To this end, CONBIOÉTICA identified some areas in greatest need of bioethical analysis, and developed a program of action that consists of the following thematic areas: (1) Bioethics and public policy; (2) Bioethical infrastructure; (3) Research Ethics; (4) Bioethics, medicine and medications; (5) Maternal mortality and reproductive health; (6) Ethics in doctor-patient relations; (7) Informed consent; (8) End-of-life ethical dilemmas; (9) Protection of personal data and biological samples; and (10) Equity and distributive justice, which translates into universal health coverage.

Promoting bioethical culture means, then, strengthening and opening the social fabric to bioethical wisdom, with the ultimate purpose of improving social conditions and general welfare from an ethical perspective, bearing in mind that this is a cross-disciplinary field that touches on all human activities, and considering knowledge as a common good.

From this perspective, our most important actions have involved first the operating development of Bioethics through strategies for applying regulatory principles and criteria in both the provision of health services

and in research. This strengthens the development and operability of the National Bioethics Infrastructure.

This infrastructure, in operative terms, is made up of State Bioethics Commissions, Hospital Bioethics Committees and Research Ethics Committees, which serve as bodies for vetting regulations and courses of action recommended by the National Bioethics Commission. To interact continuously with these bodies and other international groups, we hold virtual meetings using videoconferencing.

So far 29 State Bioethics Committees have been formally and legally established, out of a total of 32 we plan to renew, create and support. The remaining three are in the process of formalization.

The Hospital Bioethics Committees and Research Ethics Committees are located in the establishments that make up the National Health System.

Amendments to the General Health Law in December 2011 mandated the creation of Hospital Bioethics Committees and Research Ethics Committees in all public-sector, nonprofit or private medical and research facilities. Accordingly, the Secretary of Health –through the National Bioethics Commission– issued General Provisions for the Formation and Functioning of both types of Committee, which were published in 2012.

The Regulations of the General Health Law regarding medical research were modified in April 2014 and assigned the National Bioethics Commission responsibility for registering Research Ethics Committees.

So far some 346 Hospital Bioethics Committees have been registered, covering 412 hospitals, and 302 Research Ethics Committees operating in 574 hospitals and research centers. CONBIOÉTICA gives training courses and provides National Guides on the formation and functioning of both types of committee.

The Commission has also been involved in educational and social communication, and has published and digitalized various publications. It has a quarterly Gazette that offers a wide variety of information, both specialized and for the general public. It has created a virtual and physical library with a solid collection of information, and makes it

available for inquiry (training is provided on access and use) at no charge to anyone interested in the material.

A web page was created to disseminate the actions of CONBIOÉTICA, to promote the exchange of information and access to national and international networks for browsing in this field.

Another crucial aspect is academic development. In this area the Commission has taken part in various university courses, produced two series of videoconferences on many topics that have been transmitted online -with curricular value- and signed various collaboration agreements with the National Autonomous University of Mexico and the National Science and Technology Council, which have provide their full support for the development and practice of Bioethics in Mexico.

We have also developed joint activities with academies and professional groups like the National Medical Association, the National Surgical Association and the Mexican Supreme Court, to name just a few.

In 2012 CONBIOÉTICA celebrates its 20th year of existence, and a number of commemorative events were organized, which included, in addition to the above-mentioned signing of agreements, the issue of a commemorative postal stamp; the first Bioethics Book Fair; the issue of a commemorative lottery ticket in the National Lottery alluding to the 20th anniversary year.

In the same year the Commission opened its new offices, invigorating and improving the efficiency of CONBIOÉTICA's work, particularly the work of its Center for Bioethical Knowledge (CECOBE).

This is because we now have room for an extensive physical library as well as a state-of-the-art virtual library and facilities for televised bioethical actions and spaces that can be adapted as classrooms.

One essential commitment since the time of our founding has been to hold national and regional meetings for bringing together state and other committees and to deal with issues that are top institutional priorities in the field.

Another of our activities each year is the award of the Manuel Velasco Suárez International Prize for Excellence in Bioethics, honoring the founder of Mexico's Commission, who was born 100 years ago this

year. This prize was created to encourage research and discussion of the priority issues of Bioethics among young professionals.

Based on the efforts of the Mexican government, there is growing awareness of the importance of social welfare and creating a National Health System available to all without exclusion, discrimination or segregation of any kind.

Under the guidance of the Secretary of Health, Bioethics has been incorporated in the Sectorial Health Program as a policy for management and development. In this respect, CONBIOÉTICA has been its main supporter and proponent.

As in other nations, the development of Bioethics in Mexico has been the result of academic and political initiatives that seek to promote social awareness, tolerance toward minorities and respect for all forms of life –including all non-human life forms.

With these aims in mind, we have participated in outreach and other activities with institutions involved in the fields of health, education, research, science and technology, and coordinated actions with national and international organizations as well as private nonprofit groups, providing consulting and advisory services in areas of bioethics and life sciences that affect society.

The incorporation of bioethics into the National Development Plan and sectorial programs is a fundamental condition for the contemporary development of public health and social welfare policies to their fullest extent.

Aware that there is no one infallible guide for government action, CONBIOÉTICA has worked on building models to facilitate bioethical reflection in the public arena. These tools have been made available to policymakers through a training effort and through the work groups in which CONBIOÉTICA participates, both within the Secretary of Health and in other areas of government.

Great challenges lie ahead in formally and systematically incorporating bioethical analysis into the configuration of public policy, and developing inclusive schemes for making decisions that involve bioethical dilemmas. A very clear example of this is the study of illnesses and damage that

generate catastrophic expenses. In this specific area, CONBIOÉTICA is part of a work group analyzing priorities in health care in order to enrich the process of ethical evaluation.

Another element that has become increasingly important is the commitment to safeguarding human rights. In this regard, CONBIOÉTICA participates in reviewing international ethical guidelines such as the recently reformed Declaration of Helsinki. To assemble the observations this institution offered on the proposed reforms, we conducted a public consultation among interested parties in order to make this review a democratic exercise and incorporate the concerns of the research community in Mexico.

As a complement to the review of ethical guidelines, CONBIOÉTICA has taken on the task of identifying pending issues on the Mexican government agenda, from compliance with the obligations contained in current international and national legislation to the urgent need for a pronouncement on adherence to new instruments such as the Convention on Human Rights and Biomedicine promoted by the Council of Europe.

This, with the idea of expanding the field of protection in areas as significant as genome intervention, the protection of health care data or research involving human subjects, to point out just a few.

In this effort, CONBIOÉTICA's guidance has been crucial in clarifying the social and legal repercussions of incorporating bioethical considerations into new legal structures.

All of this while recognizing the necessary synergies between law and bioethics, and with the firm conviction that legal development does not render an issue impervious to ethical reflection.

For this reason, our institution is deeply committed to its role as an advisory body in issues that concern the development of public policies and legislation in the field of bioethics.

Other crucial responsibilities, in the opinion of CONBIOÉTICA, include evaluating the relevance of technological tools according to national priorities, ensuring that they can be accessible and distributed for the

benefit of all people, avoiding a thoughtless commercialization of science, strengthening national and international legislation, and developing a structure for international cooperation.

In this light, this Global Summit of Ethics/Bioethics Committees is a unique venue for exchanging information, sharing and generating reflections and converging viewpoints, with the presence of more than 50 countries and their committees, which have kindly and responsibly agreed to meet in Mexico City.

This is, therefore, a strategic platform for the global development of Bioethics; its institutional consolidation in Mexico and other countries; the promotion of projects and programs in the international context; and the promotion of a bioethics of shared minima, with a global vision.

Although we speak of a shared bioethics, of a global bioethics, of a gender-aware bioethics, I believe it is indispensable to speak, from a secular perspective, of a solidary bioethics, both from the individual and the collective standpoint, which renews its principals and deploys both its theoretic foundations and its practical application, with an inclusive and open vision in keeping with our time, while bearing in mind the future of generations to come.

Our sincere gratitude for your presence and for having given us the honor of hosting these two globally important events. •



PLENARY SESSIONS

Introduction to the 10th Global Summit: Outline and expectations

Manuel H Ruiz de Chávez

I would like to share with you now some of the basic characteristics of this Summit, the work dynamic we will follow and what we hope to obtain.

As agreed the last time this Summit was held, in Tunisia in 2012, the Permanent Secretariat of the Summit called National Ethics and Bioethics Committees of all member States of the World Health Organization to create a Steering Committee on an ex profeso basis for the meeting, made up of members of these Committees from six regions of the World Health Organization: Africa, the Americas, Southeast Asia, Europe, Eastern Mediterranean and Western Pacific; the Committee of the host country –in this case the National Bioethics Commission of Mexico– and the Committee of the immediately preceding host nation, in addition to a representative from the Permanent Secretariat of the United Nations Organization for Science, Education and Culture (UNESCO).

I wish to thank all the members of the Steering Committee: Nicole Beaudry from Canada; Ramesh Kant Adhikar from Nepal; Michel Daher from Lebanon; Hele Everaus from Estonia; Javier Luna Orosco from Bolivia; Ida Ryuichi from Japan; Mohamed Salah Ben Ammar from



Tunisia; Sambacor Sarr from Senegal; Hugh Whittall from the United Kingdom; Christiane Wopen from Germany; Nik Zeps from Australia; Mohammed Zuhair Al-Kawi from Saudi Arabia; Dafna Feinholz, who is Mexican and attending in representation of UNESCO; Abha Saxena from the World Health Organization and Julius Ecuru from Uganda, who unfortunately could not join us for today's session.

Together we have worked for several months on putting together the work agenda for the next two days. I'd also like to recognize all the members of the work groups who will be participating in today's and tomorrow's sessions. Also, Dr. Najeeb Al-Shorbaji, Director of the Knowledge, Ethics and Research Department of the World Health Organization, whose efforts and dedication have been fundamental to holding the meeting that brings us together today.

I should mention that the academic program of this Summit is the result of a series of meetings of the Steering Committee, during which a wide variety of themes of local and global transcendence were discussed and analyzed.

We also made use of a fundamental input: the results of a questionnaire sent to all the National Ethics Committees of WHO member States, inquiring about issues that should be examined and discussed on this occasion.

The primary focus in this Summit is to identify solid areas of work that reflect the multiplicity of circumstances and problems faced by national Ethics and Bioethics Committees in offering opinions and recommendations requested by the national governments and the civil society of their respective countries.

On this basis, it was determined that the Summit would revolve around four topics that, from different perspectives and in different environments, currently pose daunting challenges for the countries represented at this event, as regards ethics and health. These issues will be discussed in **four plenary sessions** to be held today and tomorrow.

The **first plenary session** will consider the role and functioning of National Committees, the main challenges they face and the scope of their profile with regard to civil society.

The discussions of this session will be based on the results of a specially designed survey. The session will be coordinated by Laura Palazzani from Italy and Miguel Montalvo from the Dominican Republic.

The **second plenary session** will address questions related to emerging technologies and health. Participants will analyze the ethical implication of the inclusion of these technologies into medical care, the importance of scientific evidence for justifying their use, and other primordial issues. The session will be coordinated by Patrick Gaudray from France.

The **third plenary session** of the meeting, to be held tomorrow, will be coordinated by Mohammed Salah Ben Ammar from Tunisia and Jaime Burrows from Chile. The session will analyze a crucial issue, which is today of particular interest to Mexico: universal health coverage.

Based on a report entitled “Making fair choices on the path to universal health coverage,” produced by the World Health Organization, participants will analyze the current and future performance of National Ethics and Bioethics Committees in the design and instrumentation by national governments of public policies for providing universal health care coverage to their people.

During the **fourth session**, a now-classic issue will be addressed, but one that remains highly important for the work of National Ethics and Bioethics Committees: Research ethics and vulnerable groups.

The session will address cases in which research is conducted on infant subjects, and reflect on the usual definitions of vulnerability and their ethical implications, as well as the existing mechanisms for protection of vulnerable groups. The session will be coordinated by Paul Ndeble of Zimbabwe and Leonardo de Castro from the Philippines.

These sessions were designed to seek a plurality of viewpoints and to productively deliberate on ideas from various perspectives. Accordingly, each session will be led by speakers from various countries and will have spaces dedicated to the exchange of opinions, to arrive at clear and enriching conclusions about what has been discussed.

To conclude today, we provided a space for parallel sessions in which the National Committees will meet according to the regions established

by the WHO. These spaces were planned for national delegates to come together at a level between local and global to discuss and identify problems common to their region, and lay the groundwork for possible regional cooperation projects to address them.

Similarly, together with tomorrow's plenary sessions, two special sessions will be held.

In the first of these, representatives from international organizations will discuss the most pressing current bioethical issues on the global front, presenting their respective work agendas and the way in which these organizations participate, primarily with the advice and technical support of National Ethics Commissions from around the world.

To conclude, and prior to the closing ceremonies, we will have a session for discussing and analyzing the future of the Summit and the appointment of the Steering Committee for the next biennial gathering; for outlining the topics and work groups that will be in charge of preparing the papers, and the agenda for the next Summit.

A no less important matter, and which highlights the diversity and plural focus that characterizes this Summit, is the four open "Market Place" sessions. During those sessions, which will run parallel to recesses in the proceedings, exhibitions will be offered in which representatives of various countries will briefly present issues relevant to their countries of origin, promoting dialogue and sharing information.

I would say we have a substantial and demanding agenda, one that will require a great effort on our part; but I trust it will enable us to meet the expectations we have set forth:

- To identify globally important ethical issues and review the evidence, the national debates that have emerged, and common approaches.
- To provide a forum for the National Committees to exchange points of view regarding their needs and shared challenges, and, thus, to create a space for learning.
- To promote opportunities for committees to share their approaches and analysis regarding key ethical aspects for

preparing and implementing public health policies, and research activities in their respective countries.

- To create spaces and opportunities to come together in regional forums to pursue the work of the Committees from a regional and continental perspective.

Before I conclude, I'd like to underscore the invaluable learning opportunity this meeting has provided, not just for the official delegates gathered here, but also for representatives of countries that still do not have National Committees in this area. I am sure that this meeting will contribute to the ongoing progress in the regional debates on bioethics and health; create a space for sharing experiences and activities carried out by the different National Ethics and Bioethics Committees; and help promote the creation of this type of committee in nations that still do not have them. In addition, special guests and national and international observers will find important resources in this summit that will surely be helpful in their daily work.

I'd like to conclude by wishing you all the best of success in your respective efforts. I hope this event meets the expectations of everyone attending, and that its conclusions provide a fundamental and positive social impact for national governments in their public policy decisions on well-being and health. •

Nicole Beaudry

Monsieur le Président Ruiz de Chávez, merci de nous recevoir dans votre beau pays. Bien entendu, un merci à nos collègues du Steering Committee qui nous ont appuyés dans la démarche et merci au secrétariat du Global Summit de nous avoir assistés aussi dans cette démarche. Merci, monsieur le Président, pour la traduction en français. Je crois que c'est important de maintenir cette langue pour les pays de l'Afrique Subsaharienne particulièrement.



Le Market place, comme nous l'avons fait en Tunisie se veut un espace de discussion conviviale entre les membres des pays qui participent à ce 10^{ième} Sommet Mondial des Comités Nationaux d'Éthique et Bioéthique. Le Market Place, comme le président vous l'a dit se tiendra à chaque période de pause, il y en aura quatre. Trois aujourd'hui et une demain. Il nous sera alors possible, en prenant un café de s'informer des travaux de nos collègues et d'en discuter informellement avec eux. Ces petits moments privilégiés nous permettent l'ouverture aux autres, l'ouverture aux membres. Ils enrichiront sans doute notre réflexion sur certains sujets extrêmement importants et nous donneront peut-être des idées que nous pourrions rapporter dans nos bagages respectifs. Je vous invite donc à être curieux de ce qui se fait ailleurs dans le monde et de ne pas hésiter de discuter avec vos collègues des meilleures façons de faire, de leurs travaux, alors des questions que vos collègues ont gracieusement offert de présenter. Alors j'espère que ça sera un moment agréable et que nous pourrons tirer des leçons, des bonnes pratiques de ce moment. Alors voilà, monsieur le président, l'organisation du Market Place. ●

SESSION 1: NATIONAL BIOETHICS COMMITTEES: PROFILE, ROLE AND FUNCTION

Presentation

The National Ethics Committees (NECs) are key elements to understand the development of the ethical reflection on public affairs particularly in health. Analysing and discussing how NECs work, their main challenges, strengths and achievements will help to portrait the state of the art of NECs around the world.

The core matter of discussion in this session was how to guarantee NECs independency and transparency during their deliberations and opinions. Additionally it provided the opportunity to identify the ideal profile of NECs and to further reflect about the critical roles of National Bioethical Committees in assuring the inclusion of the bioethical culture at all levels of society.

The agenda for the discussion:

- Existing ways of nominating National Bioethics Committees members;
 - Main academic background;
 - How often they meet and deliberate;
 - Process to choose opinion's subjects;
 - Average time spent to conclude an opinion;
 - How to deal with inside minorities;
 - What kind of problems they have/had with the political power;
 - How they interact with the media.
- 

Introduction

Laura Palazzani

Bioethics has become an institutional reality in almost every country in the world. The existence and increasingly intense activity of committees is a tangible proof of the expansion and vitality of bioethics.

We have different topics in all the bioethics committees. We've now classical topics of bioethics like the beginning and end of life; constantly appearing issues such as neurosciences, synthetic biology, enhancement, biometry and nanotechnologies. On the other hand, we have an increasing need of society to be informed about the new bioethics' topics. Society needs to be aware of the importance of civic participation in the bioethics' debate. Very few people consider that there must be a so-called «space-void» of law in bioethics. It is a belief that there must be ethical and juridical limits for the emerging biotechnologies. But the regulation is very difficult. We often see a delay of bio-law in a lot of countries, because of the difficult relationship between bioethics, bio-law and bio-politics, and sometimes the difficult relationship between legislation, jurisprudence and doctrine on a legal level. Many times, we find that a lot of countries have regulation on bioethics, but they need to reformulate bio-law because of the new scientific knowledge and the transformation of societies.

Our question in our session is: what is the role and function of ethical committees? We may say that it is a difficult task, a difficult and delicate role; that it is an intermediation between science and technology, on the one side, and society and governments, on the other. On a national level, the role and function of the bioethical committees is methodologically

speaking organized on three different levels. We have a level of a descriptive analysis on the scientific issues. This is a very important task for ethical committees. It is the task of interdisciplinary discussion and the specialist knowledge of the scientific problem. There is pluralism in science, because sometimes in the scientific issues the same phenomenon may be interpreted in many different ways. Then, we have a second important level: the level of dialogue, the dialectic place of discussion in our society, but it's characterized by pluralism and it is fragmented as regards values and principles. We may say that we need an epistemological willingness to discuss together. What is dialogue? Dialogue is an exchange of reasons, and we try in the ethical committees at the national level to justify our position, to let the others justify their opinions, and then to try to find the so called "ethical minimum". That is to find the sort of mediation; not the compromise, but the sharing of the different positions in ethics. Sometimes, it's not possible to reach shared minimal ethical recommendations, and so we find the so called «personal remark» or «dissenting opinion» of minorities. Anyway, the principle task of each ethical committee is to elaborate opinions.

What are opinions? Opinions are, in a certain way, the conceptual framework, the so-called, elaboration of scenarios, of different lines of actions for social policies to be undertaken at a public level. In these opinions we tried to find a balance between the need of science and technologies to progress and the protection of human beings. The NECS have an important task on an international level. We are dealing also with the problem of the role of international organizations in international contexts. In the international level, we need more information about the different committees, the different topics and the different opinions on the national committees; but above all, we need more discussion on international level. It's very easy to find the opinions of the other committees on the net, but it's not so easy to find places to discuss together on the same topics, not only on a continental level, but also on an intercontinental level. We know that bioethics is very different in all the cultures and there may have



analogies, differences, and we need a comparison of these ways of dealing with bioethics. We need coordination of the different committees on an international level.

Now, our session is going to be divided in four parts. The first point is a sort of overview of the questionnaires of the different ethical committees; then, we will deal with the question of independence of the national committees; the gaps between ethical deliberation and reality, and finally, the role of international organizations, in this international dialogue between all the national committees. •

Miguel Montalvo

Es para mí un gran honor estar en esta reunión en representación de mi país, y específicamente del Consejo Nacional de Bioética en Salud, que es el organismo que regula la bioética en nuestro país, el cual hemos logrado iniciar, estimular y desarrollar en los últimos 10 años.

Pienso que esta reunión es muy significativa, debido a que nos vamos a dar la oportunidad de compartir con el mundo bioético, y de alguna manera nuestros pequeños países, como el mío, se van a beneficiar de esto. De esta manera, vamos a lograr intercambios, apoyos y experiencias necesarios para llevar a cabo el desarrollo de la bioética, algo muy necesario en países en vías de desarrollo, debido a que sus instituciones aún son bastante débiles. Por tanto, la bioética tiene un amplio espacio para desarrollarse y cumplir con sus metas y logros.

En esta reunión me siento en la mejor disposición de aprender de todos ustedes y llevar a mi país la experiencia vivida acá. •

NECS questionnaire: overview and presentation

Dafna Feinholz

This session was aimed at having a more clear idea of how national committees are working around the world, how they are constituted. One of the main objectives and worries of the working group of Miguel Oliveira da Silva from Portugal, is that sometimes there are many questions really important regarding independence of committees. Why when they issue some recommendation or some advice, it is not translated into actions? That was the leading question in the session, but then we decided that it was better to go further, and try to find some other questions or issues that could be useful to answer those questions. That's why this questionnaire was elaborated. The idea was to try to see what the National Bioethics Committees are doing based on the idea that they try to work in a democratic way; this means they really want to take into account different points of views and perspectives of the different populations that live in each country, in such a way that it would be through the open deliberation, increase tolerance towards minorities, considering issues related to life, and discussing bioethical issues and related public policies, because they want to play an important role in this.

Since you have the questionnaire, I will only choose some of the results. The idea is to trigger the discussion among us. The number of National Ethics Committees or National Bioethics Committees was the first problem. Also how are we going to call them around the world? There is not a single ideal model, and there is not even one model: there are many ways of constituting the committees. This enormous variety



in the way these committees are constituted and how they function and operate was the reason why we also wanted to try to have a full panorama, or at least a closer one.

With help from the working group, the WHO and UNESCO, this questionnaire of thirty-five questions try to look for other issues that will allow us a closer vision of how these committees are constituted, but also help us to answer the questions about independence and why there is a gap between what they do and what happens. The questionnaire was constructed from the beginning in English, but then it was translated to French, Portuguese and Spanish, and it was sent online in all these languages, and then the responses were translated also in all the languages. We really tried to target as much as possible. I included a tool designed by UNESCO, and we kept it one month open, we sent some reminders to the committees so they could answer. We added contact persons, and not necessarily NECS, because not all of them were necessarily National Ethics Committees, but were related or relevant ministries or organisms in the country that could be relevant to answer the questions. Because I don't know if all of you answered the questionnaire, we added a question asking if there was not a national ethics committee in that country, if there were plans to establish one; and if there was not, there were also questions asking people, if there is no national ethics committee, how do they deal with national bioethical issues in that country. Those are the forty-two countries that responded, and we are missing some very structured and well-functioning committees that we know about, but they do not appear in the responses.

At the level of establishment, most of them are established by the state, because we asked if there was a state or there were other interdependent organisms that established them, most of them by decree or any other legislative action, and most of them are within any sub-ministries, basically Ministry of Health, Research, or Education. The appointments of the president and the members are mainly by government. There is a combination of nominated and appointed

members; and a combination between those who are official representatives and those who nominated them, or others who are in their personal capacities, regarding on who dominated them. Very few said that they only have people in their personal capacities.

About the composition. In the introduction they mentioned that bioethics is about multidisciplinary and different perspectives or issues. We asked about multidisciplinary, we wanted to know, not only if it happened, but if it was also contemplated in the statutes, and if they thought about it when a committee was established. 90% of our sample responded that they consider the multidisciplinary. The majority of the committees we have, had not a low number of doctors, lawyers, philosophers and social scientists. They also had at least 40% of community representation. I thought it was important to mention and address it in the presentation.

About gender and how the committees are built. 43% of those who responded include gender equality in their statistics, but in fact that's worse, because generally there is not equal number of men and women in any region. The size of the committees also varies. Most of them had between eleven and twenty members and are appointed for between two and five years, and their appointment is usually by the state. Regarding the scope and the mandate, here is one of the most heterogeneous findings that we have. There are some that have overlapping topics; some of them are dealing with only one specific domain. We have those who are doing life sciences and medicines, others literally answered all sciences and disciplines of human knowledge, or they are carrying out reviews of medical scientific research, some of them are really devoted only to research ethics, some others are only doing science and technology, and they review a wide range of topics; many of them are doing policies, or covering in this wide range of topics: environment, one of the important topics for some of them.

Regarding the advisory role that they play, we wanted to know who they advised, and to whom they give advice. Some of them said that



universities, researchers, other ministries and the public asked for their opinion or advice, and only half of the respondents said that they can choose their own topic. I think that's also an important issue.

Concerning the operation, most of the committees meet at least every two months. In the document you can see discrepancies, some of them on ad hoc basis; some others take a lot of time between the meetings (in general this is what prevails). The number of opinions also varies a lot, but it's more difficult to say how wide the variation is. Usually, they decide by consensus. Some of them said that it seems that most of the committees want to do it also by consensus. A few indicated that they also produce or publish when there is a majority or a minority or dissenting opinions within their own committees. It is important to say that as well as opinions, some of them produce guidelines, for either national research ethics committees, or clinical committees, or for any other public policies and they do some public outreach. Usually they are funded by the state or host ministry, and members are not compensated. If they are, it's more for the time they spend at meetings, and a few have some budget from the Secretariat.

We asked for the challenges, and it's interesting to see that the gap was not one of the main challenges they found. In fact, the responses to the gap were very unclear. It was interesting because many people understood why there was a difference between the opinion and the legislation. Some of them understood this as a potential conflict between the legislation and the opinion, and that was not the idea at all. Maybe the question was not set out right, and we didn't choose the right way to find out what was going on. But it was clear that one of the main challenges was the insufficient funding for administrative support, or to pay the members, something that normally has a negative effect on motivation. In fact, lack of motivation and lack of time were also main challenges, and some of the most common responses, which is quite revealing and interesting.

The difficulty to reach consensus was one of the challenges identified and it's important because it's the main key, it's the core of

our work. Some of them said they had difficulty on how to deal with all the different opinions and perspectives within the committee. They also identified a lack of public interest and discussion involvement in their societies. The lack of independence from a hostile official institution was there as well, but in a way they need the support of the body that established them. This is something that needs more research, to find more of these complex situations where you need the recognition and the support of a ministry and the financial support, but at the same time to be really independent.

The lack of scientific expertise was also mentioned as a challenge in all regions, and at the same time committees mentioned they need the advice of experts for specific topics. For example, in Europe, the lack of expertise was related to very advanced or specific topics. I believe that, as it said on the document, we cannot take this survey as a real description for the situation of what happens because the rate of responses was low. I think, in any case, it gives us good hints on what we can obtain in further research. I think it is important to refine the sample for the next time, because we need to try to define from whom we need information: those who are having a wide scope, those who are doing only science, those who are doing only a research ethics: which kind of committees.

It's important to say that in few countries there are more than one national bioethics committee, because each of them deals different topics. All of them are recognized as national. In some of them, there's a good coordination, and on all of them, the work covered the whole scope of bioethics. In some other countries, one of the challenges is they are establishing similar bodies that compete and overlap in a way, so it doesn't help to work better in these committees.

Now I want to talk about why we didn't have so many responses. I don't know if the committees are not working or it's just because many of us reject the idea of surveys, but in any case people are not responding so much. In the sample, we tried to analyze the reasons behind lack of independence, but we can also see how members are appointed, how they are chosen, what about the funding, how all these



could be related to independence, why the issue of gender merits further research, the efforts to interact with media, which are more effective. Although I think it also depends on the context because every country has a different situation.

For me, something very important is to develop a definition and a way to measure what's the impact of National Bioethics Committees. I also think it's important to know that there are other activities that committees do, which are related to the way they define the impact of a National Ethic's Committee. Providing guidelines or frameworks for policies, and the work they do with society in terms of education is also significant and can have an impact. But we need to try to define all those things and something more difficult: members' lack of motivation. Is it related to the fact that they don't feel independent or that they're in some way frustrated because nothing really happens? I just think that this is something we must try to find out. •

L'indépendance la CNE, indispensable dans une démocratie directe

François-Xavier Putallaz

Mesdames et messieurs, on m'a demandé de parler de l'indépendance de la Commission Nationale d'Éthique dans une démocratie directe. Parler d'indépendance c'est défendre une institution contre des pressions qui seraient exercées sur elle au point de menacer sa liberté. Or, dans nos démocraties post-modernes, les risques se sont fortement déplacés et je vais renverser complétement l'interrogation. En Suisse en tout cas, aucun régime politique, aucun intérêt pécuniaire ou financier ne pèse sur nos comités d'éthique et leur indépendance en aucun cas n'est menacée. C'est plutôt l'inverse, c'est paradoxalement l'usage de cette liberté qui peut présenter un risque majeur. Ce que je vais essayer de dire c'est qu'il y a un usage de la liberté qui peut se retourner contre l'indépendance. Or, la situation en Suisse est tout à fait privilégiée pour observer un tel changement de culture, je crois que c'est cela qui est en cause, je crois qu'il y a un changement de culture. A ma connaissance, la Suisse est le seul pays, en raison de sa démocratie directe, où le peuple lui-même (tous les citoyens et toutes les citoyennes) se prononce en dernière instance sur les questions bioéthiques. Je prends quatre exemples. Vous savez que le peuple suisse est appelé quatre à cinq fois par année aux urnes sur des questions législatives et cela simplement sur le plan fédéral mais il y a bien davantage de référendum si l'on considère ce qui se passe dans les cantons. La Suisse n'est pas un état centralisé, c'est une confédération de cantons, et chaque fois c'est le peuple qui a le dernier mot. Quatre exemples: en 1992, la



Constitution suisse a été changée et le peuple suisse s'est prononcé contre les abus en matière de technique de procréation. En 2004, la loi fédérale sur la recherche relative aux cellules souches embryonnaires a été l'objet d'un référendum et le peuple suisse s'est prononcé sur des questions techniques telles que celle-là, la loi a été acceptée à 66% de la population. En 2012, une loi cantonale, c'est le canton de Vaux s'est prononcée sur l'assistance au suicide. Vous savez que la Suisse est un pays spécial où l'euthanasie est interdite mais l'aide médicalisée au suicide autorisée en certaines conditions. Et bien, un canton vient de voter en 2012 sur l'assistance au suicide en milieu hospitalier et dans les homes pour personnes âgées et en 2015 peut-être 2016, la Constitution suisse devrait être changée. Il y aura une modification en vue de l'autorisation du diagnostic préimplantatoire. Ce sont simplement quatre exemples que je prends parmi nombreux autres. Dans ce contexte, le rôle de la Commission Nationale d'Éthique qui est composée de 15 membres, dont les sessions se font dans quatre langues, puisque nous parlons en allemand, en français, en italien et les recommandations sont dans ses trois langues plus l'anglais. Elle est aidée d'un secrétariat scientifique permanent de deux personnes, et bien cette commission national d'éthique fonctionne de manière totalement indépendante, elle n'a pas à faire de politique mais à élaborer des recommandations éthiques dont le gouvernement, le parlement, le peuple, mais aussi les medias, et aussi les associations professionnelles feront l'usage qu'ils jugent opportun. Cette délimitation rigoureuse des compétences et des fonctions est la condition du bon fonctionnement de la démocratie si celle-ci veut éviter de mettre en place une expertocratie. Nous sommes convaincus qu'il importe qu'il y ait des spécialistes mais que l'éthique ne doit en aucun cas doit être réservée à des éthiciens spécialistes. Alors je pourrais insister sur cette chance du système suisse, je pourrai signaler ses faiblesses, j'en mentionne deux au passage. Vous imaginez la lenteur du processus pour le diagnostic préimplantatoire c'est à peu près 10 ou 12 ans de travail législatif, il y a tout l'aspect du consensus puisque pour passer

devant le peuple et être accepté il faut que les lois soient suffisamment équilibrées et nuancées pour dégager les majorités, mais c'est quelque chose d'autre qui me tient à cœur, c'est l'observation de facteurs d'une inquiétante dérive émotionnelle, dérive qui est omniprésente surtout dans les medias et les medias façonnent, en grande partie, l'opinion populaire. C'est pourquoi nous assistons à un renversement du problème de la liberté et à un très rapide glissement. On assiste à un glissement d'une politique des Droits de l'Homme, à une inflation des revendications individuelles, de la dignité des personnes et le président Ruiz de Chávez l'a dit, c'est une dignité intrinsèque, inaliénable, à des critères d'une vie digne d'être vécue, ce qui est tout différent. Du respect de la vie aux requêtes de la qualité de vie. Autrement dit, les droits inaliénables, universels de toute personne humaine et qui servent de cadre naturel—objectif à tout processus démocratique— deviennent, en Suisse en particulier, l'objet d'une élaboration démocratique. Pour le dire en une question un peu provocatrice: est-il légitime de voter ou d'attendre une légitimité populaire à des techniques de sélection qui décident de qui mérite de vivre ou qui ne mérite pas de vivre? Et le problème se formule en une phrase: si les principes qui fondent la démocratie deviennent à leur tour objet d'une élaboration consensuelle n'est-ce pas l'ensemble du processus qui se fragilise? Je donnerai un exemple: en Suisse l'euthanasie est interdite mais l'aide médicalement assistée au suicide est dépénalisée, c'est-à-dire autorisée dans certaines conditions. Or, un citoyen sur 100, aujourd'hui en Suisse est membre d'une association d'aide au suicide. Un canton, le canton de Vaux vient de voter en 2012 pour que cette liberté devienne un droit et désormais dans cette région, l'assistance au suicide est garantie dans la loi, par la loi pour s'exercer dans les hôpitaux et pour s'exercer dans les homes des personnes âgées. L'engouement pour cette manière de décider de sa propre fin de vie est telle que la loi impose désormais, la possibilité de l'aide au suicide même aux homes pour personnes âgées qui refuseraient de l'accepter dans leurs murs. Et bien dans ce contexte, les commissions d'éthique doivent conserver leur indépendance et

vous voyez que le problème s'est déplacé, nous n'avons aucune pression politique, il n'y a pas un régime politique qui intervient mais une mentalité dominante et les commissions d'éthique doivent garder cette indépendance contre cet usage outrancier de certaines libertés qui deviennent des revendications non pas libres mais proprement libertaires. Et bien c'est dans ce contexte nouveau que se pose le problème de l'indépendance de la Commission Nationale d'Éthique. Je répète, elle n'a rien à craindre de la part d'une autorité politique ou d'un régime. Ce qui affecterait son fonctionnement c'est ce qu'on appelle aujourd'hui le relativisme ambiant qui à chaque instant, risque de transformer une juste indépendance en une tendance à cautionner toute revendication individualiste. Cette tendance est omniprésente dans notre société et je conclus en trois mots: le rôle indépendant d'une commission comme la nôtre tient à plusieurs objectifs. Le premier: identifier un noyau de valeur absolue, tel que la dignité humaine, qu'il s'agit de développer, qui sont des valeurs pré-démocratiques parce que seules elles rendent possible le débat d'opinion. Autrement dit, la question de la dignité humaine n'est pas un objet d'opinion. Deuxièmement: elle doit édicter des recommandations nuancées et qui soient rationnellement fondées et qui ne tombent pas dans le travers du relativisme culturel. Et troisièmement, et c'est peut-être le point important, inciter les professionnels, les proches des malades ou des patients à une pratique, l'éthique est essentiellement une discipline pratique qui fort heureusement s'avère dans la pratique dans les faits plus humanistes que les pseudos justifications théoriques d'une attitude individualiste à tendance libertaire. C'est dans ce sens, dans une démocratie directe comme celle de la Suisse, un des rôles de notre commission d'éthique qui consiste à utiliser son indépendance pour rappeler à temps et à contretemps que les revendications de l'individu souverain méritent d'être jaugés à l'aune de la dignité des personnes humaines. •

Gaps between ethical deliberation and reality

Kirana Bhatt

Greetings from Kenya. This is my first time in Mexico. I'm really grateful with the organizers for inviting our team. First, I'll do a little bit of introduction. Then, I will talk about the challenges and gaps in the different areas, like in the review process, monitoring, dissemination, results, communication, material transfer, agreement, and extension of studies. Finally I will give you my conclusion.

How does the Ethics Committee in Kenya function? We have the National Bioethics Committee, whose role is to overlook the functioning of all the ethics committees in the country. At the moment, we have twenty-one recognized ethics committees, and we will have many more as time goes by. The problem is that up to now, we only had four credible ethics committees and we needed a lot of work. However, we have many different committees, and the standard of review is very variable. We did not realize this when we were preparing the guidelines for accreditation. We put some regulations to the requirements, many committees did fulfill them. But they lacked the gap of experience. Even though they fulfilled the training in bioethics, it was not enough: they needed more experience. And Dafna, who helped us train a lot of people, also mentioned the need of experience, before someone is able to recognize these committees. Unfortunately we didn't listen to that carefully, and we made a big mistake. Now, we have time to seal that gap by making these individuals attend to bioethics committees that are recognized for long, so they gain experience.

What is the problem with the review process? All these committees, as it's required, must have the SOPs Guidelines, guidelines on how to communicate. At the national bioethics committee we have the SOPs for all of them, but we realized that in reality they don't function with the SOPs. There are great delays in communication, even though there are bystanders of reviews, because most of the people are volunteers and they're not motivated to work fast.

Another issue is the need of social science in research. For a long time, scientists didn't think there was a need to have an ethical approval to carry out research. Now, we have incorporated social sciences in almost every committee, and we are trying to sensitize scientists, but we still have a lot of work to avoid research without ethical approval.

We also have a problem with the traditional herbal medication and the traditional healers. They have a totally different concept. Whenever we ask them to design and follow a scientific study, they don't do it. For them, whatever works on ground is what we should allow them to research. This, of course, leads to a lot of conflicts between the traditional healers and us, the ethics committees, because they feel that we are trying to block their research. They don't realize the importance of science.

Another issue comes with clinical trials. A lot of people want to carry out clinical trials, but we have another step they have to follow: they must be approved by Pharmacy and Poisons Board to import the drugs, or allow any kind of clinical research. In this step there are lots of delays before we can give them ethical clearance for the final research project. We need to improve this so we can prevent some delays.

The other issue is the collaborative research. We have a lot of collaborative research done locally with foreign partners. Here the biggest issue is the role of local researchers. Most of the time, foreigners use a junior researcher in the country as a co-investigator, and this means a lot of training. We are trying to seal that gap by requiring equal participation for both partners. We are still working in this gap.

Other gap is shopping around for review. As I said, there are so many different ethics committees recently recognized, and some of them are weak, so people would shop from one ethics committee to another in order to get clearance on their proposals. Again, this would be minimized if we had a good networking so that we would have information and a good database on various research projects being carried out. There is a big gap in the data base.

The monitoring is a big issue in many countries, and we are included. We would like to rise monitoring of most of the research sites in our country, but there are various constraints: the biggest is the financial, and the staff requires a proper monitoring. Here we have problems with adherence of protocols and issues that happen in progress. They give us the proposals to review and we have established informed consent forms, but they don't work in reality. I can give you many examples of people that are recruited in the research project without any informed consent or others that only signed the form. This is a violation of human rights.

The other issue is confidentiality. In paper they say that we'll keep everything confidential, but we have had incidents where they were able to trace back the main mistakes in the research project to the individuals.

The voluntary participation. How voluntary is the voluntary participation of people from poor countries where a little bit of money is an incentive? For many of them even a gift would be an incentive. So, the voluntary aspect needs to be addressed with special attention. There's another issue with the samples, sometimes people intentionally draw extra blood to add it to their samples when they've been given consent to draw certain amount of sample. The reimbursement of participants, as I said, can be an inducement.

What are we able to do as National Bioethics Committee? One of the requirements is the compiling of the reports, submission of findings so that they can be translated into policies. However, in reality, this doesn't happen all the time. Many foreigners, after finishing their



results, leave without sharing their results, and publications that have happened elsewhere are in journals that we don't have access to, or the findings are not applicable in the country where they were done. The committee's participation is non-existent in many of the research proposals. However, we have some good research proposals where the committees are participating actively, but in the majority of cases community's participation is minimal. When it comes to the discussion of the research and the findings, the committee that participated has few benefits from the outcome of the studies.

We also have the issue of the publications. The local participants are often ignored in the publications, they are not even acknowledged in their community. It looks like people are working for the selfish motive of just getting data. Multilateral transfer agreement and custody of samples is another big issue, we are in process of finalizing the guidelines for that in order to have a tighter control about that in due course. Dealing with the specimen is another area where there is a lot of gap.

Finally, the extension of studies. We have had proposals where several studies are being carried out under one approval. Here there's also a big issue about consenting, when they do the new studies under one approval, there is no new consenting for the new studies, and that is a big gap which we are trying to seal.

In conclusion, there's a need for a local and regional networking to enable us to reduce some of this shopping around for ethical approval, also black-listing of certain researchers who were notorious for shopping from one country to another, as far as we are concerned. There is a need for a more comprehensive database. We have a database, but it's still not adequate. First, we need a very good local data base, and then we need a regional database. There's a need for more training. Monitoring is highly desired, and for it we need more funding and efficient functioning of the people on the committee. Many committees are working without any kind of sitting allowance, and I think we need some kind of incentive for the people on the ethics committees to be able to function more adequately. •

Meral Özgüç

It was very difficult to understand what we mean by gaps, but, rather than giving evidence-based answers, I will try to give a summary of the potential for gaps we had in mind, and how the ethical committees will be able to deal with them. First of all, in Turkey we had to deal with definitions, even the most basic ones like health-care ethics. When we came to bioethics, we had to discuss what are we really going to talk about, and when we could come to a wider definition that include reflections about processes and results of life sciences and research, then the stakeholders become very heterogeneous, and once this happens the potential for gaps really increases. There are many emerging technologies as we all know: genomics, personalized medicines, cloning, therapies, genetic engineering, nano-technologies. How are we going to handle all this without really creating gaps? We do need harmonization. Of course, health-care delivery is the issue with the Ministry of Health, they are the legislative and executive bodies, they give us the laws, regulations, and guidelines. When we go to the research part, we have our funding agencies and our research ethics committees. Each of them is trying to do their best, but there is not much harmony between what's going on in research and how it should be reflected on the health care delivery. There's sort of a gap in our dialogues so we need to find a solution for this. We also have a Ministry of Health and there are many regulatory activities.

In our country we have a really big gap between what the industries are producing, how the technology is running, and how the end users are grappling with this, because innovation and technologies develop very quickly. Once they are in place, there is not enough time to reflect bioethical challenges. And people like myself, on the laboratories, want to apply these technologies: we want to use them for the benefit of patients, even if the end users and the technologies have a gap in itself, but if you think about bioethical reflection, the gap increases. We have a huge challenge. This is one place where the National Ethics Committees have a lot to say to bring the reflections on the ground. For example,

we are dealing with genetic diseases and all genome sequencing is the buzzword. Now, everybody wants to use it, and also we started using it for new-born screening. When you have technologies like these, if you don't own them, there's a problem of exchange of material: sending material, transporting and receiving results.

We also have a big gap in our public awareness and public policy. I think this is one area where national committees should be very active, and this is where we might need a lot of collaboration. In Turkey, there is not much public awareness when we talk about bioethics, neither the issues about emerging technologies. We need to raise the public awareness to have more public reflection. Without public reflection, we can't really drive at public policies. We keep thinking, who are the actors that should fill the gap in the information floor? How can we make this awareness in the public? Media could be one, but they need to be educated; they should have literacy in bioethics. When you say ethics, they take it as a philosophical issue, but when you say bioethics, like I said, definitions get mixed up. So that is one area where we try to work with the media so that their awareness and education increase. And there are, of course, NGOs and academia. The question is, how can NECS work together with this different stakeholders, create an environment of harmonization and public policies, so that the public and individuals can decide for themselves about public health and health-care issues in an ethical way. When we try to work through the labs, we try to see what the gaps are. Once we learn the vocabulary, we start thinking of bioethical principles that need to be re-established, because things are changing a lot with technologies. We, for example, have a bio-bank and we've been discussing about consent. We've learned that there is one way, or two ways, or three ways of getting consent, but what type of consent do we really need? How informed are the consents for future unspecified untargeted research? We really don't know how to deal with this. Shall we just accept broad consent?

Then, the confidentiality and privacy. We learn that there is privacy in the classical form: confidentiality of patients. Then we have this big

data coming out from our results; without breaching privacy, how should we use the IT technologies? For countries like us, like I said, where many of our samples are going cross-borders to have either diagnostics or research results, how are we going to keep the confidentiality and the privacy? We don't really know and we don't have the right answer. We do research with the whole genome sequencing. Everybody knows that there are incidental findings coming out of that research. We are not well educated, neither on the clinical side, we don't know the clinical utility yet, but how are we going to give this data out? We always say people should access to their own data, we should have open access to knowledge. But, are we doing harm by giving all these incidental findings? That's one issue we should be really discussing.

Autonomy is a classical word in ethics, bioethics, but especially in countries where public awareness is in place, how are we going to describe autonomy? How autonomous are they when we ask them to become a part of research, even if it is for genetic testing, for example. We just finished our white papers for genetic testing, using targeted testing for genes. Now, we are faced with moving emerging technologies for genome. There are actual gaps between what we are really doing in the research, what are we trying to do in the research and how the people will absorb this.

How is autonomy in place when we talk about stem cells therapies or trials, when people are not really aware of what is happening? We do have a local landscape in Turkey, we have clinical ethics committees, local ethics committees, we have a bioethics committee in UNESCO; there's an association for bioethics and a research center for bioethics. I think our major issue is getting together, discussing these gaps nationally, and we are looking forward to regional and international collaborations. We need best practices; we need to learn from best practices. These are Turkey specific problems, but most of these are generic problems, everybody face them nowadays.



Closing, I would like to say that we are looking forward to regional collaborations; we like to collaborate on issues, dimensions of new educational approaches to bioethics and life sciences, changes in curricular programs of medical and life sciences schools. •

The role of international organizations

Olla Shideed

I'd like to give you a perspective from our region, from the Eastern Mediterranean region. Some of the challenges that National Ethics Committees face in the region, because to understand our role as an international organization we need to know the challenges that our member states are facing; some of these challenges are the political priority. Often, NECs are not on the top of the political agenda, so, how do we raise this? The issue of financial sustainability for National Ethics Committees, the issue of membership criteria —how do you choose members and how do you ensure their commitment given that there are often no incentives for them?

The capacities of members of NECs. This also relates to bioethics and ethics training at various levels during undergraduate, graduate and continuous education as well.

We have an issue that I'm sure other regions share as well: cultural issues that are knitted with ethical issues. How do we clear the confusion that sometimes occurs? Opportunities for networking and regional cooperation and coordination, I think this came up repeatedly in the previous sessions. Last but not least, global issues. When we have a global issue, is the solution local or is it global? How do we reach that balance? In response to this, what does WHO do? What can WHO offer to member states? What is WHO doing at large? WHO plays a convening role in terms of bringing together ministries of health and NECs, because the NECs are placed in different places in the countries. Our role is to bring them together, to have that coordination between them. Again, to play a convening role in promoting the networking and cooperation

among National Ethics Committees, fostering regional networks, fostering global networks and platforms for National Ethics Committees. The Global Summit is an example where WHO serves as a Secretariat and brings together, every two years, interested National Ethics Committees' members.

As well, WHO plays a major role in capacity building of existing National Ethics Committees, such as provision of online courses, making documents available in various languages of the six regions, trainings and other issues as well. WHO uses its forums to raise awareness regarding important ethical-related issues and how NECS can contribute to solve these problems. As well, WHO plays a major role in developing normative ethical guidance to countries, and you can find outside some of the documents which are products of WHO.

What have we done as a region? This is the global perspective for a region. We have had two successful regional meetings of National Ethics Committees: one in 2007 and one in 2009. The first one, in 2007 was a joint meeting between UNESCO and WHO to support National Ethics Committees in the Eastern Mediterranean region. This was a successful example of how when UNESCO and WHO come together, they can both collaboratively serve the NECS. There are plans for a third meeting. Why do we think that these meetings are important? Because they provide opportunities for NECS to share their experiences about their establishment, how they maintain them, the challenges they face and how they approach to them, and achievements and best practices. It is also an opportunity for these NECS to consult the international organizations on relevant issues, emerging challenges and how they would advise them to approach. These meetings also advocate for establishment of National Ethics Committees in countries where they do not exist, and strengthening the ones that do exist in member states. It also serves as a platform for coordination of the work of NECS at regional level.

To conclude, international organizations, whether it's UNESCO or WHO, their support to National Ethics Committees starts at a national

level. This will ensure sustainability and continuity that will reflect positively in a regional level and subsequently in a global level as well. •

Dafna Feinholz

The idea is to present what the UNESCO is doing and to find ways of collaborating better to support your work. The idea is to know what the WHO does, and then how can we both work to benefit you together.

I want to talk to you about some of the things that we are currently doing and planning. We have project ABC to help establish National Bioethics Committees, so we support countries before they establish the committee, and give help at the national level in the same way WHO does. First, we work with all the relevant stakeholders, not only to establish the committee, but after the committee is established, we have a particular, formal and very concrete program of three years of training for the committees. The idea is to establish member states, not only the committees. Once they are established, we continue working with them to strength their work. We continue supporting them and advising them on specific topics, as well as to outline public policies and even to prepare some of the advice and opinions. We use the expert because, first of all, we have the International Bioethics Committee, and we also have regional networks of experts, for example, here in Latin America we have a very strong one: *Red Bioética*, a multidisciplinary group of expertise that we put in use of the committees. We also foster the communication between committees, particularly when there are specific topics. We also support the national committees to communicate with relevant governmental authorities at the national level to support the independence of the committees. We even have specific partnership agreements between National Bioethics Committees, particularly those who are newly established and those who are working properly.

Based on what was expressed in the questionnaires, for example, they asked if somebody would help other committees' establishment and their cooperation with other committees. This is already part of what we envisage in our program. In the questionnaire, there was also a plea for promoting education in bioethics at university level, and that's one of UNESCO's activities.

Production of educational material is something we also have, co-curriculum case books, IBC reports, and there are many publications in Latin America and Asia. It's interesting that we keep asking for more forums at regional and international level, in Europe we have, at least two meetings, and we have this global summit, so it also speaks about the need to have more communication among us. Everything is available free online.

Here, in Latin America we have a network for National Bioethics Committees, so there are a lot of publications. There is a specific journal running since ten years. We are particularly working on a project with Salvador, Jamaica, Ecuador, Brazil, Paraguay, Colombia, Chile, Argentina, Uruguay, Trinidad and Tobago, Peru, and Dominican Republic. The International Bioethics Committee and the Intergovernmental Bioethics Committee have been producing normative instruments as well as the three universal declarations that you know. Also, the IBC produces reports that are used by policy makers, researchers, etcetera.

Now we are also in UNESCO, the section is also in charge of the Secretariat of the World Commission of Ethics of Science and Technology. We are envisaging meetings of the three committees, IBC, IGBC and Commerce together, and the idea is to try to build additional models during these meetings, to bring the National Bioethics Committees to these discussions. Also we would like to bring the universities and chairs, and we are working in establishing one network of young bioethicists, in the long run. In the middle-long run, we want to have a big international forum of bioethics, ethics of science and technology, but the first step will be to include in the sessions of the three committees all the National Bioethics Committees. Since the

intergovernmental committee will be there, the information of the national committees can come to the governing bodies of UNESCO: the Ministers of Education and Ethics, Science and Technology. This forum, we hope, will bring the bioethics leaders. The idea is that the national committees are feeding the international dialogue at the same time that international norms and context are influencing the national debate. Maybe it can also bolster the authority and the effectiveness of the committees at the national level if they are known for participating at an international level, and they can influence the standards, the production and bring the transnational bioethical issues, also at the government level, with the intergovernmental committee. •



SESSION 2: EMERGING HEALTH TECHNOLOGIES

Presentation

Advances in new health technologies fascinate everyone, especially when outcomes are spectacular. The media are quick, sometimes too much so, to embrace medical advances, and, increasingly, patients and their family demand them. However, what the public does not see is the difficult trek from innovation to full scientific validation and acceptance. Social justification and cost determination of new technology are necessary before they can be fully implemented. But this is complicated by many factors: a) health ministry technocrats and politicians who are often not interested in new technology; b) economists who have to measure the productivity gain resulting from technology; and c) industry which has a profit-driven agenda.

Many principles are called on in discussion of ethics in healthcare, but for the purposes of the discussion of new health technologies, there are three central ethical aspects of modern practice that are particularly relevant: a) Competence, where clinical practice is based on specific technical training and competency; b) Respect for patients' health care decisions referred to as "informed consent" and; c) Maintaining the primacy of patients' needs, keeping market-driven considerations out of what should be a medically ethical decision-making process.

Questions raised in discussion of the development of new health technologies should include the following:



- Has the new technology been adequately tested for safety and efficacy?
- Is the technology at least as safe and effective as existing, proven techniques?
- Is the individual proposing to perform the new procedure fully qualified to do so?
- Is the new technology cost-effective?

Additionally, the development of new medical technologies, specific ethical concerns must also be addressed. Ethical principles often seem simple to enunciate with regards to application in medical care. Industrialized nations in general have shared the idealistic goals of continual medical progress, and that no citizen should be denied quality health care because of their inability to pay. However, the economic drivers of new technologies can often be in tension with these ethical principles, and in most developing and less developed countries, medical technology is often inaccessible to those who need it most.

So whilst technology has undoubtedly improved the quality of research and patient care, scientific and technological developments in medicine and surgery have also created unprecedented ethical dilemmas for physicians, as well as for health economists, hospital administrators, policy developers, and judges.

In this session, was looked at how ethical considerations in health technology are likely to remain an important component of medical education, clinical practice, and the political evolution of our health systems.

Introduction

Patrick Gaudray:

I want to point out that I'm not very happy with health technologies as they are set up right now in our world. I will start by quoting a few important authors.

The first one is from Francis Bacon, because he was really the founder of what I call techno-science. Of course, techno-medicine is part of techno-science. He said that, "the end of our foundation is the knowledge of causes and secret motions of things; and the enlarging of the bones of human empire to the effecting of all things possible". Somewhere else, he promises that techniques will give us an almost eternal youth, healing demon curable diseases, improving brain capacity, the production of new species and the production of noble foods, so everything will come from technology, and everything for the best of humanity. I'm always puzzled by this because, a few centuries after what he said, I'm not sure that we have progressed for the best of humanity.

Another French author, Antoine de Saint-Exupéry, said this about airplanes, but it can be used for bio-engineering, bio-technology: «*Nous sommes tous de jeunes barbares que nos jouets neufs émerveillent encore*» / «We are all young barbarians that our new toys still amaze». This should make us think a little bit about those toys, and what we can do with them.

There is one quote from a Canadian sociologist, Michel Freitag (2001):

«*En face de la guerre des étoiles il y a la faim, le manque d'eau, l'errance. Face à la révolution informatique, il y a l'éducation gâchée,*



l'analphabétisme. Face à la "création" de nouvelles espèces biologiques, il y a la menace qui pèse sur celle qui existe déjà dans leur propre "savoir-vivre", leur propre genre. Face à l'affirmation du « tout est possible », il y a l'évidence sensible, morale, esthétique que tout ce qui compte existe déjà sauf la justice entre les hommes.» / «In front of star wars, there is hunger, shortage, homelessness. In front of the informatics revolution, as they call it, there is wasted education, analphabetism. In front of the creation of novel biological species, there is the threat that faces all those which already exist in their own savoir-vivre and their own kind. In front of the assertion that "anything is possible", there is a sensible, moral, aesthetic obviousness, that all that matters already exists, except justice among humans. »

Pat Mooney, an English-speaking Canadian activist against GMOs, said during a meeting organized by the Deutscher Ethikrat on Synthetics Biology that "ethicists are about a nanosecond in the history of any new technology in which they might be heard. •

Ethics of new and emerging health technology

Michel Daher

It's my pleasure to give an overview about the ethics of new and emerging health technology.

Lebanon is a small country on the Eastern side of the Mediterranean Sea and the confluent of three continents:

Europe, Africa and Asia. That is why it's a very important country, where cultural diversity and population are very significant for bioethical and ethical debates.

I would like to congratulate CONBIOÉTICA for organizing this summit to promote bioethics, to bring people all over the world and putting a very interesting program, and my thanks go to the scientific and organizing committee, and specially Dr. Manuel H Ruiz de Chávez, for his kind hospitality. I would like to start with this citation of Henry Ford who said that "Coming together is a beginning; keeping together is a progress, and working together is a success." I think that being here is a successful initiative from Mexico, the WHO and UNESCO, and we hope that we will stay together.

Health technology, as a definition, is an applied science that includes all matters used by health professionals to promote, prevent, treat, and improve people's health. We have three kinds of technology: (1) the existing technology that we are familiar with and we always ask



ourselves, do we have to keep it or move to another technology? (2) We have the new technology and we are asking ourselves, is it an improvement in our daily practice? How can we assess this new technology? (3) We also have the evolving technology and we ask everyday: is it important to apply this evolving technology when we have so many ethical and economic problems?

Health technology needs to be evaluated and assessed. The evaluation is to see if it is doing what it's supposed to. Every new technology must be submitted to a strict evaluation. The assessment is a step further to consider if it is worth doing it, the outcome for our patients and the value of this technology. Every evaluation and assessment must be submitted to the major principles that we all know: beneficence, not maleficence, respect of patients and justice. We have to put in all our implementation of technology. We have to search for the welfare and the rights of our patients.

Technology must be submitted to a personal commitment from everyone who is applying and using it. Competency is very important to give the treatment in the best way and in a competent manner. Physicians have the responsibility to ensure that people are using technology in a good way and with an appropriate technical performance. The constant medical education is very important to continue the improvement, our implementation and assessment of new technology. In every institution, hospital or diagnosis area, we should ask for individuals' credentials when they're using technology. We must define the educational programme in which new professionals and health professionals will be educated to learn about this technology and acquire experience using it. We have to maintain our performance and skill through constant education, and remember the concept of "learning curve" before we start using this new technology.

We have four statements for the use of new technologies. First, the new technology must be tested for safety and efficacy. This is done by a controlled clinical trial: observations, complications or health hazard must be reported in a publication, peer review, scientific literature, and

this research must be reusable by other people, to see if it can be reported by others and published in other journals. Secondly, we have to ask: is the technology at least as safe and effective as existing proving techniques? Because, why moving to a new technique if we have a full satisfaction with the current technology? We have to see the safety, efficacy and need for this new technology, and compare the results with the previous procedures and therapies. Three, is the individual proposed to perform the procedure fully qualified? Here is very important to have committed people applying the technology, and we have to look over the credentials of individuals for this new technology. Last, but not least, we ask if the new technology is cost-effective. Here, many factors must be considered. We have to compare it with the current technology and see if we have a cost benefit by reporting the interest of this technology and the hazards that can happen while using it.

“Ethnomics” is a new term that we are using more and more, because we are talking about high technology, new technology, and some people don’t have access to it, or if they do there’s not enough people to use it. Health professionals have the role to make it more affordable and equitable. In every country, even developed ones, some people might not have health insurance, like people living in poverty: they cannot use the technology as others. This creates some tension between equity and choice, but should we stop using this technology? Or should we use it for some people and not for others? We also have to consider the resources and demand in a country with limited resources: how can we afford to use high and emerging technology, when we cannot afford basic health care? We have to be prepared because in the future we will have more and more problems with clinical ethics and these new specialties are moving on —organ and tissue transplantation, genetic engineering, reproductive biology, cloning, gene therapy, nanotechnology, etcetera.

Where are we going? We are going to a more complicated situation and an emerging technology. Many of our colleagues will talk about some of these examples: telemedicine that will be reported by Najeeb

Mohamed Al Shorbaji and Nicole Beaudry; Neuroethics by Hugh Whittall; renal transplantation, synthetic biology, bio-banking and stem cells by Ryuichi Ida. As a conclusion, we can say new health technology and humanity can coexist. If there is a good collaboration between policy makers, economists, managers, health-care workers, all will lead to some kind of progress. Planning services must recognize that service proliferation cannot go forever. We have to put the priorities in our research to see to where we can develop these emerging technologies. Science unfortunately always moves faster than our ability to understand it, or when we conclude for bioethics guidelines.

This made me remember a story by Jean de La Fontaine in *Les Fables de La Fontaine*. The race between the hare and the turtle, « Le lièvre et la tortue ». À la fin de cette histoire la tortue est arrivée avant le lièvre et la moralité c'est qu'avec une endurance et une continuité on peut arriver à suivre et à devancer les résultats néfastes de la science.

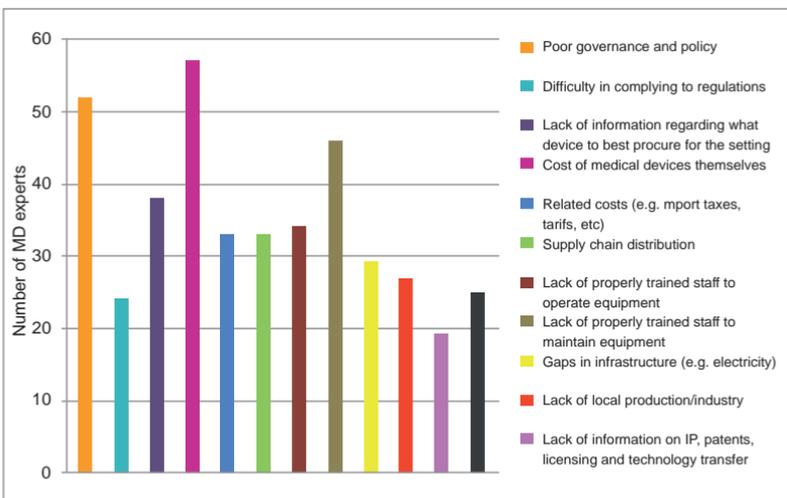
We don't want to go beyond sciences, we want to go in the same direction, and make the race together with sciences for the good of medicine and all mankind. I want to finish with this citation of Albert Einstein: "I fear the day when technology will surpass our human interaction. The world will have a generation of idiots". When we look at the picture all around, we see that technology sometimes is taking us to a world we do not want. ●

Assessment of new health technologies

Mohamed Salah Ben Ammar

As you know, health is global. The social determinants of health are the governors, there are human resources, finances, but technology is very important too. WHO is working on this field since many years ago and all these publications are on medical devices. But, are we really acting in this? The challenge of the health system is to offer health technology, because it must have good results. Are the funds we have enough? Are we using health technology in the right way?

Main barriers to access to medical devices in low-resource settings



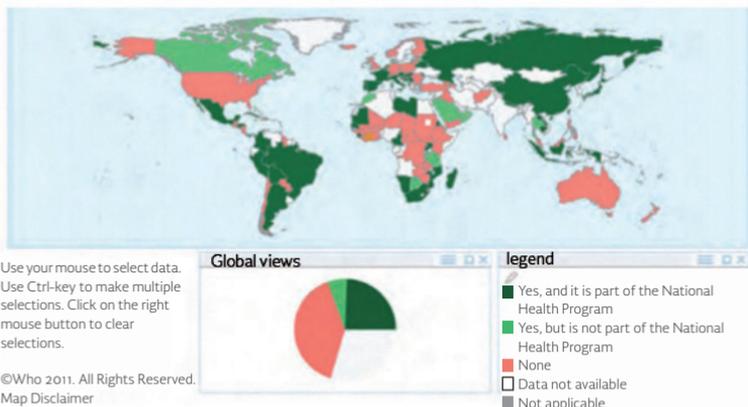
Michel Daher said something very important: health technology ethical principles should be beneficence, responsibility, intellectual freedom, democratic deliberations and justice.

In this slide, I would like to show you that the cost is the barrier to access medical devices in low resources settings. The second barrier are the poor governors and policy; the third, lack of properly trained staff to maintain equipment. When we visit hospitals, especially in poor countries, this lack of trained staff to maintain the equipment is very important.

Imagine banking ATM transactions slowed by misplaced regards; retail stores with no price on the products; auto manufacturing with no guarantees. In the medical field some doctors, especially in our countries, are working like that: they decide by themselves, they choose and they use, and it's not a very good system.

The fields of technology have been set delimiting health care robotics, robotics surgery, nano-surgery, and it's very hard to choose medical devices because they are extremely different. For example, if you study in France, you would choose French material; if you study in Germany it will be easier to get German material. Everything can

Figure 12. Distribution of countries with a national health technology policy



change with the context, and medical devices are not the exception. They can vary from one millimetre to one meter, from one gram to one ton, you have thousands of products.

The definition of health technology assessment is the systematic evolution of properties, effects and impacts of health care technology; it should include medical, social, ethical and economic dimensions, and its main purpose is to inform decision making in health, coverage decision, incorporation at hospital, pricing decisions and clinical guidelines. Health technology assessment contributes to more efficient resource allocation and sustainability of the health system.

This is the health expenditure around the world in 2006. Africa and some countries in Asia have less than \$25 dollars per inhabitant. If you look at the maternal mortality, you can see that the health expenditure and maternal mortality are similar. Poor people have much more maternal mortality.

This slide shows you that poor countries that do not have health technology assessment don't have health technology policy either. As we can see, the poor don't evaluate their technology; don't evaluate what they introduce in their health care system. Over 50% of the increase of allowed expenditure of Minister of Health in my region is consumed on health technology. Yet, a high percentage of the population lacks regular access to quality, essential medicines and other products. The message is over 90% of medical products are imported, and much investment made in procurement are wasted on inappropriate medical products. This is a conclusion of a WHO report.

We are spending money in developing countries, in health technology without assessment, without rational use or rational choice. In other words, the poorer you are, the more you use bad health technology. My conclusion is you need health technology assessment. Without context you will use technology poorly. Without context, health technology assessment is not an answer. This is the health technology level of question and evidence and Michel Daher said it: safety and efficacy, safe effectiveness, should we do it here? This is a good question and



also how should we do it here? This is an implementation question. How to develop health technology assessment? Appropriate level of decision making, to be informed by health technology assessment, strong support by senior decision makers, well-trained human resources with high analytic capacity, institutional arrangement for guaranteeing scientific independency, and include process, context and formation from stakeholders. This is very important for having technology adapted to our context: context and format evidence based on health technology assessment, closely linked to governmental structure.

This is a global summary to reach what we want to reach, rational use, access, acceptability, safe use, affordability and availability. All of this is possible because if we use health technology assessment, the less resources, the most important assessment is to do the best allocation of resource where most needed. This is a resolution of WHO Assembly in 2007, asking countries to have health technology assessment. •

Ethical issues in information and communication technology for health

Najeeb Mohamed Al Shorbaji

I will be focusing on one type of technology which is called information and communication technology. Recently I took over the department related to health, ethics and knowledge. My department used to be called Knowledge, Management and Sharing. Then, having the ethics group and the team, this added a lot of value to what I do and what I have. In my department, I have two units. One of them is about e-health, which is the use of information, communication, technology and health, ICT, and the other one is the global ethics. For me it's a little bit of a struggle to compromise, consolidate and bring things together in a meaningful way. Having a presentation on this particular topic is really timely and essential, so that people around the table be aware of the issues around the use of information, communication and technology for health.

Just to emphasize one fact about the WHO core functions, we have one core function in the organization: articulating ethical and evidence-based policy options. This is where the ethics part comes in the organization. All we do in the organization is one of the six core functions. Convening this summit and being the Secretariat, working with UNESCO is a translation of this particular one. That goes hand in hand with what the UNESCO info ethics program is trying to do in terms of identification of major ethical issues in production, actions, access, dissemination, prevention and use of information in the electronic environment, which is the use of ICT.



My basic thesis is the premise of knowledge for health. When we talk about technology we talk about how technology is being used to support health programs and improving health outcomes in populations. The advances in knowledge and technology have contributed substantially to improvements in health, but these gains have not been distributed or shared equally. This is the equity issue with disparities in life expectancy and burden of disease, especially between low and middle-income countries and high-income countries. That really enforces the message that has been set by his Excellency Dr. Salah and other speakers in terms of inequity to access to knowledge and technology.

ICT is about managing data and information. It's a specific type of technology. It's a specific type of application that focuses only on the use of the information which is the mainly component of it. The name ICT means information, communication and technology. Information is the currency, the raw material; it's not the infrastructure, but the content. ICT assists and extends the ability of mankind to capture, store, process, understand, use, create and disseminate the information at a speed and scale which had never been thought possible before. This is the challenge: the amount of information we have, the actual speed we have, the different formats where it is available and the inability of people to absorb amounts of information available.

There are ethical issues that we have been able to identify in terms of the use, availability and utilization of technology. One of them is the lack of access to ICT resources by individual communities and countries, because of cost, politics and expertise. The widening of digital and also knowledge divide, this means that many things are in digital format and this has led to deprivation to access to some of these materials. We see this in many countries, in the African and Asian regions, where electronic information and websites are available, but the infrastructure is not there. What we are trying to push is to make sure that printed materials and other types of local technologies are also available. Because it can cause: depriving people of access to electronic information resources such as electronic journals, e-books and e-learning materials which are

loaded on high internet connections and remote servers because of unaffordability, usability and linguistic and cultural limitations. And a lot of what is published on the Internet in electronic format is not being used or is not useful for people in remote areas.

The quality of health information on networks and corporate digital resources has imposed ethical constraints, as lack of accountability has resulted in lack of information on the Internet, spread of fraud, pornography, and sales of illicit drugs and counterfeit medicines. That's why we have initiatives like Health On the Net (HON), a global initiative, the NHS choices in the UK to make sure that websites and information resources on the Internet have quality. This is a big challenge when it comes to forming the opinion of the public and influencing decision making in countries.

Privacy and confidentiality are among the big issues. Any unauthorized access to personal health data stored in local databases or in the cyberspace, and this is just one cartoon on how the Internet is actually monitored by certain countries, certain individuals, by certain authorities to make sure that whatever is communicated on the Internet is monitored and recorded, maybe to be used against individuals at some point. There's use of personal health data without consent, including its collection and storage, we can see that in a number of occasions when people actually volunteer data on the Internet, or in electronic health record, and no consent has been secured, so the data is being used by people in different formats. Of course, trying to breach the privacy is not a new thing, but the way it has been developed and monitored in the XXI century, our places, our home, offices, any outlet, any access, is very frightening.

There are also responsibilities for medical errors resulting from the provision of health services at distance such as telemedicine, telehealth and mobile phone. When telemedicine started, it started as point to point, which was a little bit more secure. On the other side, we can see Internet and the cloud as a way of connecting so many different points together, but it also has made the networks much more vulnerable, in terms of privacy and confidentiality.



The concept that has been mentioned at least twice during this morning is big data, its big promises and big problems. What is big data in relation to traditional and institutional data? It is the size and multiple sources (personal, institutional, environmental, geographic and financial). It is unstructured and it has numbers, texts and images, multiple locations and multiple ownerships. In terms of health, health has always been that intensive, ethics-dependent, multi-disciplinary and collaborative, which means, health actually depends on data for its growth, decision making and planning, and all what we do in health is actually based on data. The utilization of big data allows discovering new relations, information and knowledge among different data elements, which is one of the promises provided by big data. Knowledge discovery, therefore, allows health researchers and then decision makers to create knowledge and evidence from different types and formats, including the disease prediction using tools of public health informatics, medical informatics, bio-informatics and all the related technologies about human beings, the environment and molecules. The integrated approach of data management through the web, the mobile health and the electronic health smart cards can bring value as long as there are inter-operable and open standards. Big data has the potential to accelerate research and provide answers to some of the most difficult questions of our time, such as solutions for multi-drug resistance, by knowing how the disease behaves and how the different drugs actually impact, and collecting data from different populations.

Privacy and the big data is a huge challenge. Just an example, Facebook has 1.31 billion monthly active users from all countries of the world, and people volunteer data about themselves: where they go, what they eat and how they behave, and where they are travelling, what medicine are they taking. That data is actually the wealth of today. It is the money, the currency. Nobody knows how ethical is the use, how regular or how legal it is. Users voluntarily provide personal and location data assuming that other friends would benefit from that, when you tell people about what you do, where you live and what you are eating,

you assume that people will enjoy that, but there are other people actually watching and capturing that information to make plans and decisions, produce certain food products, or other types of things to sell and market. Once data has been collected, individuals have absolutely no control over who uses it or how. When we put our data on the Internet we just give away a part of us to somebody else. Personal data collected through social media and other personal records has become of strategic importance.

“Health data could become the next big battle ground.” This is actually a quotation from this morning, because Google is developing a service that will be called Google Fit, it would combine information from health apps and personal fitness devices. The people will actually be volunteering their data to Google and they will do something about that. We know that Google is a data-processing and data-management company. Apple, the rival, announced the healthkit, which will put together data such as blood pressure and weight by a growing number of health care apps in iPhones and iPads; Samsung is also launching a health platform. Each one of these big companies is competing to collect data from people using these personal devices, and they do something about it by selling.

The reuse, which is usually unethical, unfortunately has become critical: personal data collected in one country or for specific purposes is reused for another purpose. That was mentioned this morning to emphasize that when data moves between countries, there is no control on that data, whether we like it or not. What we hear about the right to be forgotten, for example, the data of clinical trials being done in one country and another country is just part of the unlimited and uncontrolled scope of what can be done in countries with this data. More serious, data is deliberately and unilaterally transmitted without authority’s consent across borders by foreign entities.

Last year I talked in a conference about data colonization, which means companies go to certain countries to collect the data, they bring it back to the headquarters of certain companies without even providing

any feedback or any value back to the country that has been collecting and helping the data. This is to me exactly like taking the raw material for gold or raw material for the cocoa and making the Swiss chocolate. The petrol is another example.

What can be done? We should think of development and adoption of ethical guidelines at national and international levels that can help national authorities, institutions and individuals to understand better. We have to work on awareness of individuals, practitioners, policy makers and law makers about the ethical issues related to the use of data. We have to improve accountability and transparency principles, which can be enforced by national and international bodies. We need to balance between the individual and society rights when we talk about ethical issues. We need to provide better understanding and research on these particular issues because there's actually a lack of that, especially in certain countries in the world. International collaboration, the UN agencies, regional bodies, governments, civil societies and the private sectors need to work together. There's the example of UNICEF, the WHO, the European Council, the European Commission and many others working together to enhance and improve the situation. This is an invitation also for other parties to work collaboratively in a network mood and in an open and transparent way to improve the situations in regard to the use of data, its collection, its utilization, and its communication. •

La télésanté clinique au Québec: un regard éthique

Nicole Beaudry

Je vais faire une présentation sur une technologie spécifique, la télésanté. Je vous présente brièvement l'effet de la télésanté sur la pratique clinique et les soins de santé se fait de plus en plus sentir au Québec et la commission croie que cela va aller en s'accroissant. Déjà en 2010, près de 260 mil activités de télésanté de nature clinique, administrative et éducative ce sont tenues. Or, les enjeux éthiques que soulève l'usage des technologies d'information et de communication n'avaient pas encore fait l'objet d'une réflexion d'ensemble. C'est pourquoi en 2013 nous avons étudié les conditions de développement qui seraient optimales sur le plan de l'éthique. La commission est partie de la prémisse que la santé occupe une place primordiale dans le bien-être humain et on a déduit le principe directeur, c'est ce que vous trouvez en haut à la première case. L'adoption de nouvelles technologies doit être encouragée si elle permet d'offrir de meilleurs services de santé à la population, au meilleur coût possible. C'est sur ce principe que nous avons élaboré notre avis.

Les résultats de ces travaux sont présentés ici en quatre grandes étapes. La première c'est une vision à partager. La télésanté doit être au service déjà et reposer sur une demande, ce qui implique d'évaluer les besoins et de faire la démonstration de l'utilité clinique et de maintenir un rapport coût/efficacité avantageux. La deuxième étape c'est de comprendre le phénomène de la télésanté. Il y a des caractéristiques particulières qu'il faut prendre en compte quand on

fait l'évaluation éthique de cette technologie-là et aussi il faut considérer les défis. Par exemple, un défi de taille est l'évolution rapide des technologies. La troisième étape c'est qu'il faut soutenir la réflexion et la décision au moyen d'un cadre éthique par des principes à respecter et des valeurs à promouvoir. Enfin, il faut répondre aux enjeux prioritaires qui sont l'innovation et la transformation du contexte de soins. Alors la télésanté doit soutenir les changements dans l'organisation. Cela requiert que la prestation des soins soit adaptée pour assurer le déploiement de la santé dans des conditions acceptables. Il faut redéfinir les rôles sociaux des différentes parties prenantes. Deuxième enjeu : la qualité de la relation professionnelle et la protection des personnes en situation de vulnérabilité. Il y a une nouvelle forme ici de présence qui n'est plus directe mais qui requiert un intermédiaire technologique. Les modifications qu'apporte la télésanté à la relation clinique peuvent créer ou accentuer les situations où les personnes sont plus vulnérables. Il faut prendre cela en compte. Troisième enjeu : la médicalisation du milieu de vie et l'autonomie des personnes. Le milieu de vie est lieu d'intimité, de sécurité et de liberté. C'est le respect des valeurs des personnes qui doit guider la taille de l'équilibre entre les considérations de vie privée, de sécurité et de bien-être. Le quatrième enjeu : la confidentialité des renseignements de santé et le respect de la vie privée. À cause du partage accru des renseignements de santé variés qui ne peuvent pas être amassés en grande quantité et stockés sur une longue période, il faut un encadrement suffisant pour protéger la vie privée. Je vais vous parler du cadre éthique. Un système de santé comme vous le savez n'est jamais neutre à cause de la manière dont il est structuré, financé et gouverné. Il incarne de ce fait les valeurs qui définissent la conception que la société se fait de la santé, du bien-être, des droits et devoirs de chacun à la matière. La commission dans son avis a retenu quatre grands principes éthiques qui sont au cœur du système de santé québécois. La première colonne s'agit de l'accessibilité de soins pertinents et de qualité. Les individus sont en droit d'avoir accès aux meilleurs soins de santé possible selon leur besoin clinique,

sans égard à leur capacité de payer, leur statut social, leur identité culturelle ou ethnique, leur lieu de résidence. Deuxième principe éthique : une distribution juste et équitable des ressources. Qu'elles soient financières, matérielles ou humaines, elles doivent être utilisées de façon responsable et allouées selon des critères transparents, respectueux des besoins de la population et du bien commun. Troisième principe, le partage des responsabilités entre les différents acteurs. Le maintien et l'amélioration de la santé et du bien-être devraient reposer sur un partage équilibré des responsabilités entre les individus, les familles, les milieux de vie, l'ensemble des secteurs d'activités et les pouvoirs publics. Quatrième principe: le consentement éclairé des personnes. Le consentement de la personne, à la fois une exigence éthique et légale, doit être obtenu pour toute intervention en matière de santé. Ce consentement doit être donné librement par la personne. C'est-à-dire en dehors de toute influence aux contraintes indues et après qu'elle eut été suffisamment informée des différentes options qui s'offrent à elle, de leurs risques, de leurs bénéfices. Dans le cas de la télésanté, ce principe requiert de prendre acte des changements qu'introduit la télésanté pour adapter le processus de consentement. Nous avons fait cette analyse-là prenant en compte qu'il y a quatre valeurs-phare pour orienter la réflexion et la décision. Alors, la commission a pris acte qu'il y avait au Québec des valeurs importantes en matière de soin et de santé. La confiance, l'autonomie, la solidarité, la bienfaisance, la bienveillance et la non-malfaisance. Ce constat est le résultat du processus d'analyse des conséquences plus qu'un ensemble de valeurs données d'avance. Ces valeurs sont au moins d'une utilité en elles-mêmes puisqu'elles peuvent notamment servir à la prise de décisions dans certaines situations. Alors voilà, je vous ai présenté brièvement le cadre éthique de notre analyse. Nous avons à la suite de cela, fait 26 recommandations au ministère, organisme, au cadre professionnel auquel elles peuvent s'adresser. Alors, je ne voulais pas vous présenter ses 26 recommandations-là, je les ai résumés en cinq points essentiels qui s'adressent comme je vous l'ai dit à différents

intervenants au niveau gouvernemental, ministériel, professionnel, académique, administratif et clinique. Alors, les cinq grandes recommandations: la première, mettre en place des mécanismes de veille, d'évaluation, de liaison et de transfert de connaissances plus adaptées pour rendre disponible des données de qualité sur l'efficacité des applications de télésanté, parce que nous n'avons pas suffisamment de données. Deuxième bloc de recommandations, soutenir les usagers et les professionnels dans la transformation du contexte de soins que cette innovation entraîne. Troisième bloc, soutenir la pratique professionnelle, notamment au moyen de lignes directrices et de formation pour maintenir et améliorer la qualité de la relation clinique, compenser les limites de l'intermédiaire technologique et prévenir les situations de vulnérabilité. Quatrième bloc, respecter l'autonomie de la personne lorsque des soins sont rendus à distance au domicile de l'utilisateur (ce qu'on appelle les télésoins à domicile). Et finalement, garantir la sécurité des renseignements de santé lorsqu'ils circulent ou sont conservés en dehors du réseau de santé. Ces recommandations visent à accompagner le développement de la santé sur le plan systémique. Finalement, la commission croit qu'il faut que le Québec prenne le temps nécessaire pour apprendre ce qui se fait de bien ailleurs en télésanté pour s'assurer de réussir les réformes entreprises dans le système de santé québécois. La commission considère que cela pourrait même constituer un devoir éthique de la part de l'État pour garantir des services de qualité aux citoyens. Alors, merci de votre attention et vous pourrez trouver la traduction anglaise de cette présentation sur le site de la commission au www.ethique.gov.ca •

Novel neurotechnologies: intervening in the brain

Hugh Whittall

What I would like to do is just give a very brief overview of the report we published almost one year ago: “Novel Neurotechnologies Intervening on the Brain”. This was a report we prepared and published in our usual way over the course of about eighteen months with a working party that included people with scientific and clinical expertise, people from backgrounds in philosophy, law, regulation and social sciences. We did it following a broad consultation engaging the public, people with difficulties, neuroproblems and also going out discovering facts from regulators, producers, and so on. It was quite a major report, and I will go through this fairly rapidly.

The first question was why was it so important? What we see is that there are an increasing number of people with serious neurological and mental health disorders. Some of these are dementia, for example, which are also associated with changing demographics, increasing age profile, but what we see is the limited effectiveness and the limited potential of pharmacological interventions, and now an increasing development of technologies do act directly on the brain. The specific examples that we looked at included these: one is a deep brain stimulation, highly invasive whereby electrodes—two holes are drilled into the skull, electrodes are dropped directly into the areas of the brain that are believed to be associated with the problems—. It is used quite successfully in many cases, in treatment and moving disorders such as Parkinson Disease and in some cases for neuropathic pain. There is some research into the use of deep-brain stimulation for mental health



disorders such as severe depression, which has failed to respond to other types of therapy. This is a highly invasive technology. The second is transcranial brain stimulation, it's less invasive in the sense that the intervention doesn't physically interact in the brain, but electric or electromagnetic currents are applied onto the skull, which then affects the brain. It is being used largely in research and for drug-resistant depression, but people are increasingly looking at other types of disorders in which it could be effective. It is incidentally being used, and there is some growing evidence that it can enhance people's abilities in certain areas such as the performance of mathematical tasks or others. There is a non-medical application here, which I'll just ask you to note for the time being. We did also look at another technology which is neural stem cell therapies, in which neural stem cells are injected directly into the brain. Again, another highly invasive technology that is still quite novel and under trial.

The point is the special status of the brain, if you go to our report you will find an extensive discussion on the significance of the brain. We don't want to mark it down as being highly exceptional, that it has to be treated in such a different way to other parts of the body, but nevertheless because of its function, because of its centrality to so many of our functions. Given this status of the brain and its importance, if it goes wrong, it is important that we try to fix it, so there's a need. The basic tension is the need to try and assist when there are problems in the brain, but at the same time, the uncertainty that we have about how to deal with it, what consequences it might have, and this translates into these principles of beneficence and caution.

That's not enough to help us through managing the whole set of issues that arise here. What we developed was a virtue-guided approach, and identified three particular virtues—I don't want to suggest that these are the exclusive virtues relevant here or that they are not applicable in other situations—. One is the virtue of inventiveness that is exercised through innovation, through developing new ways of approaching issues around ailments of the brain. The second virtue is

humility, on one hand recognizing that we have a limited understanding of the brain itself, and on the other hand I think about not overstating our technological capabilities, which is something that happens far too often. The third is around responsibility. This should be exercising in all kind of ways about being cautious and being honest, including through publication practices. These set of virtues can help guide our actions in many ways.

Now we can recognize some particular interests that need to be considered in the context of developing neurotechnologies—these are not unique to neurotechnologies or to technologies in general—. One interest is safety. To recognize the risks that may be associated with implantation of whether stem cells or electrodes in the brain, etcetera, we have seen reports of unattended effects, and that must be recognized. The second is autonomy, there are several aspects related to this; one is that the capacity of people with brain disorder to make decisions may be limited and, on the other hand, the effects of some of the treatments that we give may themselves affect people's decision-making capabilities or their self-conception if there are effects that alter personality. The third is privacy. There are certain technologies that intervene in the brain that collect data and this can go to some interesting questions about privacy, of how or where that data can be collected or where it might be available. Questions of equity, the fourth interest, are important because the access to technologies is very limited. Finally, trust. In many ways, the willingness of people to be involved in research phases depends on trust of those scientific and medical professionals proposing it, but at the same time, again those claims that are made in public about the potential of technologies can build or undermine trust as well.

What is quite interesting at this point is to see how this set of interests we identify, how they relate, and they map really neatly on to the ethical principles that Michel Daher developed in a paper with others. Michel's work is very much behind this. In section five of the paper, he identifies a set of ethical principles that in particular should



Key interests

Safety	<ul style="list-style-type: none"> • Risks associated with implantation
Autonomy	<ul style="list-style-type: none"> • Decision-making capacity • Self-conception
Privacy	<ul style="list-style-type: none"> • Collect sensitive information • External interference
Equity	<ul style="list-style-type: none"> • Access • Stigma
Trust	<ul style="list-style-type: none"> • Undermined by unsustainable claims

be brought to bear in this area: autonomy, dignity, beneficence, justice and competence of the health professional. I think it is not difficult to map these five principles in our report on to the five principles in this document. I don't think either of us would claim that we've developed an exhaustive and specific instance, so it is just encouraging that we can reinforce each other's work.

That's the kind of framework that we developed. Now, if we recognize the need for therapies, where there whether are a lack of other options and the status of the brain giving reasons both to intervene and to be cautious. The crosscutting themes, across the various technologies are around the need to support innovation while protecting patients. A further one is, how important is to collect and disseminate information and evidence? Not least because some of these technologies are used on small numbers of patients, so the experience gain in one place is actually relatively small and we need to bring this all together if we are going to properly inform ourselves for the future, for the benefits of patients, and maintaining trust. In neurotechnologies in particular we see a lot of hype, we read far too regularly of a new imaging technique that can read your thoughts, that knows what's happening in your brain, and it's simply not true. We get some ideas, we can see some activity, but it is simply not able to do

that. The new technologies that are being delivered, and the time scales in which they have the potential to deliver them are much longer than it's often claimed. What we find is the risk of a loss of trust through hype and over claiming of the potential of the technologies.

We developed this much more in a report from a previous year about emerging biotechnologies: how these technologies are often driven by commercial, technological and political elites. Biotechnologies are not necessarily driven by need, societal concerns and questions of equity. If they discourse around what gets developed; why, how and for what purposes, if it's driven by technological decisions and commercial interests, this is not necessarily going to meet social concerns and social needs. An important point is to try to broaden the discourse at all stages of developing technologies, including neurotechnologies, so the public discourse can identify public interests, the public good and public priorities that can help inform and guide the direction of these technologies.

More specifically, we made some particular recommendations. One, because of the potential impact that these technologies can have on the individual who is at a research stage, having these interventions, how they can affect their lives quite dramatically, either through side effects or vast improvements, or having been offered them in research contexts, they may not be available afterwards as a therapy, people must have good information, counselling and support during those phases. Second, research trials often involve very small numbers of patients. In the UK, we have seen that there are a number of practitioners who are using stem cell therapies, who are using deep brain stimulation, and they are actually not sharing the results of the work. We are trying to encourage them to develop clinical registers so that we can bring together the results and better inform future research in development. I mentioned earlier that neuro-stimulation devices are already being used for cognitive enhancement in totally non-medical settings. As things stand in the UK, anything that claims to have a medical application has to be regulated, has to be approved under the medical devices



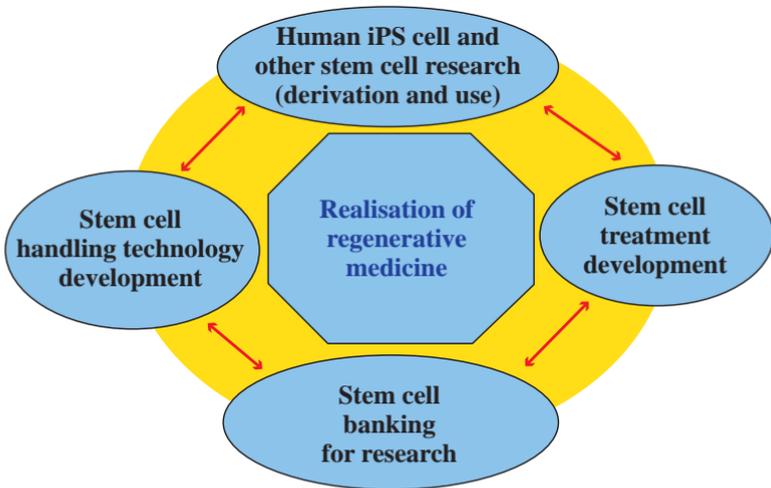
directive of the European Union. If the same piece of kit is being offered so that somebody's conceivably get a buzz and do their crossword a little bit quicker, it is not regulated at all. What we are trying to recommend is that if the same neuro-stimulation is being put on to the market for any purpose, it should be subject to the same kind of regulation. Finally, in the particular context of neuro-surgery for stem cell trials, there is still uncertainty around the ethical basis for using sham surgery: to what extent is it reasonable to put needles to somebody's brain and then not putting in the potential therapy? We find there still a little bit of uncertainty, and no adequate guidance around that kind of placebo approach to research in this particular context. There is much more in the report. Please go and read it, but for the time being, that's a quick overview. •

Regenerative Medicine using pluri-potential stem cells

Ryuichi Ida

I thank Dr. Manuel H Ruiz de Chávez and the staff of the National Bioethics Commission of Mexico for having a precious occasion to introduce our new law on the safety of regenerative medicine. The word regenerative is a rather Japanese-English word; the regenerative medicine means a medical treatment for recovering or reconstructing the functions and the structure of the human body.

Project for realization of regenerative medicine



You know very well that Dr. Yamanaka won the Nobel Prize with the invention of IPS cell induced pluripotential stem cells. With the support of such a scientific development the current government took the policy for revitalizing Japan and Japanese economy. The regenerative medicine is one of the three arrows, said the Prime Minister, for Japanese economy. The government has established the project for realization of regenerative medicine using pluripotential stem cell, not only IPS cell but also embryonic stem cell. In that project we have four parts. The first is the research for human IPS cell and other stem cell including ES cell and somatic stem cell. The second is the stem cell handling technology should be developed in a rapid way. The third stem cell banking for research and as well as for a clinical treatment is very important, because we cannot always create stem cell for each patient or research participant for the regenerative medical care. The banking of IPS cell is now going on in Japan, in particular in Kyoto University, my previous university. The fourth is stem cell treatment should be developed. We are now at the first stage of clinical trial, of clinical research rather different from a clinical trial in the sense of a clinical trial of a pharmaceutical product; we are now doing a clinical research using IPS cell, derived cells in a hospital in Kobe.

First of all, in ethics we have only very few legislations. Almost all ethical regulations are done with the non-binding guidelines. In 2000, we have the Law on Regulation of Cloning Technology in Human Being. This is a law banning the human reproductive cloning. However, from 2001, you have many guidelines or revised guidelines up to 2010. These are guidelines for a different kind of research including human ES research or the green card trials on using human stem cell research and so on.

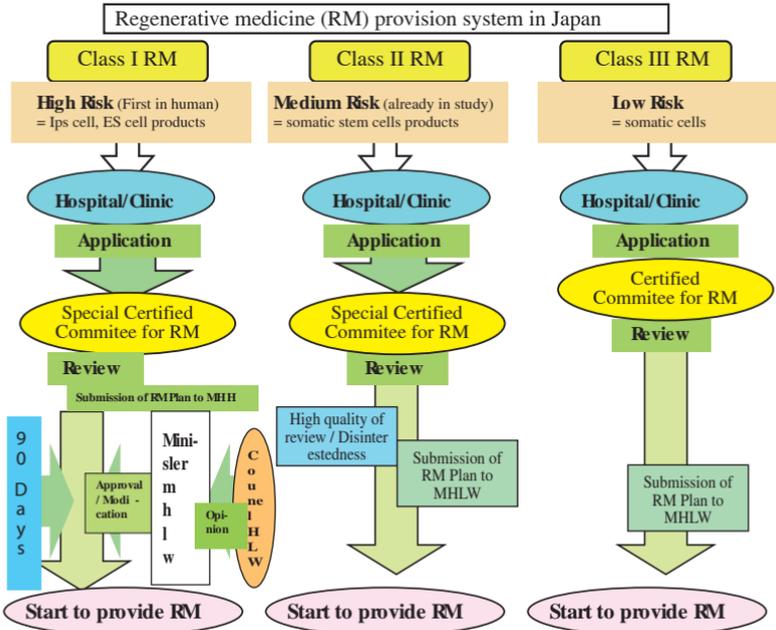
Finally, last year, the Diet of Japan enacted two types of laws. One is the law on promotion of regenerative medicine. This is just the law stating the policy of promotion of regenerative medicine; it is not for regulating the regenerative medicine. The Act on the Safety on Regenerative Medicine is the first law in Japan covering from the clinical

research to the ordinary medical care using a different kind of cells. It means plural stem cells or somatic stem cells as well as normal somatic cells, so that from IPS cell research to cell therapy, are included in that law. Together in the Act on the Safety of Regenerative Medicine, other legislations on pharmaceutical affairs were revised in order to include under this regulation the cell products because the cells differentiated from IPS cell and ES cell should be used in the regenerative medical care.

This is the approval system for regenerative medical product: the cells for the regenerative medical care. The upper part is the traditional approach; the current approach is from clinical research and clinical trial of cellular products, and then approval and marketing. It takes a long time, sometimes many years, so that it might be too late to be approved after the various clinical research and trials. The government decided not to revise the current approval process to a new approval process with the so-called temporary conditional approval with time limits, which we call it a fast track. In this new process, we start from clinical research and then clinical trial of cellular products. If the safety is acquired, the government would give temporary approval for marketing. After some time of marketing, reapplication for the final approval should be done and the last step is the final authorization, so the marketing will be continued.

We have now this kind of regenerative medicine system. The first IPS cell, ES cell and some other somatic stem cell are first done in research laboratories, or sometimes hospitals or clinics. Some medical doctor will produce a cellular product in order to go directly to the regenerative medical care, or, if the medical doctor asked to the pharmaceutical farms to create some new cellular products, they ask for the production of such a product, and under the revised Pharmaceutical Affairs Act, and then go to the regional medical care in hospitals or clinics.

This is a regenerative medical care review system. We have three class medical review. The first one is high-risk regenerative medicine. RM means regenerative medicine. The hospital or clinic should first



apply the clinical trial for using IPS cell or ES cell under the review of a special certified committee for regenerative medicine. If it is reviewed successfully, the clinical research plan goes up to the Minister of Health, Labour and Wealth (MHLW), for the final governmental approval or sometimes some modification of the plan to this hospital or clinic. If the approval is done by the minister, they can start to provide regenerative medical care. The Class 2 of regenerative medicine has a medium risk. Because, the difference between Class 1 and Class 2 is that in Class 1 they have a high risk, because it is first human clinical research, but Class 2 is medical care or clinical research, using somatic stem cells. Somatic stem cells research has already been done in Japan since several years, so the risk is minimal. The application from the hospital or clinic goes to special certified

committee for regenerative medicine for review, and if the review is successful, they can start to provide medical care. The Class 3 of regenerative medicine means they have a low risk, because in this class only somatic cells are used and not stem cells, and each hospital or clinic may apply to the certified committee for regenerative medicine. This satisfied the committee for our aim, maybe established in each hospital or in some other universities. The review may be easier than Class 1 or Class 2, because there is only a low risk and if the review is successful, they can start regenerative medical health.

What are the issues of RM Safety Act? The first one: will each regenerative medical treatment plan be appropriately classified and reviewed, according to the three risk levels?, because there are three levels according to the level of risk. If the level is high, you should pass the process of Class 1, and if the risk is not so high, but not low, it goes to the Class 2 process; and, if the risk is low, it would be easier to provide medical treatment and you can go to the Class 3 review. The providers sometimes attempt to characterize their plans to an easier level or submit them to a softer review committee, there for how to prevent them? The second one is: will each review be effectively done? Because the quality of each IRB committee and assurance of effectiveness is very important, even if the safety is assured. The third: will the control on the third level work effectively? Because in cell therapy in different areas like aesthetic surgery or so-called «health treatment clinics», they may use a cellular product for the patient. So, the effective control on free treatment is important. The fourth: how to assure the effectiveness of each regenerative medical treatment? Because the law provides only the safety of the regenerative medicine but not the effectiveness. The safety does not always mean the effectiveness at the same time.

For the moment, the safety is the first concern for the government, and the effectiveness will follow if the safety is assured. Now let's talk about the perspectives of Japanese framework of regenerative medicine. The first is the assurance of effectiveness: how to assure the

effectiveness of regenerative medical care, which assures safety? This is not properly planned now. The second problem is the reform of our IRBs system. We have now more than one thousand three hundred IRBs in Japan. For regenerative medicine, the IRBs or the ethics committee should be certified by the government so that a new system of the ethics committee system will be introduced. The certified regenerative medical review committee is a part of the starting point of this reform of IRB system in Japan. •

SESSION 3: UNIVERSAL HEALTH COVERAGE (UHC)

Presentation

One of the most pressing ethical concerns globally is related to universal health coverage and equal access to health care.

During the past decade Mexico started making significant efforts to expand and strengthen health attention services in order to reach universal coverage. This encompasses ethical dilemmas in, for instance, setting priorities, the allocation of resources, etcetera. An ethical framework could help governments reach the best option, not only financially but also ethically speaking, for the wellbeing of populations and the sustainability of national health systems. In this case the experience of NECS around the world should be very valuable.

The session was devoted to a discussion on the ethical challenges and concerns that countries face as they roll out universal health coverage. It includes reflections of several NECS representing different regions on the forthcoming WHO report Making fair choices on the path to universal health coverage, which addresses key issues of fairness and equity on the path to universal health coverage.



Introduction

Mohamed Salah Ben Ammar

The objectives of this session is to emphasize the ethical questions and issues that confront National Bioethics Committees as they support their governments, the implementation of universal health coverage, and discuss the current and future role of National Ethics Committees in this regard, both at national and global level. What role can National Ethics Committees play as countries implement universal health coverage? I introduce the topic and afterwards Dr. Andreas Reis and Dr. Norman Daniels will present “Ethical priority setting for progressive realization of universal health coverage”. Finally we will have six countries’ —Mexico, Bolivia, Cuba, Sri Lanka, Estonia, and Sweden— experiences and then we will have a general discussion.

Universal health coverage is a direction, not a destination. Many organizations, especially World Health Organization, work on this subject. I will present some ideas that Andreas Reis will elaborate on afterwards.

Health expenditure is growing but in some counties, citizens are paying from their pocket to be treated and to have the right to be treated at the hospitals or private clinics. Health care expenditure accounted for 5.8 trillion dollars in 2008, and in 2010 it accounted for 6.5 trillions of dollars and it continues to grow. Before, the percentage of GDP spent in health care used to be 9.7 but now it has gone up to 10.4. To achieve universal health coverage, countries must advance in at least three dimensions, and everybody will be back to these three dimensions: expand priority service, include more people and reduce out-of-pocket payments.

The question we ask ourselves when expanding priority service and critical choice is which service to expand first. Do we include more people? And if so, who should be included first. When reducing out-of-pocket-payments the dilemma is how to shift from out-of-pocket payments toward pre-payment. These are the three main subjects.

From my point of view, we can imagine the first level is prevention technology like vaccine, health promotion, large coverage, low-cost intervention. These should be the priority for all the countries, because is the basis of all the health system. But universal health coverage should be built on solid foundation as all the Declarations say: the right for health is the right to health care service and it is a human right. It needs to make choices and to be accountable for them.

Universal health coverage is a direction, not a destination and not one country, not even the richest ones can fully achieve this coverage objective. All countries want to reduce the gap between need and utilization, improve quality, and improve financial protection. Often, it translates into reducing explicit inequalities, in benefits and funding per capita between groups; relatedly, universal health coverage as a means to an end: that is having a fair society.

There is no standard package for health service action to progress towards universal health coverage. Every country already has a health system. This is the starting point for any reform. •



Ethical priority-setting for a progressive realization of universal health coverage/Making fair choices on the path to universal health coverage

Andreas Reis

I will make my presentation on ethics and universal health coverage. Priority setting in health care, in universal health coverage, is a common concern from many of our member states and also the National Ethics Committees. Universal health coverage is also one of the top priorities for WHO. While “universal health coverage” is a relatively recent term, WHO has a long history of promoting the access to health care for all. The WHO constitution of 1946 already stated that health is a universal human right, and I quote, “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”. WHO has taken many initiatives to promote health care for all. For example, in 1978 Alma-Ata, and then in 2005, the Commission on Social Determinants of Health, and more recently, promoting primary health care and universal health coverage.

But it is not only WHO that is promoting the implementation of universal health coverage. In 2012, WHO pushed for implementing UHC, received a very strong support by the General Assembly of the United Nations. It adopted a resolution urging governments to move forward towards providing all people with access to affordable quality healthcare services. The resolution also recognized the role of health in achieving international development goals and moreover, it affirmed WHO’s leading role in supporting countries to respond to the challenges of implementing universal health coverage. This, of course, also

includes supporting National Ethics Committees, as they advise their governments.

We should not forget that UHC has a lot of ethical underpinnings. WHO's Director General, Dr. Margaret Chan, recognized this "I regard universal health coverage as the single most powerful concept that public health has to offer. It operationalizes the highest ethical principles of public health. It is a powerful social equalizer in the ultimate expression of fairness".

WHO has received requests of support from more than seventy countries in advice for UHC. The plan of action of WHO also includes offering guidance on how to move forwards in ethical manner to UHC. This is why WHO established a consultative group on equity and universal health coverage to develop this guidance. This was a very multidisciplinary group composed of ethicists, economists and policy experts from different countries, and the drafts of this document were circulated for external review, including to some of the National Ethics Committees.

What exactly does universal health coverage mean? All people receiving quality health services that meet their needs without being exposed to financial hardship in paying for their services. This is a very broad and inclusive definition. WHO's working group was very clear that we should stay realistic: given the resource constraints that does not entail all possibly effective services, but a range, a comprehensive range, of key services that is well aligned with other social goals, such as environment, transport and so on. •

Norman Daniels

One of the central issues in universal health coverage is how to expand the famous cube.

Expand the blue to fill more of the rest of the cube. There are three dimensions that are talked about here – expanding the range of



services, which would be the front-back dimension; reducing the out-of-pocket payments through cost sharing and fees, and extending the numbers of people who are covered. But even if you were to fill this cube, the blue filling everything and we had universal health care, we should not expect that we've achieved health equity in a system, and that is because there are many determinants of health beyond the health care system itself. Public health and social determinants are key producers of population health and its distribution. Universal health care is an important contributor to health equity, for it insists on equity for everyone whom the society can keep healthy, cannot keep healthy, but it fails in some ways to address the problem of health, the distribution of health, that is effective outside of the health sector by the inequalities that exist in a society in the distribution of other determinants of health. My conclusion from this is that universal health care is a requirement of social justice, but it's only part of the social justice that we are concerned with.

The document that was produced by this group contains a strategy for prioritizing services; specifically, there is the goal of dividing services into three categories of priority: high, medium and low. Then, looking at the trade-offs that exist between some of the dimensions of the values that are concerned. We might think that the middle category of benefit maximization is the sole concern of the strategy, but we must compromise benefit maximization by looking at the other values that are concerned as well. In fairness, the conception of fairness was taken to be focusing on the worst-off groups in society.

We could imagine, for example, a long history of inequality between some groups that decision makers, in a particular setting, want to do in a way that fails to maximize benefits for the society in the aggregate, but it's targeted in some ways that, improving the fairness, reducing the inequity between a traditionally excluded group and not. Similarly, we could worry that some of the costs of health care that are not addressed by benefit maximization need to be addressed, so universal health coverage also has to think about the financial risk protection that a system affords. There are going to be reasonable disagreements

among people about the trade-offs between benefit maximization on the one hand, and fairness or fair contribution on the other. This requires some sort of process for making decisions that is fair and has legitimacy and holds people accountable.

The strategy says we should group preventions into high, medium and low, where green here is the high, yellow the medium and red the low. We might think that there is no overlap problem in the cases where there is a clear colour that is standing out as a medium. So, if one goes to just between two and one and a half on this slide, you have a medium category that has no disagreement about how to categorize it. Nevertheless, there might be some disagreements about how to promote high-ranking service, say close to two in the red domain, compared to something a little below two in the yellow domain. Those disagreements are important to address, even though there are no overlap between them.

The main determinate that was used in deciding the grouping was cost effectiveness, and cost effectiveness has come under a lot of criticism, and I think there are two fundamental issues that are normative, and then there is another one that has to do with measurement. The one that has to do with measurement, which is not mentioned on the slide, is that a lot of the cost effectiveness is really not about cost but about prices, and we know that prices can shift extensively and change the cost effectiveness ratio that's produced. But there are normative problems. Even if one had a good measurement of costs - and cost the decision makers - then still cost effectiveness ignores the distributive effects of cost effectiveness and it ignores the financial risk protection that has to be given in a population. There are going to be reasonable disagreements about how to trade off cost effectiveness against concerns about the distribution of the healthy life years, or concerns about the financial risk protection.

In addition to that, there's a general problem of whom to cover next, and what the proposal is that we take the worst-off groups and hard-to-reach populations, and other relevant groups who are systematically disadvantaged in a society. But there still is a trade off because, if we

are looking at worse-off groups, then we may be compromising health benefits and reasonable people will disagree about how much to make this trade off. There is room for discussion and deliberation about how to make those trades, and how to identify what falls into the different packages of high, medium and low. •

Andreas Reis: The third dimension of the cube is about reducing direct payments and out-of-pocket payments. We know from many countries that often, even small direct payments are important variables to access, especially for the most vulnerable and the poorest populations. Direct payments are a cause of financial burden and often enough, they result in catastrophic health expenditures.

The expert group recommended the following: a shift away from out-of-pocket payments and toward mandatory pre-payment with a pulling of funds. When countries are making such a shift, they should seek to first eliminate out-of-pocket payments for high priority services and, they should also eliminate direct payments for low-income groups and other disadvantaged groups if that can be done effectively. Sometimes that's not easy. In third, the financial contributions that are required should be made dependent on the ability to pay and the receipt of services shouldn't be made dependent on need.

Norman Daniels: This approach leads to an identification of some unacceptable trade-offs. The first one I want to mention is giving priority through funding and to low as opposed to higher ranking services. To expand lower-medium priority services before there is new universal coverage for high priority services is identified as non-acceptable trade off. Unfortunately, that is a trade-off that is often made in many countries.

A second, unacceptable trade-off is to give financial protection for costly services before there are substantial health gains for the population. This kind of trade-off is also subject to a lot of disagreement that takes the form of lobbying for particular patients who might get protection from the financial burden at the cost, at the opportunity

cost of providing more useful services to larger parts of the population. There are two other unacceptable trade-offs that are worth mentioning a very common one, helping well-off patients before worse-off ones and so expanding the coverage for well-off groups before doing so for worse-off groups when the cost and benefits are not vastly different. This is something that happens in the area where there is a lot of disagreement.

The fourth concern is to first include in the universal coverage scheme only formal workers, or those with the ability to pay and not informal workers, and the poor, even if such an approach would be easier. I mentioned before that there were significant reasonable disagreements that took place. So, I wanted to describe some conditions that Jim Sabin and I have proposed; the acronym A4R is “accountability for reasonableness”, not something that is an easy term to swallow, but it has become widely accepted as a characterization of a fair process in a range of health systems.

One thing it emphasizes is publicity and this is a focus on the rationales for decision, not on the decision outcomes only. There is also a concern that the people involved in the decision making find rationales that form a basis of agreement among them and therefore, that they think rest on relevant considerations. In this context, our view is that stakeholders in the system should have a role in vetting these reasons, and this broadens the deliberation often to include a range of people who may then advocate for particular views which are not understood or accepted by others in the group. There has to be a deliberation that is responsive to the range of situations that people are talking about.

Finally, these decisions that are made have to be revisited on a regular basis and in light of new evidence in our units. There ought to be an appeals process, because, sometimes, decisions that advantage a group or the society as a whole, don't necessarily advantage individuals and they have to be examined carefully to make sure that there are no under burdens imposed on individuals. That's what an appeals process could do. The other conditions that I've mentioned - publicity relevance and revisability - have to be met and that is a task of enforceability.



Unfortunately, and this is a task for any sees represented here, is that there has to be training of people to address these problems of priority setting. Many people in bioethics have a background in either clinical consultations or research ethics, but few have training in population health or population ethics, and that's what's involved in thinking here about priority setting; how does a health system address the health needs of a whole population? There is a need for training people with an interest in bioethics in these issues of priority setting and in the issues about involving or expanding services and covering more people and financing health care to avoid out-of-pocket payments. This training plays an important role in providing people who can participate and consult on the fair deliberative process that I'm saying is necessary.

I think that every country represented by the people in this room has an important role in facilitating the training and implementation of universal health care by helping bioethicists to understand this broader picture about priority setting.

Comments

Christiane Woopen: I have just a question as to the concept underlying these deliberations, and it pertains to the notions of health, wellbeing and quality of life.

The WHO has definitions and I wonder in which relationship they stand to each other. You have the definition of health, which is health as a state of complete physical, mental and social "wellbeing" and not merely the absence of disease and infirmity; and you have the definition of quality of life, which is defined as individual's perceptions of the position in life and the context of the cultural and value system where they live, and in relation to their goals, expectations, standards and concerns. It is a broad-ranging concept incorporating in a complex way of a person's physical health, psychological state, level of independence, social relationships, and personal beliefs in relation to salient features

of the environment. What I want to point out is that on the one side, quality of life seems the overarching concept; on the other side, health seems to be the overarching concept. References have been made as to the difficult relationship between universal health coverage and social justice. As it seems here, universal health coverage is social justice. I think we have to elaborate a little bit more on the underline concepts and to be more precise, perhaps abstaining from formulating ideals which are wonderful - to having aims to strive for - but which are not feasible in everyday life, and that does not depend on whether you are in Germany or in Kenya, or Asia, or somewhere else; it's not feasible, it's nowhere feasible. Which is the relationship between these concepts?

Andreas Reis: You are, of course, right, the WHO definition of health is very broad and very inclusive and has been criticized on many occasions for that, but I think it's really quite revolutionary for the 1940's. The report "Fair Choices" that we just presented recognizes that health is very much dependent on the social determinants of health and that for truly achieving universal health coverage, countries need to also tackle their root causes. That said, it would have been beyond the scope of this report to address this broader issue and it has been addressed in the report of the Commission of Social Determinants. This report really focuses very much on the difficult choices that health systems have to make in moving forward towards universal health coverage.

Norman Daniels: I would have to say that I don't think the definition actually is an appropriate definition for health itself. I think it confuses wellbeing more generally with health. Nevertheless, I think the distinction that is made about the importance of providing universal access to health care is important, despite that definition and what this report was focused on was the choices people have to make to do that. We set aside the debate about the definition of health and I was able, as a critic of that definition, nevertheless to think it was something useful about focusing on the choices without going to those fundamental questions about health. •



Challenges in the system of social protection in health

Gabriel J. O' Shea Cuevas

I am going to speak about the great reform approved by the Mexican Congress in 2003. Creating and establishing the System of Social Protection in Health. This system increases the public funding to guarantee universal health coverage. What does this mean? For all the families that were excluded from traditional social security systems, they can now enroll in the Seguro Popular, “popular insurance”. This is a new public insurance scheme that guarantees access to a comprehensive health care by law.

The bioethical principle supports that health care is a social right. Universal health coverage in Mexico translates into social protection health mainly in the following. In the first place, the universal enrollment. This is legal coverage and entitles all Mexicans without social security rights to benefit from health services funded by public-organized insurance. Number two, the access to a comprehensive health-services package. This guarantees a universal health-care package. The way we designed this health package was by using cost effectiveness analyzed which has been progressively expanded and by reducing the out-of-pocket- payments of each Mexican to provide high quality health care coverage.

The system of Social Protection in Health, or Seguro Popular, is a public insurance program. As for June of this year, we have around 56 million people enrolled in this system. This is the equivalent to the 50% of the population here in our country. The benefits offered through the Seguro Popular are mainly embodied in two plans. The first one we call it CAUSES. It's a low and medium plan called universal list of essential

health services, and the other plan is called high-cost interventions, we call it fondo de gastos catastróficos, or catastrophic health fund.

How do we procure the money for this health system? We have three main systems insurance here in Mexico. The first one is the IMSS, or Mexican Social Security Institute. This is where workers, former workers, retirees and their families enroll in social security. The other one is ISSSTE; this is where the government workers and teachers are enrolled, and the Seguro Popular. Mainly, the public insurance for Seguro Popular comes from the federal government.

The way we provide the financial protection for this population is through federal contributions. The family fee is banned because 98% of our population doesn't have the economical capacity to pay for it. The way we transfer the money to the states is as follows: 89% goes to CAUSES, that's the list of essential health services. The 8% expands goes to catastrophic fund protection for specialized services and high-cost diseases; finally 3% goes to infrastructure needs. That's to build new hospitals and to get equipment for those who are already functioning.

This is the way we have been working the last ten years since we started in 2004. We had 5.3 million Mexicans enrolled. Now, we have almost 56 million. This year we're going to close with 57.3 million enrolled in the Seguro Popular. The number of medicines available has been increasing it started with 142 medications and now, it has 634 medications. The number of interventions attended has also increased almost three or four times up to 285 interventions nowadays.

The Seguro Popular covers 285 primary care interventions and most illnesses have been reported with a major percentage of hospital discharge. As we said before, it includes 634 medicines for attending all those 56 million Mexicans. The catastrophic health fund that of course is the 8% of the total resources includes 59 medical interventions and covers the most expensive illnesses: 59 interventions and 19 diseases. So, CAUSES includes 285 health care interventions, including the catalogue of 634 medicines. We have too a health insurance for children under 5 years of age which is called XXI Century Health Insurance, it includes 140 interventions. And covers all the diseases in

this age group. By December 2013, we had already around 5 million 4 hundred children affiliated to it.

We have another program called Oportunidades. This program guarantees a basic package of health-care training and provision of food supplements for children from 6 to 59 months of age. We have around 15 million people affiliated as to December 2013.

What's the role of the National Bioethics Commission of Mexico in the universal health coverage? On the Health Sector Program for 2013 and 2018, we foster to respect for human rights, we encourage research to following the ethical criteria, we incorporate the bioethical perspective to design the public policies and we promote observance of international bioethical criteria.

Our challenges now in Mexico are the ones related to increasing the coverage plans in order to reduce the gap between the Seguro Popular enrollees and the Social Security enrollees. We have to improve transparency with regard to the resources of the Seguro Popular and the use of funds. There is a concern about the use of funds and the efficiency achieved with the available resources. The last one is to introduce the universal health benefit plan. •

Institucionalización de la salud

Ernesto Luna Orosco

El fenómeno salud-enfermedad es holístico y multifactorial, esto significa que la solución a sus problemas o la búsqueda de metas, como la cobertura universal de salud, va más allá de los alcances restringidos al propio sector y sus respectivos estamentos.

Por tanto, siendo coherentes con la definición de salud de la OMS, que incorpora entre sus componentes el bienestar social, la cobertura universal en salud debe incluir la solución de las causas determinantes de males sociales que provocan enfermedades individual, familiar, social y medio ambientalmente (siendo la pobreza y sus agravantes la más representativa de todas).

Caso contrario, las soluciones serán siempre fragmentarias y la cobertura universal de salud seguirá siendo un utopía, como hasta el presente.

Lo dicho encuentra su confirmación en los siguientes indicadores:

- Mil 200 millones de seres humanos, es decir, más de 17% de la población mundial vive con menos de un dólar al día. El 20% de la población mundial percibe y controla 80% de la riqueza, mientras 60% sobrevive con 7 por ciento.
- El gasto público anual en salud fluctúa entre 20 y más de 6 mil dólares por persona, dependiendo de las realidades que tiene cada país.
- Para 5 mil 600 millones de habitantes de países de ingresos bajos y medios, más de la mitad del gasto sanitario se cubre con pago directo, es decir, gastos de bolsillo.

- La pobreza sigue siendo la primera causa de enfermedad, cobrando diariamente la vida de 28 mil niños; de 136 millones de mujeres que darán a luz, 58 millones no recibirán ninguna asistencia durante el parto y puerperio.

Esta dramática situación no puede soslayarse, siendo un imperativo ético el involucrarnos en reflexiones y acciones que abarquen no sólo la nosología humana, conocida por todos, sino también las que llamo “nosología social y nosología medioambiental”, afectando ambas la seguridad misma del planeta.

Debido a la limitación del tiempo de esta sesión, que no permite abordar esta problemática, me limitaré a un análisis muy específico de la institucionalización de la salud, que significa reconocer el beneficio de la salud como un derecho perfecto; es decir, inalienable e imprescriptible, que debe otorgarse en condiciones de calidad a través de una dinámica regular y sostenida de la organización sanitaria con planes, políticas y acciones claramente definidas, bajo el mandato indefectible de un marco legal, encabezado por la Carta Magna de toda Nación o Estado.

Con esta consistencia, que a nuestro juicio resulta ética y jurídicamente incuestionable, la salud deja de ser un concepto y se convierte en un precepto macropolítico, que reclama o debiera reclamar ser prioridad de Estado en todo lugar, tiempo y circunstancia, debiendo entonces preguntarnos: “¿está la salud institucionalizada?”

La respuesta no puede ser absolutamente igual entre los países, tanto más si comenzáramos a ejemplificar situaciones de realidades, seguramente específicas y por tanto parciales, limitándonos tan sólo a decir que la salud para todos, entre comillas, proclamada por primera vez en Alma Ata hace casi 36 años, está lejos de convertirse en realidad por una diversidad de razones, motivando que la propia doctora Margaret Chan, Directora General de la Organización Mundial de la Salud, hubiese dicho en su discurso inaugural: “creo que el mundo está más desequilibrado que nunca en materia de salud”.

Ahora bien, de esa diversidad de razones, queremos resaltar algunas:

- Primero, las constituciones de muchos estados no reconocen o no incorporan el derecho perfecto a la salud como un derecho legal y, por tanto, exigible; hablan más de un mandato ético, pero no de un derecho exigible, presentándose además tendencias a disminuir el beneficio de la salud en países avanzados.
- En segundo lugar, muchos otros estados si bien lo reconocen constitucionalmente, no lo respetan o lo cubren parcialmente, generando desorientación y falsas expectativas en la población. Es el caso de Bolivia, mi país, con una constitución muy rica en reivindicaciones para la salud, pero que no se cumple.
- En tercer lugar, el abordaje de la salud sigue siendo sanitarista y curativo sin asumir que sus determinantes merecen un manejo multisectorial y multidisciplinario, siendo la deficiente organización sanitaria y la ausencia de políticas sostenidas de salud un problema estructural de muchos países, agravado por un manejo discrecional de quienes detentan el poder.
- En cuarto lugar, temas como la guerra o el crecimiento tecnológico e incontrolado, provocan un grave desequilibrio de las macroeconomías, determinando un ingente secuestro de recursos financieros en detrimento de los avances sociales, incluida la salud.
- En quinto lugar, lo dicho se agrava con el alto crecimiento demográfico, la aparición de nuevas enfermedades, la creciente contaminación ambiental, los desastres naturales, la crisis alimentaria y el cambio en los hábitos alimenticios, los conflictos bélicos, el terrorismo, la violencia social, los accidentes de circulación y las limitaciones de acceso a los servicios de salud, por una tendencia cada vez más centralista, de atención puramente hospitalaria.

En función a esto último, planteamos modificar el modelo sanitario, centrado en los mega hospitales insulares y monolíticos, donde la complejidad, los altos costos y la enorme concentración de pacientes

impide una atención de calidad, promoviendo, en todo caso, el funcionamiento de redes integradas, integrales y complementarias de salud y atención médico-sanitaria, con incremento en el número de establecimientos mucho más simples que al abarcar mayor extensión territorial y ampliar la cobertura se aproximen al poblador, permitiéndole a él y su familia un acceso más universal, directo, oportuno, barato y humanizado.

Este modelo que obviamente incorpora el control sistemático de la mujer embarazada y el niño sano, la consulta externa para el diagnóstico temprano de las enfermedades, el seguimiento regular de enfermedades crónicas y la atención resolutive de patologías simples, plantea además el rescate y fortalecimiento del médico clínico de familia, elemento fundamental de vinculación entre la sociedad y los establecimientos de salud.

Por tanto, la modificación del modelo sanitario que se propone tiene una profunda connotación doctrinal, económica, social y ética, porque implica verdaderos cambios estructurales en la organización sanitaria misma, más allá de medidas econométricas, ambiguas o puramente coyunturales.

Ante este desafío, el factor más importante que entra en juego es transformar el pensamiento y comportamiento de los recursos humanos, anclados aún en lo puramente biológico sanitarista, y ahora tecnológico, que reemplazando las capacidades humanas del clínico, nos esclaviza y atrapa en una vorágine de consumismo al parecer irrefrenable, fuertemente propiciada por los intereses económicos y mercantiles de trasnacionales globalizadas, que hacen de la enfermedad un lucrativo negocio, distraendo perversamente los verdaderos rumbos que debiera seguir la salud universal y los recursos humanos que de ella se ocupan, para lograr en definitiva que la atención primaria de salud deje de ser tan débil o simplemente enunciativa en foros y conferencias, y se convierta en un mandato ético con compromisos y responsabilidades claras.

Si lo dicho se cumpliera, estaríamos viviendo el nuevo paradigma del que habla Capra, con una visión integradora y sistemática de la salud, y

que asumiendo la autotransformación de cada uno de sus componentes, se revitaliza, recicla y autogenera de manera permanente.

Este trabajo no estaría completo si además de manifestar inquietud por la institucionalización y mejoramiento de la salud como he pretendido mostrar, no concretáramos como Comité Nacional de Bioética de Bolivia las siguientes propuestas:

1. Fortalecer políticamente al sector salud, ejerciendo mayor protagonismo en el contexto estatal y social con potenciamiento y movilización efectiva del ciudadano en aras a la reivindicación plena de su derecho a la salud. Los políticos y los gobiernos, en general, tienen que entender que la salud es la primera razón de Estado.
2. Cambiar radicalmente la formación y capacitación de los recursos humanos en salud, con una orientación de recuperación clínica y mayor contenido social, ético y humanístico.
3. Dejar de propiciar o auspiciar el centralismo de la atención médico-sanitaria con crecimiento y proliferación de hospitales, como lo vienen haciendo varias agencias de financiamiento internacional. Es un gran negocio construir hospitales y equiparlos.
4. Cambiar la visión puramente sectorialista y localista de la salud, promoviendo la construcción de sistemas integrales de desarrollo, especialmente en el área rural.
5. Racionalizar y regular el uso y consumo tecnológico.

Por último, y coincidiendo con el exsubdirector general de la Organización Mundial de la Salud, David Tejada Rivero: “Tal vez sea necesaria una Alma Ata II para relanzar, sin distorsiones, los conceptos que dieron origen a esa conferencia en 1978”, por supuesto con las debidas actualizaciones y profundizaciones de los grandes cambios mundiales y de las experiencias de estos casi 35 años transcurridos. ●

Universalidad: Responsabilidad del Estado

Daniel Piedra

Los primeros atisbos de lo que llegaría a ser el llamado Sector de Salud en Cuba surgieron del certero y valiente diagnóstico con el que Fidel Castro denunció las múltiples injusticias a las que se veía sometido el país, en el conocido alegato de defensa “La historia me absolverá”, en 1953.

Cuando en 1959 triunfa la Revolución con la toma de poder del Estado, la situación en la que nos encontrábamos los cubanos no había mejorado respecto a la de 1953. De los escasos seis mil médicos con que contaba el país, la mayoría se encontraban radicados en La Habana, sede también de la única Facultad de Medicina con que se contaba entonces; eran pocos los habitantes de las montañas y zonas rurales del país que habían visto a un médico. Los indicadores de salud no podían ser más desastrosos.

Esta situación amenazó con conducir al caos cuando ya la escasa masa de médicos se vio reducida súbitamente a la mitad, debido al éxodo inducido por la potencia que se erigió a muerte del Estado Revolucionario Cubano. Muchos profesores de medicina de nuestra única Facultad siguieron el mismo camino.

La Ley fundamental de aquel naciente Estado, sin embargo, insistió en consagrar el derecho de los cubanos a la atención y protección de su salud. Pronto habría una Ley de Salud Pública, la ley 41, que haría que se fueran estableciendo las bases de lo que sería un sistema nacional de salud pública.

Los principios plasmados en este sistema resultan novedosos y singulares en la medida en que son los que animan y conforman toda su actividad, reflejándose en resultados indisputables.

Durante la década de 1980 quedó consagrada la excelencia del sistema con el completamiento de algunos de sus programas básicos, así como con la dotación de la necesaria infraestructura que garantizaría su funcionamiento.

Muchas gracias por su atención, y vayan mirando lo que les tengo que mostrar: la expectativa al nacer en Cuba; los indicadores de crecimiento poblacional; la fecundidad; la tasa global de fecundidad; la tasa de crecimiento de población, extremadamente baja; las principales causas de muerte en Cuba, que este perfil se parece muchísimo al de cualquier país desarrollado; el programa materno-infantil, que en Cuba está plenamente en funcionamiento desde hace años; la mortalidad preescolar y escolar, que son realmente envidiables, quisiéramos que fuera cero y es a lo que enfilamos nuestros esfuerzos. Los indicadores son el resultado de las medidas que se tomaron.

La nutrición, el problema de la nutrición, que es una prioridad dentro del Sistema Nacional de Salud; la estadística de desnutrición, de la cual estamos también orgullosos, por cuanto no somos un país rico, no somos un país con gran abundancia de alimentos, ni muchos menos, sin embargo, sabemos manejar adecuadamente lo poco que se tiene; los resultados lo muestran.

El programa de inmunización, es ejemplar en nuestro país; las enfermedades transmisibles, muchas se han ido eliminando; la mortalidad por enfermedades infecciosas y parasitarias; la prevalencia de VIH-SIDA; la industria biotecnológica y farmacológica de que dispone Cuba en este momento; el programa nacional de control de cáncer; importantes contribuciones del potencial científico cubano; la atención a la discapacidad; la red nacional de genética médica; la matrícula en las universidades, etcétera. •

The Paradox of Sri Lanka's Health Achievements

Anoja Fernando

When one looks at global maps related to health, all this is, one finds that Sri Lanka is often depicted in a different colour to that of his immediate neighbours. Here, for example, it is the same colour as Australia, New Zealand, Europe, Russia, Canada, Brazil, Argentina, indicating that Sri Lanka is rather different from its immediate neighbours, at least in the field of health and disease. I will speak briefly of the three best health achievements in the past century: universal health coverage, improvements in maternal and child health and gains in vaccine preventable and other communicable diseases.

Infant mortality rate came down from 140, that's the line in blue, to 10 per 1000 life-births, and the new natal mortality rate, from 75 to eight, there's a red line, starting from the time when Sri Lanka, then known as Ceylon, gained independence from Britain in 1948. Sri Lanka has the lowest maternal mortality rate in South East Asia. We had a steep decline in maternal mortality rate from about 1500 deaths at the time of independence in 1948 to a low of 31 deaths per 100,000 in 2010. The expanded program of immunization carried out comprehensively with the help of UNICEF has been a great success. Even during the 30-year war with the Tiger Terrorists, immunization of children in the North and East of the country was carried out without a break, after arranging a temporary ceasefire between the combatants. The last case of polio was in 1993, but we had to wait until the entire South East Asian region had eradicated polio to be certified polio-free by the who and that happen early this year, when India finally eradicated

polio. Most of the other childhood communicable diseases have been almost eliminated, or greatly reduced.

Since gaining independence from Britain in 1948, successive democratically-elected governments in Sri Lanka have followed socialist policies in providing free health care and free education - including university education to all its citizens. From 1950 to 1970, the health service was based on the primary health care model underpinned by equity and social justice, and included universal coverage. This was before Alma-Ata, which is held for all PNC model for developing countries.

Female literacy and the general high status of women in Sri Lanka were important factors contributing to the improvements in maternal and child health. In 2010, Sri Lanka was ranked 16th in the world for gender equality in the Global Gender Gap Index, ahead of many developed countries. Please, don't forget that the first female head of government in the world was a Sri Lankan, Sirimavo Bandaranaike.

Another important factor contributing towards universal health coverage was the Sri Lankan National Pharmaceutical Policy enunciated by the late Professor Seneka Bibile in the early 1970's, ensuring good quality drugs at the lowest possible price and in the minimum numbers necessary for creating diseases, in other words, the essential medicine concept. This was a landmark document and would influence the WHO to later develop its action program on essential drugs for developing countries. Professor Bibile was called "the Sri Lankan who challenged the global giants", meaning big pharma- or the transnational pharmaceutical companies. That was a difficult time for Sri Lanka, when a Western country enforced sanctions and aid cuts if the policy was not reversed. I believe a similar drug policy was also formulated in Chile about the same time.

What is the paradox we are speaking of? People born in rich countries on average, can expect to live longer than those born in poor countries. At low levels of income, an increase of income is associated with large gains in life expectancy. However, at high-income levels, the curve flattens out, and further increases in income are not associated with



significant increases in life expectancy. But some countries do not follow this general pattern. Sri Lanka, with its per-capita income of around 2000, would be expected to have a life expectancy in the 60's but it is up there in the 70's with other similar countries like Cuba, Chile, Costa Rica and China.

This slide shows Sri Lanka having the best neonatal mortality rate in 2004 among the eleven SEARO countries. This table gives some statistics and indices of a few selected countries such as population, per-capita income, life expectancy, infant mortality rate. Sri Lanka compares quite well with those of the giant US, twenty times richer.

In this table, we see five countries with healthy life expectancies. In the first column, we have the real per-capita income; in the second, the real life expectancy at birth, and the third, the per-capita equivalent of the real life expectancy, and in the fourth, the life expectancy equivalent of the real per-capita income. Let me explain by taking Sri Lanka. The real per-capita income is \$2,140 dollars; the real life expectancy is 75.3 years. For a life expectancy of 75.3 years, the predicted income would be \$9,890 US dollars. That is five times higher than the real income. For a per capita GDP of 2140, the predicted life expectancy would be 61.2 years, but the real life expectancy is 75.3 years. All five countries in this table have higher real life expectancies than those predicted according to the real incomes, for example, Australia, two years more; Chile six years more; China nine years more; Japan about five years more and Sri Lanka - 14 years more. This is the paradox. It is almost a little health miracle.

This phenomenon, good health at low cost, has attracted the attention and interest of others for a long time. Let me give a few examples. At a conference sponsored by the Rockefeller Foundation in 1985, three countries and one state in India, Kerala, were studied. About Sri Lanka, the factors identified include: expansive primary health care system provided free to the whole population; pro-equity strategies across several social sectors, and something that is not in the slide, a range of actions facilitated by the country's political system and the culture of civil society participation. At another conference, they

identified that the system had developed over a long period, that it was endogenous and not very aid-dependent. They also recommended that the WHO and international donors should support pilot projects similar to Sri Lanka's approach in other developing countries. What then were the lessons learned by Sri Lanka? What were the factors – positive factors – responsible for these achievements? The three most important are: political commitment of successive governments since Independence in 1948, the importance paid to public health measures in the national agenda, and addressing the social determinants of health. And there are very many others, but the time does not permit me to deal with these.

What of the future? We should not remain complacent, but strive to improve more and more, and face the emerging challenges of high-tech medicine and high cost of drugs. •



Good quality well accessed medical care – dream or ethical imperative

Hele Evereus

At the Estonian National Ethics Council we usually have one targeted issue for every year, because we are not working full time for the Council. It is our hobby to do the work at the National Ethics Council, and it has been one year's work to prepare the publically open workshop seminar on this issue. Estonia is a small country. Its area is comparable with Netherlands but we have ten times less people in Estonia, population is only 1.3 million.

The most important characteristics of health-care systems, as you well know is effective coverage, affordable and with quality of care. Considering Estonia, after having back our independence, after 50 years, 1991, the first thing to do - of course among other important reforms - has been also to have the Health Insurance Act, and it is very important that it has been decided to have monetary system of health insurance for all employers, self-employed, farmers and their dependents, business, full-time students, and pregnant women. Social debts paid by the state are for registered unemployed and military servants. So that I think, without coverage now, 5 to 8% of the population, this is not a bad result. I think we can be quite happy. However, what is the content of this coverage? What is inside the story? This is also very, very important. Our people are not happy at all about the still long waiting time to be attended even at the level of family doctors waiting time can be really different for different diseases. For one patient waiting time of two days is already having to make a decision; for some others it can take even longer.

Now I will explain the cost of our health care. We have a social tax of 33% divided between pension, insurance and health insurance, and what is quite unique is that our income tax is 21% this is a flat tax. This is influencing over our money which is going to be distributed for different aims. Health expenditure and pharmaceutical expenditure per capita as a share of GDP are low. This coverage has been obtained with very little money. It had its results also. I have to say, all other things, pharmaceutical, equipment have the same price as everywhere, also buildings, but of course, this is only the cost of salaries of medical professionals. But now quite a number of medical doctors and nurses are leaving the country to have better salaries.

We are having a big discussion in our country now on how to increase health care expenditure, because the costs are increasing every year and very much, and we want to have good medical quality for patients not just coverage. There is under discussion now, also, the greater role for the private sector.

If we talk about the quality, which is so important under this coverage, there are different things we have to keep in mind: safety first, effectiveness, avoid underuse and overuse. Decision makers have been the most important, of course, medical professionals, but I think the patient is the most important in all this system.

Right time for every health equity and efficiency are substantial too. This is a different aspect. We have to take into account, of course, all health-care access quality and cost. They always have been matters of societal ethical concern. This is why we have been discussing this matter in our small ethics council.

Do we have really a good quality system in our medical care? No. Estonia is lacking in an integrated national strategy for quality improvement in health care. There are few quality management tools focused on the process and outcomes. At the same time, if we think about cost, sometimes bad quality is much more costly than real good quality. If we speak about equity access, we have to keep in mind real good quality health care. Of course, we are talking; it's really easy to say that "health care professionals and health care organizations have

an ethical responsibility to serve the interest of patients”, and patients certainly have an interest in the quality of health care. But, what is the nature of this interest? What level of quality do patients want? What level are they entitled to? Six aims for improvement I have already mentioned. Altogether, assist to health care is not privilege. It’s really what a person needs. Justice and utility really require responsible, intelligent and fair-minded policies to assure access.

This has been an ethical dilemma; it’s hard to balance the percept of autonomy, beneficence and distributive justice. I’m very sure values and ideals remain significant. Very importantly, remain as an action guiding, even where they cannot be fully realised today maybe, in certain concrete circumstances, but we know what we want to achieve in the future, because I so much like the Slovenian proverb, “a healthy man has a thousand fishes, a sick man has only one”, and this is what we have to work for. •

Co-payment – a challenge to priority-setting and universal health coverage? A Swedish NCC perspective

Lotta Eriksson

First, I will give a brief comment about the Swedish health care. The Swedish health system is committed to insuring health of all citizens. Swedish health care is built on the principle of the generality in contrast to the principle of selectivity; it means that all citizens, even the wealthiest can enjoy welfare service seen as a public social right. Revenue taxes are the predominant sources of funding for health. Contributions from national government are another source of funding, while patient fees cover a small percentage of costs. Sweden's current system of health finances differs substantially from voluntary insurance, plans: the system covers the entire population with comprehensive benefits. Only dental care has restrictions for those over ninety years of age. The public's perception of the system remains favourable and the commitment to the principles of equity and solidarity of universal access are quite strong. Many of the challenges confronting Swedish health care can also be seen in other countries, include issues of access, quality, efficiency and funding.

In Sweden we have an ethical platform for priority setting. The platform was developed by a governmental enquiry called the Priorities Commission, including representatives from Parliament and also expert members. The commission presented a report in 1995 and two years later, the Parliament endorsed a governmental bill based on the proposals from the commission and also made changes to the Health Care Act. The ethical platform, the guiding principles for priority setting in Sweden is human dignity, need of solidarity, cost effectiveness which

is subordinated to other principles. The most important function of the principle of “human dignity” is to show explicitly the grounds on which priorities may not be set. The purpose with the principle is to prevent, for example, discrimination, stigmatization of human beings.

The first two principles of the platform are reflected in the Amendments in section 2, in the Health and Medical Services Act. It says first, “The goal of all health care services is good health and health care on equal terms for the entire population”; the second being: “the person with the greatest need for health care shall be given priority”. The Swedish Council has discussed questions related to prioritization and access to health care over the years. It was involved in the process when the ethical principles for priority setting were formulated in the mid 90’s.

In 2009, the Swedish Council gave an opinion concerning a proposal from a research institute to reformulate the ethical priority-setting principles in Sweden and also introducing the principle of individual responsibility, as a way of rationing health care. The Swedish Council rejected the proposal from the institute, and strongly opposed the motion to include a principle concerning individual responsibility. There were several arguments, among them, it would be impossible to definitely distinguish between ethics lifestyle versus inherited factors. You can find the opinion on the council’s website.

Regarding the impact of the Council’s opinions, so far the ethical platform remains the same. As an example, last year, the Council pointed out on the consultation response from a governmental inquiry, concerning pricing, supply and market conditions within the pharmaceutical and pharmacy area that the governmental agency decided on drug subsidies should include other values, besides cost effectiveness in their deliberations.

As a result of their opinion, the council now has an on-going ethical debate with this agency. A last example, last year in November, the Council organized a seminar 2013 on ethical and health economics aspects on orphan drugs. The main questions discussed were how can we justify high cost for orphan drugs in contrast to other drugs? Can

we afford it? There were participants from different governmental agencies, researchers, interested groups, organizations and politicians for both county councils and parliaments. This is just a few examples on how the Swedish Council works.

I would now like to introduce you to our on-going project: co-payment and out-of-pocket payments in health care. This project is a follow up to the opinion on priority setting in 2009. We have a working group within the council with both experts and political members.

Co-payment is a new issue in Swedish health care. It has been implemented in just a few county councils, approximately three or four out of twenty one. The council makes a distinction between out-of-pocket payment and co-payment: in the first case the patient pays the total cost of the health care services or product. In the latter is used when the patient pays for part of the cost. The Council focus on co-payment in their report and the following questions are in focus: is there a principal difference in degree or nature between co-payment and out-of-pocket payment? What services should be covered by the public fund system and what may be paid for by co-payment or out-of-pocket payments? The goal of the report is to accomplish a set of criteria guidelines for co-payment in the public health-care system. Co-payment raises the ethical conflicts between, on one hand, patients who can manage to pay, can improve their quality of care and strengthen their ability to make their own decisions. On the other hand, there is a risk for increasing inequalities in health care, with larger health gaps between groups and society. Out-of-pocket payments and co-payments within the public health system could also be in conflict with the principles of needs of solidarity in the ethical platform and the fundamental values of the Swedish Health Care Act.

The questions that need to be asked are: can the introduction of the co-payment lead to a change in principle and affect the health system, shifting from a general high standard system (the same for all, to lower-base level system)? And: will it have an impact on people's willingness to contribute to publically-funded tax based health care system?



Allow me to give you some examples on health-care services and products that are being under consideration in the Council.

In some regions in Sweden, the patient can choose some model outside the public health supplies and pay just for additional cost. Is this really a problem from an ethical point of view? Well. To be able to pay to get another model out of this implies within the base raised at the ethical conflict between, on the one hand, the interest of patient issues, and among several models more patients can get access to newer model faster. On the other hand, the risk that the private provider of public health sells in a much more expensive device than the patient needs. There are also concerns about possible future consequences for other areas in health care. Another example, cataract surgery co-payment for advanced lenses.

Another example discussed within the forthcoming report is co-payment for advanced lenses when you have a cataract surgery. Recently, a few county councils gave patients the opportunity to pay extra to get a lens that would also correct the patient's vision. This example poses almost the same ethical dilemma as the example before. I will just give you some of the arguments, pros and cons, discussed in the council.

Arguments pro: patients are given an opportunity to have a concomitant refraction correction when they have a cataract surgery, to buy glasses; patients who can afford get more choices and a new market is created.

Arguments against: only people with the ability to buy at extra cost and the price is rather high. This opportunity can lead to the displacement of more urgent procedures. The procedure takes longer than a normal cataract treatment and you have to have surgery on both eyes, risks of indication slippage, acceptance for co-payments in other areas of health care.

I finally, I'll just give a few more examples that are discussed in the forthcoming report: assisted reproduction, psychotherapy and to get a single room at the hospital. The report will be translated into English and will be found in our web page in late autumn. •

SESSION 4: RESEARCH INVOLVING VULNERABLE POPULATIONS WITH FOCUS ON CHILDREN

Presentation

The importance of ethical, professional and regulatory guidelines for biomedical research is widely recognized, although their effectiveness and relevance have been questioned, particularly where “vulnerable” populations are concerned. For instance, there is no realistic means of giving effect to potentially conflicting requirements in different guidelines.

Notions of “vulnerability” remain highly contestable. Certain populations, such as children, are generally thought to be “vulnerable”. Even then, it is not always clear in what sense children are vulnerable in research participation, how they should be protected and by whom.

There is also no consensus as to the extent that children should be legally permitted to be involved in research that is of no direct or personal benefit to them. In ethical literature, there has been a general shift away from a categorical definition of the term ‘vulnerable’ (e.g. through classification of particular types of people), and towards a more pluralistic assessment, so that different safeguards are required for different types of vulnerability.

Such a move requires a more holistic assessment of risks and benefits, and in a manner that is sensitive to situational or contextual conditions. Incorporating the latter is important as many of the challenges are systemic in nature.



Persistent inadequacies in low resource settings include deficient governance systems, underdeveloped clinical and healthcare infrastructure, lack of transparency, and insufficient community engagement.

However, it is questionable if ethics review bodies in developing countries have the resources and capability to engage in more rigorous evaluations of the vulnerability of research populations and to ensure that appropriate safeguards are in place. A more inclusive set of guidelines could ultimately fail to identify the very people that they attempt to protect.

In the context of these broader ethical deliberations on biomedical research involving

vulnerable populations, particularly children, the Working Group prepared a session taking an initial look at the different ways that “vulnerability” has been defined in existing guidelines and the key issues that have arisen. In addition, it considered the feasibility of a more inclusive definition of “vulnerability” and the implications of using one safeguard to cover all potentially vulnerable groups.

Introduction

Calvin Ho

This particular subject or topic on vulnerability is especially important to us because naturally, this is a critical feature in ethical and regulatory guidelines, with regards to biomedical research. Naturally, also one of the primary goals of research governance is to safeguard the wellbeing and welfare of research participants, especially the vulnerable. There is, however, a lack of consensus of how vulnerability should be understood or defined; I will provide you with an overview. Working with vulnerable participants, or what we conventionally recognize to be vulnerable is important for a number of reasons and of course, that also relates to an increasing focus in biomedical research, at least in Singapore, on a number of conditions, so we have ADHD for instance, and autism on the one hand. This is increasingly being seen as a developmental issue so researchers find it helpful to start working with children having this sort of conditions. What are some of the requirements that they ought to observe? I think that's something that we hopefully will have some time to consider and discuss. Of course, at the other end of the age spectrum, we have the elderly, typically with, or more likely to have conditions like Parkinson's as well as Alzheimer's. Again, these are important conditions to be looked into, and here we have to work potentially with subjects that may not have a stable cognitive ability or capacity, or perhaps, even, none at all. Of course finally, working with vulnerable participants would be important in improving the evidence-based knowledge of certain kinds of drugs, specially, for children.

Vulnerability is understood in different ways. Of course, the conventional thinking of vulnerability is to associate them with particular sub-populations. We will focus on two particular sub-groups, and that would be those without cognitive ability or with limited cognitive capacity, and children or perhaps we might want to call these legal minors, because children would also probably include young persons to a certain degree. Of course, that's one approach to understanding vulnerability. Another approach is a somewhat more analytical approach that's been put forward by a number of scholars. One approach is to think of vulnerability in terms of various characteristics associated with it, and here I've listed a number of them: first, the cognitive feature is quite clear, and of course the juridical feature is again very apparent for children, for instance, where you have parents or guardian, or a legal representative making decisions on behalf of a minor, or otherwise, a legal representative, depending on the country involved, deciding on behalf of someone without mental capacity. There are also arguments that perhaps, a better way to think about vulnerability is not through rarefied kinds of categories or even characteristics, but to have it somewhat more open-ended, to consider the sort of risk and benefit entailed and from that sort of weighing and balancing, put forward what ought to be understood as vulnerable groups in research. So that's one of the views that's been put forward, and then, of course there's this other notion of layers of vulnerability: we are all vulnerable to different degrees. These are perhaps different aspects that we could think about vulnerability. In this particular session, we also hope to explore some of these attempts at defining vulnerability. Regulatory approaches tend to be quite mixed, certainly that has been our experience working with a number of countries. Of course, these differences are still important, although they may be new ones, because they can have long-standing and far-reaching implications on the sort of research that can be done, and the sort of vulnerable subjects that may be included in research.

We see a need for greater conceptual clarity in our current understanding of vulnerability, and of course, this will, as mentioned, define the sort of research and the sort of subjects that we could include in research. We've also tried to consider different ways in balancing the risks and benefits. Of course, that goes to the definition of risk, as well; and also, the larger problem of how we ought to understand benefits, especially for research, that either involve population or otherwise are carried out in places where they suffer from low resources or poor governance.

Finally, there is a discussion on the roles and responsibility of individuals who decide on behalf of these vulnerable groups of subjects, what should be involved in the decision-making, how they should decide, and, finally, as governing bodies at national level, what are some of the pertinent considerations. •



On the concept of vulnerability in research

Alastair Campbell

My task is simply to look at one country's approach to the issues of this session, the views in Singapore at the moment, from the Bioethics Advisory Committee, of which I'm a member, and also a recent act, a Mental Capacity Act. My paper has three points, in the first one I will simply talk very briefly about the Bioethics Advisory Committee in Singapore. Secondly, I want to look at its recommendations, which are not yet agreed but are proposals, to do with children in research, and thirdly, to look at persons with mental incapacity and how that would be approached in Singapore.

There is this balancing act between the development of biomedical sciences, which has been very powerful in Singapore, and the protection of individual's rights and welfare. The BAC has been going for fourteen years now and its task is really to look at these ethical and social issues related to human biology and behavior, and research. There's a major focus here on the protection, rights and welfare of individuals, but also on other aspects like public education on bioethical issues. Any report produced by the BAC is always sent out for public discussion and response before being finalized.

When we come to ethical governance, then the governance of research is premised on, first of all, respect for the human body, for welfare and safety, and for the human individual; secondly, we are concerned about the religious and cultural perspectives and traditions. You may know that Singapore is a multicultural society with three main religious groups; and thirdly, with privacy and confidentiality. And the main emphasis in the guidelines on ethical governance and research is

on free and informed consent. Of course, this is why the whole question of children or minors, and the question of persons with mental incapacity, becomes a matter we have to look at more carefully. What I'm going to do is to focus on these first two groups - children and mentally incompetent adults - and the second section of my talk, will be about current ideas of how we should approach the participation of minors or children in research. One of the terms that's used is "assent", and it's not favored in BAC reports. There is no clear legal standing for the notion of assent as a procedure. In its current draft guidelines on research, the BAC retains the use of the notions of consent, on the understanding that a child's consent can be informed only to the extent that it's reasonable given the child's age, rather like in the UK, the notion of Gillick competence, and that a combination of parental and child consent is the normal requirement.

One of the other features of Singapore that's surprising to me as a Scotsman, because in Scotland you become mature at sixteen, but in Singapore you have to be twenty-one. So anyone under twenty-one in Singapore is a minor, in terms of the law, and so, the BAC's proposed recommendations concern research involving individuals less than twenty-one years old. These are divided into two sections, those that present more than minimal risk in invasive procedure, where consent from parents and consent from the child should be obtained, and to researchers to respect the child's right to refuse to participate in research, and so on, their entitlement to explanation and of course, again, consistent with the understanding of the child or the minor. In the case of those that involve no more than minimal risk, for example, surveys, the suggestion is that the IRB should be able to waive parental consent, and simply allow young persons to agree to participation without the involvement of the parent. However, the whole thing is complicated by a piece of legislation which relates to clinical trials. When you come to another act, in Singapore, the Clinical Trials Regulations, we then have a tighter control of the question of consent. So, again, the BAC has suggested a clinical research, presumably involving mainly pharmaceuticals, that has a reasonable expectation

of benefit in a child, might be allowed to proceed, even without the child's consent if the parents give consent. And here, the welfare and the best interest should be the first and paramount consideration - the young person should not be exposed to greater risks than those in their everyday life, so the minimal risk criterion. The child or young person has a right to express their views, and their negative preferences should be respected. Now you notice that is a rather looser phrasing at this point in relation to clinical research. Refusal might be overridden in a situation where there is not an obvious risk, or where there is benefit for the child. Say, the problem again is the uncertainty that a level of acceptable risk is unclear and one would expect some benefit before you would override any refusal by the minor.

Secondly, then, I want to talk briefly about the Mental Capacity Act in Singapore, which allows for a deputy to be appointed by the court or a donee to be appointed, and this would often be by the person themselves, making a lasting power of attorney declaration prior to losing competence. Either the deputy or the donee can give or refuse consent for medical treatment. And they may decide on the person's participation in clinical trials. This means that persons who are incompetent, nevertheless, may take part in research, if this is agreed by the donor or the deputy. However, the powers given to these individuals do not extend to life-sustaining treatment or a treatment necessary to prevent a serious deterioration in the patient's condition; and at this point, any decision would be a decision made by the medical practitioner involved and not by the donee or the deputy. The deputy or donee must act in the donor's best interests, and must carry out the donor's instructions and make decisions and so, they can give consent for the person lacking capacity, provided 1) that the individual has previously indicated a willingness to participate, or 2) and this is like a substituted judgment, consent would, in the judgment of the deputy or the donee, have been given by the individual, had that person been able to make an informed choice.

The main guiding principle here is, first of all, you must consider whether the patient would regain capacity, in which case you would not

make any decision because they could make a decision later. Secondly, you should consult widely before making a decision about getting involved in research, and you should look at the person's past, present wishes, beliefs and values, and other factors. So our act, the MCA act is really very comprehensive in how one should approach any decisions made on behalf of this particular group.

There is no simple definition of vulnerability, and we certainly shouldn't put a whole class of individuals, whether these be minors or persons with incapacity as necessarily vulnerable, we have to look at the situation. Secondly, when we are considering this a holistic assessment is required there shouldn't be a quick decision one way or the other, in relation to whether research is ethically permissible; and the most general standard that applies is the best-interest standard, although it's unclear, I'm afraid, in any guidelines we have in Singapore, just how direct that benefit should be. For example, if it were benefit to a group of which that individual was a member, is that enough? Or should there be some benefit to that individual? And of course, any likelihood of harm will necessitate greater justification for involvement of vulnerable persons, so the degree of risk is highly important in terms of decisions here. •



Towards an ethical framework for the involvement of children in research

Hugh Whittall

I'm going to talk, briefly, about a report we are currently working on. So we have a working party looking at the issue of the involvement of children in clinical research. This is an on-going piece of work, so I'll be reporting not any conclusions, but rather just some initial thoughts and observations, and an indication of the direction that we are travelling in. The starting point that we had for this was really the rather binary question of how to resolve the kind of really long-standing dilemma of how you develop evidence-based health care for children given that we are frequently giving them drugs and other interventions that have not actually been researched or tested in children, while on the other hand, providing proper protection for them. Whilst we saw that as a kind of a simple question, it didn't take long before we started talking to people to realize that we really ought to introduce a third aspect to this, and this was to raise the question of what the role of children themselves should be in terms of making decisions about research involvement. It wasn't just a question of protection, but also about participation, and in a sense this took us immediately to the question of vulnerability, because of the sense that the point about protecting children, because they would seem to be vulnerable. The notion of vulnerability sort of runs through this, the work that we are doing at the moment, because if we take a rather uncritical response to the question of vulnerability, this leads the problem in itself.

I wouldn't normally talk about the process here, necessarily, but I think in a way it's quite important to note that we are working with

an expert working party, it involves people with expertise in medicine, nursing, ethics, law, social science, etcetera., and we've got an international dimension as well, with people who are working at the major research center in Kenya. But importantly, we are also working with children and young people themselves throughout the process of this particular piece of work. In the course of our gathering evidence from various people, we've got a stakeholder group that includes young people and their parents. We are working through communities in school groups, as well, putting together focus groups both in the UK and working with others in Kenya. We have particularly targeted also children in schools, we are going to talk to children in schools so that we are not talking to people who have been involved in research, but also children and young people who wouldn't ordinarily have thought to take part, who wouldn't have necessarily given a thought to this or have got involved, for example, just in an online survey. We've also had what's been a really interesting piece of work which was, we set up a mock research project, a mock research ethics committee, and we shadowed it with some children's research ethics committee, so that we put a proposal through one committee and then had children as well comment on the proposal and the conclusion that the adult committee had made. This was a really interesting, got some really interesting views, and we've captured that in two fifteen-minute films that are available through our website, that are actually quite instructive in terms of how research ethics committees work in this area. The latest stage that we've got to was to hold a stakeholder conference. We drew together all the input that we'd been getting so far and prepared more background material for this. We held this discussion with other young people, people involved in the UK's Children's Research Network, with parents, with researchers, and academics.

We find ourselves with two starting points. One is the perspective that we are now taking on research. Research with children, and I say with children, because we are absolutely certain that we should not talk about research on children, but research engaging children,



research involving children is essential. We shouldn't apologize for it. Too often we seem to have this still prevalent notion that research with children is intrinsically ethically suspect, because we are doing research on people who are vulnerable. We were certainly for developing the idea, and the stakeholders during our meetings, whether they were parents or children or others, certainly endorse this idea, that we should not be apologetic about research. We should recognize that it's essential to carry out research involving children in order to deliver better health care.

The second point is the one I made earlier, that we should be carrying out research with children and not on children. In a sense this comes back to the challenge about the question, about vulnerability, and if we do engage children, if we do our research with children, we involve them, we listen to them, and we talk to them. Actually, one of the ways that we can reduce the potential vulnerability is precisely through that kind of engagement, and this again will be a theme that I think will come through forcefully during the course of our report. The second starting point concerns our approach to children and their parents. We should think about children as social agents. We do this from an early age. I should say that when we talked about children being social agents in our discussions, within our working groups, within the conferences that we had, we were told very firmly not to call them social agents. This is not a term that meant anything to them, and so we've got to find different types of language. But the point is that children from an early age are not merely the subject of research, or subjects of protection. They're engaged people who are involved in social environments, in particular, within their families. So, from a young time they have social agency; we of course have responsibilities to look after them, but that is rarely going to be wholly a one-way process. We have, for quite a long time now, recognized the importance of family-centred care when we think about delivering health care, not specifically research, and about how children are usually embedded within social family networks. Families aren't always perfect, but we must recognize that the decisions that are

made by, with or about children usually involve other people. They are rarely decisions that are simply made by parents or simply taken by children. We need to, in some ways, unpack the kind of role that parents have within the decision-making environment in terms of decisions about children's involvement in research. Parents, of course, must have concern for their children's welfare, but one of the things that parents also do is support their children in helping them to become decision makers, support their children in helping them to become citizens; they support their children in helping them to develop their own values, which might include the values of altruism, which might motivate children to be engaged in research. Of course, this is a developmental thing. There is a very different situation for the child of three, six, ten or fifteen, so the extent to which the parents and the children engage with each other, the ways this happens will change over time to the point where the child becomes an independent decision maker. But even then, one fifteen-year-old child may want to make a fully independent decision, another fifteen-year-old child may well want to discuss it with their parents, or ask their parent to make their decision for them. All of these things happen, all of these things are possible, so I think we have to recognize the parental role, the way that decisions are made within families, are always going to be very complex. It kind of raises the question, then, of what this means for the notion of vulnerability, if we are questioning the idea that we are protecting children because they are vulnerable. But I think it would be wrong to abandon the notion or to think that it doesn't have a role to play in this. There were some very clear messages that came out; first, this was that the notion of vulnerability should not be dismissed, it can be a useful alert, it can be a flag; if we recognize the potential for vulnerability, we need to stop and examine the situation. But we must ask the question: vulnerable to what? If we consider there is the potential for vulnerability, what it is. It is not simply to say, "Let's stop!" What is the actual challenge? Is it the risk of harm? Is it a risk of people being distressed? Is it about the inability of people to make a decision for themselves? And we can think of



ways that we can deal with those particular challenges, in a way to think about how we can lift the layers of vulnerability that might be there. Let's remember that not only children can be vulnerable: we all can be vulnerable in different circumstances, whether it's about being in an alien surrounding, in a hospital, whether it's being at a time that is difficult if we've just have a pretty poor diagnosis, if we are ignorant of particular facts. All of these are things that can make us vulnerable, whoever we are, and one of the things that we can do is to try to alleviate each of those conditions to reduce the vulnerability and increase the opportunity for participation by the person.

The notion that we are developing is this question about challenging the idea of vulnerability, allowing us to give the opportunity to ask the questions about what needs to be addressed, and looking at information, engagement, and empowerment of the person who we would otherwise see as vulnerable, not dismissing in any way whatsoever the questions about recognizing the interests of individuals and protecting them from the clear harms that might be involved.

How does this play out, what are the kind of things that this might mean in practice? What might this mean in practice? Questions for example about study design. If we are talking about involving children, let's not wait until the end of the story, let's not wait until we have got them in a clinic in front of us. Why not get them involved at earlier stages? We've got a good example in the UK of young people's groups that are part of a children's research network. What this facilitates is that researchers can put their draft research proposals together, and run it by the children's research network and get some feedback on their proposed information sheets and on study design. We are told that if you put this in front of groups of children and their families, they often take the studies to pieces; they rip them up, because researchers don't necessarily anticipate the kind of things that would concern children or their parents. There was a very nice example I was given of a researcher who was asked, "What do you think is the main objective for children involved in this clinical research?" and the researcher said,

“To get healthy, to get better”. When the children were asked, “What’s the thing that you really want to do?”, and the child said, “I want to go to school like everybody else does”. That’s a kind of simple observation, but if then you organize your clinics for ten o’clock every Tuesday morning, that’s frustrating precisely the thing that the child wants to do. So, this question about design can work in fairly simplistic ways, but important ways for the child, and involving the children in design can be quite important, and their families. The second area that we’re looking at is the role of the research ethics committee. There are often anxieties that the RECs can be too paternalistic. This is sometimes because within the membership of the committees there is a lack of understanding, a lack of expertise about the state of health, about the potential for the research. We need to make sure that research ethics committees get input, not only from pediatricians, who will know about the potential for the research, but also possibly from children, and families, and parents who know what living with the condition is like, who know what kind of offer of research might be a reasonable offer to make. Research ethics committees, in many ways, need to make sure they are getting expert advice, and sometimes, the experts are going to be the children. •



Informed Consent in Research Involving Children with Cancer

Michel Daher

I think that it was very important that children with cancer can be considered as a special vulnerable group, and to talk about this category of patients who are submitted to research. Cancer in children is not very frequent; if we consider that we have ten million of new cases every year in the world, we only have one hundred sixty thousand children diagnosed with cancer, although this is not a final number, because, in some developed countries, cancer registry is not accurate. The specificity of cancer in children is that it is more curable than in elderly patients. We can consider that in developing countries the chances are almost fifty-fifty, while in developed world it can reach 80%. Reporting to the United Nations Convention on the Rights of Children, we can see that two rights are prominent in this convention. First, that this category of patient must be protected from harm, and this is the first principle, or basic principle of ethics; but also, that they have right to express their views and have them taken into consideration. What are the needs of a child with cancer and his family? We may say that we have almost seven needs, the first need is the need for information, and I think that this is the introduction to all the treatment, and then you can prepare and put a care plan, treat the symptoms, take in consideration psychological, social and spiritual support for the patient and the family. Information is the principal right. That is the difference between legislations, on what to inform the patient, and about truth-telling in general and information particularly. It depends on the cultural and religious variables, and of course, ethical and legal norms in different

countries. Children with cancer will be admitted in a clinical research, and this is a very good approach, by submitting to clinical research, we could cure more and most of these children. The researchers, and of course, clinicians, must take in consideration the challenges that they have to deal with cancer patients, especially with children with cancer, and concerning this particular part of the research, the informed consent. To say that informed consent is a process means that is not only one time that we deal with the patient, it's an on-going process while we present the information, while we explain the meaning of the research to the patient and his family, answering questions and discussing. All this must be an on-going process along the research process. This can include the right for dissent, which is a right to refuse at any time and to be dismissed from the research study. The elements of informed consent are mainly the competence of the patient, who is able to decide and understand what you are telling him, and second, voluntariness, of course. And the elements are well known: the disclosure by the investigator, and understanding by the subject who is submitted to research, and of course, being able to give his decision. The consent form must be very complete on this point, including all this, the possibility to be dismissed from this research, and of course, consent.

Why informed consent in cancer patient is important? First, this is the second principle in ethics: the respect for persons. Because of past abuses in research, we have to, actually, develop all the time this informed consent and keep it very accurate. We refer to the Nuremberg Court and recently to the update by the Declaration of Helsinki. What must be disclosed to the patient? First, the purpose of the research, of course, the procedures that he's going to be submitted to, the risk that he can encounter in this case, and of course, the benefit that the patient would get from this clinical trial, and that the confidentiality of the patient will be respected at all time, and of course, the compensation in case the patient would have some injury or some hazards from the research study, and all the time he must understand that his participation is a voluntary one and that he can withdraw at any time from the research.

Concerning only the informed consent, can a child or a young person consent, for him- or herself, without the additional consent of a parent or guardian? Yes. The answer is yes, most of the time, if the person is mature, and if the adolescent can take decisions for himself. I think that the parental consent, in this case, wouldn't be mandatory.

Is parental consent always needed? No. We need the parental consent only if the patient needs additional protection, or he is not able to understand or to appreciate what the research entails, or if he doesn't understand properly the information given to him. What constitutes assent and dissent? Assent is an affirmative agreement to participate, but it is not an informed consent in itself. When the patient cannot give an informed consent, or when the family is doing that, we should request the assent of the children which can be an alternative to get a clear informed consent. In the same time, it must accompany the consent of the family. In the other way, the dissent is the opportunity for the children to say no. He must understand that he can refuse to be submitted to this research or to the treatment, and it gives him a recognition so that he can withdraw from the research study.

How much children should be told about the research when they are not the ones giving consent? Yet, the answer is as much as they can understand. It is for the clinician or the investigator to appreciate how the child is able to understand the information that he is getting. We consider that it's important to give him all the information because it's psychologically good, and it may be less frightening for the children who are submitted to a research study, it can increase trust from the parents, the health-care professionals and all the group of investigators. This would lead to further cooperation from their children in the research study and it demonstrates respect for the child. As much as we can, we should give information, it will be positive for the process of research.

Is it acceptable to involve children in research if they won't directly benefit? Sometimes children are submitted to procedures, or lab tests, or some other kind of investigation, and they are not getting a direct benefit from this procedure. The answer is that it can be acceptable, given that it can't either be harmless to patients or increase their risk.

It benefits the children as a population without a major risk for the patient, and of course, all this time, we have to consider that the comfort of the patient is paramount during these investigations.

Finally, how can we make sure that the existing power relationship doesn't impact on the consent process of children and young people? Sometimes the child is put in a power relationship with family, with the investigators, with the environment. I think that we have to minimize the effect of this power relationship, but by making it clear to the patient that he can say no at any time, and that he can be able to withdraw from the clinical trial or research study, and this will give him some power. When the research is done in an educational setting, and it happens, most of the time, with children that are in an educational setting, it is important that the researcher makes it clear to the patient that he will be able, even though he is in an educational setting, he may withdraw from research if at any time he decides that. In conclusion, clinical research has been and will continue to be essential to improve survival, decrease disease and improve the treatment for children with cancer. We saw that the curability of this disease is very high and is increasing; it could reach more than eighty percent, in our time. Informed consent is central for the contact of cancer clinical trials, and for a good patient care. The participation of children is very complex; it is not like in adults, who have to decide for themselves. Here, most of the times we have a limitation with the age of the patient, the power imbalance between children and adults, and in some cases, the health status of the patient. And it is important for researcher and clinician to understand these challenges so that progress in cancer treatment is achieved in a sound, ethical and in a regulatory fashion. •

Safeguarding Children: Pediatric Medical Countermeasure Research

Christine Grady

I am here today on behalf of the US Presidential Commission for the Study of Bioethical Issues. I'm going to talk about a particular project that the Commission did, related to pediatric research, and it pushes the envelope a little bit in a number of directions.

The first question is what circumstances, if any, might justify exposing children to greater than minimal risk in research? Another question is, other than limiting risk, which we pretty universally believe in, what other protections can we or should we use to protect the rights and welfare of children in research. And third, thinking about the particular possibility of a bioterrorist event, which is an unknown and unknowable kind of event, how does that affect the contours and the ethical decisions about research, especially, with children.

We are a presidential commission, we were put into place by an executive order of the current US President, we are at his behest, we serve as an advisory commission to the President of the United States, and when his administration is over, we will be over. So we are not a permanent commission in any regard. We are, however, multidisciplinary: scientists, lawyers, physicians, bioethicists from the different parts of the United States. We've done a fair number of projects since 2010 when we first came into being, but I'm going to focus on "Safeguarding Children Pediatric Medical Countermeasures Research".

Early in 2011, the United States government conducted an emergency preparedness exercise they called Dark Zephyr. Basically, the goal was to test local, state and federal responses to a simulated anthrax attack

on a sort of typical US city. The conclusion was, in this test, that about eight million people would be exposed to an anthrax exposure in this kind of attack, about two million of those people would be children. The planned response to an attack would be to give everybody antibiotics and an anthrax vaccine. One of the many conclusions of this exercise was that there was no evidence supporting a clear plan for how to deal with the children in an event of such an attack. Later, in that same year, the National Biodefense Science Board in the United States recommended that, based on the scientific knowledge of how the anthrax vaccine worked in adults, and the facts that there were no data in children, that the US government should conduct a pre-event study of anthrax vaccine in children. But then they added an appendix to their statement which says, "Pending for review of the ethical considerations". That's how it came to us. It came to us through the Department of Health and Human Services. The Secretary of Health and Human Services asked us to look at this issue of doing research in children for them to be prepared for public health emergencies, with the particular focus on the anthrax vaccine, but not limited to that.

We have public meetings, and by law all of our meetings, all of our deliberations are done in public. They are open to the public, we do invite people to come and speak to us as subject matter experts, but also, community representatives, in some cases. We also published a request for information from anybody who wants to respond in the US Federal Register. There's also a website, some targeted outreach to get comments from particular groups. That's the process that we use in this case. We recognized, of course, that the general focus on pediatric research is protection: everyone recognizes that research with children is ethically distinct from research with consenting adults. The children have a generally respected diminished amount of autonomy because of their ability to understand and their ability to make voluntary decisions, and those diminished capacities make them vulnerable. They also don't have the legal—in the United States, in many jurisdictions as well— or ethical capacity to consent to accept risk for the sake of others. We have an obligation to protect them, and we recognize that

of course parents or their legal guardians make most decisions on their behalf.

We turned back to a previous US Bioethics Commission, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, which was the first US Bioethics Commission in the 1970's, and wrote the Belmont Report, which delineated several principles that many of us believe are guiding principles for research in general. That commission also did a report on research involving children, and it was a very important report at the time, and it has served as the basis for the regulations that guide us in the United States. The Commission in the 70's said, "The ethical principles at stake are the moral obligation to protect the community and the moral prohibition against using non-consenting persons at considerable risk to their wellbeing for the promotion of the common good". Our regulations in the United States, based on the work of the National Commission in the 70's, basically protect, add additional protection for children by regulating risk. There are different sections to the regulations, and proposed studies are reviewed based on whether they expose children to minimal risk, whether there is more than minimal risk but a prospect of benefit, whether they might be more than minimal risk, but a very vital question to answer about the condition that the children have, and those three levels of risk are allowed to be reviewed and approved by a local IRB. The regulations also allow for this sort of exceptional category - research not otherwise approvable by a local IRB that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children, and the regulation says that this requires a different process, a national level review and a very public national level of review.

Basically, the central ethical tenet of these regulations and the National Commission's work is that research with children is ethically permissible only when the research exposes children to minimal risk, unless there's a prospect of benefit to the children in the study, there's a prospect of vital generalizable knowledge about the children's condition, and then maybe this is an extraordinary circumstances'

category. Our current commission also recognized, based on the work of the National Commission, that there's an ethical obligation to safeguard and improve the health and wellbeing of children by doing research, coupled with recognizing that they are vulnerable and need to be protected. Over the past fifteen years, and certainly in the United States, there have been some changes in views and in policies that have evolved from a strict focus on protecting children from research to a greater recognition that we need to protect children through research, by understanding how to treat them in a number of situations, and we need rigorous data to support the safe and effective use of drugs, biologics and devices in infants, children and adolescents. Of course, that comes with the responsibility to conduct that research very carefully and to make sure that the research is scientifically necessary, clinically useful, and ethically sound. With that backdrop, we have a very unusual situation here, in terms of medical counter-measures. This is a measure of whether or not we should be doing research and under what circumstances. We should be doing research that aims to protect children in the event of a public health emergency, but is balanced against the need to currently, or all the time, protect children from unjustified risks in research.

The Commission came to the conclusion that there were two ethically distinct scenarios to consider. One was pre-event medical countermeasure research, and the other is post-event. Basically, this just means the Biodefense Board said we should do pre-event research, meaning, do research now to know whether or not the anthrax vaccine is safe and might be effective in the case of a bioterrorist attack. Pre-event research is complicated ethically because it involves healthy children that don't have the condition that the study is meant to study, there is no direct benefit for those children in the study, and there is an unknown likelihood that the benefit of learning about the particular intervention will ever be needed. In fact, the hope is that it will not ever be needed. There is not even really a clear sense that this will definitely offer benefit to children as a group. That's different than post-event studies; these are studies that would be done in the event of a terrorist

attack, and in that case, children are already exposed. In the event, it might be possible to do research that would provide direct benefit to the children that have been exposed, or to gather important generalizable knowledge about the condition of exposure to whatever the agent was. But in that context, research is very complicated: there's chaos, there's all kinds of reasons why it would be very difficult to do good quality research. The Commission came up with a couple of recommendations about this. The first was that, in pre-event paediatric research, MCM research should pose no more than minimal risk except under extraordinary circumstances. This goes with the general tenet that children can be involved when there is no more than minimal risk. What we came to conclude was that there were some kinds of studies that could be done to prepare for the possibility of a public health emergency that only involved the minimal risk for children, and so that those were the studies that should be done first. If there were any reasons to do pre-event studies that involved more than minimal risk, that that risk had to be capped at what we call a minor increase over minimal. I'll come back to that. The second recommendation had to do again with mitigating the risk for children, but before beginning pre-event pediatric studies of medical countermeasures. Other kinds of studies with young adults, and in animal models and in mathematical modelling and other kinds of studies that could be done to give us more information, should be completed, in order to be able to identify, understand and characterize the research risks that children might be exposed to. Then, if there was a reason to start research in children, then we would start with the oldest children, and employ a progressive age de-escalation process, since older children, adolescents, often have the capacity to understand what they're being asked to do in a way that younger children may not. Then, we applied these two recommendations to the specific case of anthrax vaccine, and said that there need to be a third examination of the data that already existed in young adults. This is a vaccine that has been used extensively in the military, so there are a lot of young adults who have received the vaccine. We need to really comb those data to understand the risks

and determine whether they are or could be considered minimal, and then do additional research with the adults that would inform research with children. Then proceed under the two regulatory categories, one being minimal risk, if possible, and the other being the exceptional category, which require a different process.

We recommended that if minimal-risk research was impossible, then pre-event research should only be done if it's done through this extraordinary national level review process, and only if it poses no more than a minor increase over minimal risk, that there is no way to justify anything greater than that in this context, so that there should be no substantial risk to health and wellbeing, and that this national process has to occur. Let me say, briefly what this national process is envisaged as. This is basically from the federal regulations of the United States. Basically, it says that in the case of extraordinary circumstance where research cannot be approved under another category and cannot be approved by an IRB, therefore it would be a category of no prospect of direct benefit to the children, no study of the condition that children already have, and higher than minimal risk, then the Secretary of the Department of Health and Human Services needs to consult with the panel of experts in order to determine that: (1) the research presents a reasonable opportunity to address a serious problem that will be conducted (2) in accordance with sound ethical principles and (3) that provisions are made for parental permission and meaningful child assent. The regulations say this, but no more, about what those things mean. The Commission took on the task of trying to specify what some of those details meant in section 407, and the fourth recommendation was to apply the framework that we had proposed. Let me just say a few words about this framework.

The three parts, remember, are a reasonable opportunity to understand a serious problem, and so we thought there needed to be more attention to how do we know if this is a serious problem, so there needs to be in each case of a possible threat, whether it be biological, or chemical or radiological. There needs to be some data to understand the consequences of exposure to that particular agent, the likelihood

or threat of that exposure, and that's a pretty unknowable thing, although there are certainly lists of more credible threats that the Department of Homeland Security and others maintain, and that it would be a serious problem that would present an opportunity to understand something of vital importance to protecting children in the event of such an attack. The second thing that we took on were the sound ethical principles that might guide this extraordinary circumstance. We suggested several. One is that there is an ethical threshold of acceptable risk, even in an extraordinary circumstance as this. Secondly, there should be great attention to the details of the research design, so that it's ethical and there are some details at the left of the slide that I'm not going to go through. That there need to be put into place certain requirements at the end of the trial that would ensure the ethical treatment of children and their families, including a protocol for distribution of the product that was tested so that all children could benefit from it in the event it was needed, and also compensation for research-related injury, for the children that were in the study. There also needs to be community engagement for this kind of research, especially both pre- and post-event kind of research, and attention to transparency and accountability. The third element is securing adequate provisions for soliciting the permission of parents or guardians; it is a challenging process in any event.

Let me just say one word about post-event studies. As I mentioned earlier, the ethical and regulatory differences are there, but the scientific and logistical challenges are enormous. There would be stressful and confusing circumstances, parents and children might not be in the same place and there might be only different kinds of studies that can be done. It would involve different parts of our federal regulations and we thought, as a commission, that there were two things that we needed to say. One was that, if there was not a pre-event study and there was a bioterrorist attack, then post-event research was absolutely necessary, but that it should be planned in advance and that there should be certain things that the IRBs must ensure, and I won't go through them, but they are on this slide, and that there need to be sort

of regulatory preparations as well. Just to end, I think the Commission's conclusions were the health and security of children are paramount, that children should be protected in the event of a public health emergency, but also protected from unjustifiable research risks, and that we should have an unwavering commitment to protect children from unacceptable research risks, and through research that promotes their health and wellbeing in a number of circumstances. ●



BIOETHICS ON THE GLOBAL LEVEL: ISSUES AND CHALLENGES

The role played by international organizations in the strengthening of NECS is critical. From different perspectives, and at a different levels, organizations such as WHO, UNESCO, DH-BIO or WMA provide technical support, guidelines and knowledge useful for increasing NECS' capacities to help governments deal with ethical dilemmas arisen in local contexts.

Thus, international organizations are excellent partners for NECS. Their global perspective is critical to harmonise guidelines on issues like research ethics, biobanks, etcetera. During the session, international organizations presented their actual working agenda, perspectives and future projects.

Christiane Woopen: I want to begin with my first question to Hans van Delden from the Council for International Organizations of Medical Sciences (CIOMS). They have a working group on the revision of the CIOMS ethical guidelines of bio-medical research, and this is a subject that is interesting for us. What are the main challenges, or what are the main changes in research that brings you to revise the guidelines, and what will all of us have to think about in the future when we want to do responsible research?

Hans van Delden: This is a huge challenge. What these guidelines and the revised guideline should look like is not a document that really captures the past, but actually that serves the future. We are trying to write something that will be helpful for the next ten years. Of course, the danger is that we write something that nicely captures what we



have come to see in the past ten years, instead of what is apt for the coming ten years. We are trying to strike a new balance between protecting individual interests and the interests of society. Quoting Christine Grady, “I think we’ve come to the realization that we do not only want to protect people from research, but actually also protect people through research”, that research can be a means to protect people, because if we do research, we will get knowledge, and that knowledge might actually be a way to serve their interests. If we acknowledge that, then we indeed have to have another picture of research, but also another picture of the guidelines. One issue in that respect is whether you want research to have social value. In the CIOMS there is an intent to have a guideline on social value, and it is a pity that the Declaration of Helsinki did not have that. It covers, of course, risk benefits, balances, but there is not really a pre-requisite condition that research should always have social value and in CIOMS we thought that this really should be the case. We will have a guideline on social value and that means that committees in reviewing a research protocol will have to be convinced by the researcher, obviously, that indeed there is a potential for future benefit for society in this particular protocol. There are all kinds of challenges here, but that is one of the attempts to make this future-proof. There are other issues, which actually have also been talked about this morning, such as how to, acknowledging vulnerability on the one hand and on the other hand involving people who are vulnerable in certain respects in research, at the same time. In the CIOMS we try to be as specific as possible about why we do certain things. According to Christine Grady, “if we do involve children in risky research, then, when is that OK? And, is risk limitations the only instrument we have in, sort of, protecting their interests?” My answer – and probably hers – would be that there are other instruments as well. We can really also have a discussion on which instruments to use to protect, on the one hand, the vulnerable side of these people, but on the other hand also their interest in being part of research. There should be an opportunity to involve them in research.

Christiane Woopen: I come to Laurence Lwoff, from the Council of Europe. Where do you draw the line between things you can solve, or think about at least, on the level of principles and universal rights, and things where we should all agree upon, and those where we say that there are differences in moral, habits, attitudes and so on, that are justified on the cultural level? We are on the global summit; so many cultures are coming together. We don't want to melt them, we want to preserve them, but there are things where we should really have a consensus on – on protection of human subjects and so on. How does the Council of Europe deal with this line between universal rights, or universalized laws, legal rules, principles, and cultural principles?

Laurence Lwoff: The Council of Europe is a regional organization compared to the geographical scope of this event. I think that was important when you mentioned principles. There are some core values which are the basis for developing principles. I dare to say that those developed at the Council of Europe, even though being original organizations, have been recognized of having universal value by, for example, the reference to the Oviedo Convention in the Declaration of UNESCO. I would say where it becomes possibly a little bit more difficult is when you start developing provisions in the legal instruments based on the principles; both because the devil is in the details, so to say, and also because, even though agreement in principle can be reached there, there might be situations where you have tensions between principles, and the hierarchy of those principles may vary. This can obviously be the case at global level, but also at European level, at regional level. When you are talking about a legally binding instrument, you would define the provision in a way which were quite simple, giving the fundamental principle. The way it will be implemented will be developed possibly in the explanatory report, as examples, but then the margin for manoeuvre will be considered to be greater by the state. That doesn't mean that it's completely opened. This is part of the discussions in agreeing and in principle. The explanatory report intends to describe

the intentions of the drafters, so it sets some limits to the state. This is especially important when you go on something like the decision-making process, the guide on end of life, which is a very sensitive issue, whatever level you take. I think this is not a legal instrument, it goes much more into the details, so it can go further in referring to the different positions, to the different attitudes, the different roles of the people involved and you can develop on that, while considering that all these elements are not jeopardizing the principle that is behind it. But we also have to acknowledge that on certain issues it's not possible to get agreement, even at the level of principle. I think this is the case on certain end of life issues and on certain beginning of life issues, which are probably the most difficult areas. It's not solved even at regional level, due to the nature of the discussion. What matters is not the end result of a standard-setting activity, but the whole process, because the process of developing a legal instrument involves exchange and consultations. It is more meaningful, since the discourse is developed with a better understanding of what the elements and the stakes are, and because there is a greater possibility to reach not only minimal consensus, but consensus on what all the necessary principles should be to protect the value on which we agreed.

Christine Woopen: I agree that ethical deliberation is not necessarily finding the minimum, because morals mean more than finding the minimum. I turn now to Jim Dratwa, from the European Commission. We not only have research ethics committees, ethics and bioethics committees dealing with something else than research but bioethics, but that they've broadened the scope to energy security, surveillance, technologies, so that seems to be a completely different realm of topics. How to deal with this and how to guarantee that, we, in our national ethics councils, have the experts to deal with all this topics?

Jim Dratwa: On the role that we see for ethics committees, for ethics councils, it dovetails in a way with the discussion we had yesterday, highlighting the differences between our different national committees

and also looking at the particular path dependency, the particular history, which led different ethics committees to do the work that they do. More fundamentally, it touches on the question of the role of ethics councils, the role of the work that we do, all of us in our different ways. Very specifically, it is indeed the case that at the level of the European Commission, whereas if you look in the early 90's, the inception of the different structures we have in place were very much centered on biotechnology and on the biomedical, so really the core bioethical issues –end of life, beginning of life– but also with a particular take already at that time on biotechnology. There's being a remarkable evolution too, which is an evolution that is marked importantly by the EU Charter of Fundamental Rights, an evolution bringing this ethical reflexivity to all areas of public policy, to all the key issues of our time. Indeed, energy choices are very important, as are information and communication, technologies. This is a very exciting project that we've just completed a few weeks back on the ethics of security and surveillance technologies. Think of Edward Snowden, think of what happened to you on your way here as you were passing at the security checks at the airport and more broadly, really, the question of what world is it we want to live in. The next opinion that the European Group on ethics will be tackling, the next of the issues are to do with, within the realm of health and health technologies, this key interrogation on the different modalities of involvement of the public, of the wider public, in the production of knowledge and innovation, and also in the production of this ethical reflexivity.

Very concretely on the issue of expertise within our respective organizations, or committees or councils, I think one of the learnings that we've acquired as different organizations and also as a community of friends and colleagues, is the fact that we don't know it all. This is much taken at heart in the way we organize our work, which is about involving as many stakeholders, as many different voices, different forms of expertise, although of course this concept itself has to be reflected upon, as many different voices to broaden the ethical reflexivity debate, our horizons, in terms of ethical deliberations. Not



relying on expertise that we would have in house on every possible topic, but relying on the notion that we can't know it all and that we have to take the different voices from outside as well.

Christiane Wopen: You have provided important considerations about encouraging us to broaden the scope, and to just pick up the most pressing subjects in the country and just to invite the experts you need for them.

There's a question of networking as well, so I come to the WHO, and Abha Saxena, who has a lot of experience in that, now in being the prominent Secretariat for the Global Summit, and to put all the email lists together and identify the partners. You'll try to bring the NECS together on a regional level, and so on, what the UNESCO does as well, but we saw on the Steering Committee that the networking is a tricky thing. Whether resources can be pulled, or whether the relationship between NECS and international organizations can be organized in a way that everyone knows from each other and that not two organizations have to do the same thing twice, what are the main challenges of bringing NECS and bioethical institutions together so that they share their information?

Abha Saxena: Yes, networking is always a challenging task. It's not something we are taught in our formative years, it's not a course that people do, so you learn to do the networking on the job, so to say. What I found most challenging was this presentation for the Global Summit. It was more challenging, partly because of the different natures of ethics committees across the world, different countries have established different mechanisms for the National Ethics Committees. They are not the same. In some countries, they're bioethics committees; in some countries they're commissions; some countries have research ethics committees. They all do similar functions, but still they're slightly different, since they are under different ministries, under different umbrellas.

We work in the area of health, who is focused much more on public health and health-related issues. It is by working with other organizations, for example with the UNESCO, that you see what sort of institutions they are looking after, so that we can get together. We work with different colleagues in one country as well, seeking common issues that they can talk about on the table. We look for a middle ground, because some NECS may be focused more in research, but still they're talking about ethical issues – research still involves human beings. They are still talking about risks and benefits to different groups of people, and they can still talk on the same table with other NECS who are perhaps looking at more societal level issues or who are looking more at let's say even energy-related issues.

We can still be on the same table and then talk of the same issues in a different context.

They learn from each other, while one national ethics committee focuses on one area, another ethics committee might have a different perspective that may enrich their own point of view. That is an achievement. It's challenging, but it's also rewarding.

Christiane Woopen: What we should think about as well is not only that the NECS that are present here bring some information back to their NECS, but that we make something out of this global summit. We should really be aware of thinking what we can contribute as a global summit, being here together. Finally, I'll come to Dafna Feinholz and back to the issues the World Health Organization is mainly dealing with, since the UNESCO's scope is broader. You have your organizational complications at the moment with all the committees and restructuring, we all know that, but what do you think are the main challenges we have to deal with? Do you think the global summit can contribute something?

Dafna Feinholz: Well, the restructuring in the UNESCO administratively can be very burdensome, but I think thematically it's going to be very



interesting because we've got now together bioethics, and ethics of science and technology. Already UNESCO was very well positioned in order to address bioethical issues, because we have all the science, the natural sciences, the human and social sciences, the science and technology, we have the communication, we have education, so that's why it's very natural to discuss bioethics in a very wide way, which is always related to health but it doesn't have to stay with health. That's why it can cover National Ethics Committees in this wider scope of action. That's why we've tried to work with these types of National Bioethics Committees to bring them together, also, when they are in their work regionally, and also internationally. We are also trying to bring them into how we can bring the interNational Bioethics Committees to the international dialogue. This natural mandate of UNESCO has also been translated, in having the two unique global forums for discussion of principles and to define frameworks. So, in UNESCO, you also take into account these differences in culture, in education, in religion and so forth. That's why we have been able to establish three normative documents to give the framework for bioethics. Now, we are also going to have the working together with the World Commission for Ethics, Science and Technology. We have identified important gaps between legislations. There are principles, but you have to have some other guidance to implement them, and that's why we also have the reports that are being produced by some committees, and then you have capacity building which is based on the documents we have, so that we work together with the committees. Now, there are lots of gaps, and some are between the legislation and the frameworks, and the possibility to implement a legislation. There are gaps in education, there are gaps between the possibilities in countries with the national committees.

Global justice will be the umbrella for the committees to work. So that's for example why the IBC is going to work now on benefit sharing. There is potential work to be done together between the two committees, for example, addressing ethical issues of converging technologies, so then you can have the scope of more related health

issues by the IBC and all those who are without the realm of health by the committee. This is a way of bringing them together and, of course, taking them into account, in collaboration with the Council of Europe. It would be good, for example, if the global summit were to address some of these injustices at the national level in the capacity to create and use knowledge as well as to benefit from science and technology. We are also planning to bring together the national commissions to the floor, now we are planning for the medium term, to have meetings together with the IBC, the IGBC, and COMEST, because we really want to foster the dialogue between the three committees, and the idea is to build into this one-week meeting, for example, modules to bring National Bioethics Committees. In that way, the issues that the National Bioethics Committees are discussing at the front line can be brought to the global forum, let's say, of both governments and international experts, independent experts, which is the case of IBC and COMEST, so that the issues that are discussed at the national level can be brought to the global level, and at the same time, the global reflection can be then brought back home. There should be a double way, and also the possibilities in some of the reports and some of the recommendations are being shaped there or some normative act, normative documents, to have included the perspective of the National Bioethics Committees in the making of these documents.

The IBC is going to develop the two new reports, one on benefit sharing and one of human rights and human genome. We are changing a little bit the way they are going to develop these reports, and seeking for inputs on the very early stage of their development asking for governments. We are seeking for some guidance or some opinion of National Bioethics Committees and different bodies on what could be important for policy making. These reports will be really targeted and focused and could address the possible gaps that exist at the national level.

Christiane Woopen: Who wants to make a remark or ask a question?



Hans van Delden: In ten years from now could the global forum really be the international forum to provide guidance to governments in ethical issues? Because we now have, we have commissions within the UN bodies, right? And the global forum does not have that really very firm mandate from a UN body. From what you said, could the global forum develop into something that could really provide ethical guidance to governments, to a think-tank? This emerged from what was said about involving the National Ethics Committees into the work of the IBC, you actually wonder whether this global forum could maybe become even stronger in providing guidance more than just exchanging experiences.

Dafna Feinholz: If the global summit is addressing the idea of bringing the national committees to the Bioethics, Ethics Science and Technology Forum at UNESCO, that's one thing, that's one forum, one global forum with the governments, with the relevant global bodies making that reflection. In that sense, that was the interaction, and there could be direct interaction between the governing bodies of the UNESCO so that someday they could reach even the General Conference. Now, the global summit is always a place of exchange of views and opportunities to advance in reflexions that then can be brought to this other global level. There is the idea to have direct contact, interaction with them, and here. If the challenges that we identified are reflected here, then probably some of the things will be brought back there, but I don't really mean that there should be a body making recommendations.

Jim Dratwa: I wouldn't want to leave the colleagues under this impression; there is already intense collaboration between the different international organizations that are sitting on this panel, and there is also reflection, but we could gain a greater insight on how to optimize these aspects. There are indeed different occasions throughout the year in which different national ethics councils or commissions are brought together. This raises a number of issues. Let me just highlight two for consideration.

One is to ensure that there is no duplication and that there are optimal synergies between those different configurations, and the other issues are related to the other councils or commissions left out. What happens to the others? Who do not come to this, who do not come to the various summits and forums that were mentioned, and I could add in the international dialogue that the European Commission is convening. We have the pleasure and privilege of inviting a number of national ethics councils, but there are many more that we do not see. In our reflection on the benefits that can be derived from our coming together, in terms of exchange or information, in terms of joint endeavours, in terms of mutual learning, in terms of capacity building, let's also have a moment, have a thought for those who were not with us in this room, and let's think how they can also be usefully invited.

Alastair Campbell: I think it's great to hear the way the different organizations are talking to each other and collaborating. Let me give you a view from the region, as opposed to the international view. It can be quite confusing: WHO and UNESCO each have regional offices; in addition to that, the EU has an office in Singapore, but it was very obvious, very early, on that all they are interested in is trade, money, but not in ethics. And yet, we were a partner in an easy grant as the Asian partner. Singapore is a small country, counting the expats there's about five million people, so the bioethics committee is relatively small and it's great. We have people on the two UNESCO committees, both the governmental one and the IBC, we've also of course got people coming to the congress, people coming here and so on. But, I hope that the various organizations will look for regional, as well as international, collaborations and for priorities in relation to bioethics in the region.

Joachim Vetter: We have heard about converting technologies, and big data. Are big data and health technologies something that has been challenging on the agenda of CIOMS, as well as other organizations?



Hans van Delden: Yes, but it's fair to say that the prime attention now is on bio-medical research, because we are revising the bio-medical research guidelines, and you cannot put everything into one guideline. It's there on the list to be dealt with, but not for right now. I would say that that would not be a major item in the biomedical guidelines.

Laurence Lwoff: Those two items are what I would call transversal issues, in the Council of Europe, and at the moment, in bioethics, as you know, we are starting working on emerging technologies, and I would say that concerns about privacy, linked to the massive productions of health related data, their processing and storage will certainly be key issues, and that will be addressed at the conference next year. Independently of that, the data protection sector in the Council of Europe is also working on those issues from their perspective of real data protection, we will plan a joined activity, but it is more of a transversal issue to be addressed from different perspectives. The idea of that conference next year is to set some kind of agenda, but not necessarily only for the Council of Europe, but within the Council of Europe, possibly also by different bodies. I think those are issues that are difficult to address in one singular guideline, but it's important to look at the different aspects of it. Management of health-related data is certainly a huge challenge.

Abha Saxena: Just in relation to guidance on new technologies and big data, especially in relation to big data, I think the approach is very much in a way concerned about developing guidance in the use, storage, management, sharing of big data. It's a huge issue, we are in the process of developing guidance for, specially, the area of electronic, medical and health records, but also in relation to combining big data bases, having all different types of information in them which can be very helpful to solve some of the big issues that we have, but it also could be potentially risky to the individuals.

We have a whole unit on e-health, we have developed guidance for dual-use technology, which is part of the new technologies being used

that could be harmful or risky to humanity. But we also have other departments working on how to deal with issues related to data management. It is on our agenda, and we will be working on it. We're also working in relation to surveillance, for example and the use of data in surveillance technology.

Dafna Feinholz: For UNESCO the agenda will be more related to genetics, because they are going to work more on genetics and human rights and potentially in converging technology, so all these issues probably will be addressed, but in those terms.

We're really struggling in achieving more collaboration, more coordination. This forum is not only good, so you know what we do, but also for us to know how to better work with you and for you.

Jim Dratwa: The idea indeed is to hear you, to discuss with you, to have proper conversation so that these things can be improved. What Laurence indicated with regard to the Council of Europe also applies to the European Commission, although in a different way. Now, specifically on big data and health technologies, the clinical trials regulatory framework has been finalized, we are in the process of revising the regulatory framework on data protection and privacy. This is of course a very important one, and we've just completed this important report, an opinion of the European Group on Ethics, on the ethics of security in surveillance technologies, reading big data and not only state surveillance, but also from corporate actors. The involvement of public and different stakeholders in the production of knowledge innovation in the health domain is also very much about big data in the health area.

Manuel H Ruiz de Chávez: Perhaps we could think of a strategic plan for the next two years, I think that the time is short, we have the information and we are able to set up a strategic plan in order to get priorities and then to work on them. We have to bring bioethics nearer to the people because we think in terms of policy and so on, but most of society doesn't know what bioethics is about, and we have to make



a big effort in order to disseminate and promote the knowledge of bioethics, and the benefits it has for society, the individual, have from bioethics.

Laurence Lwoff: Ethical issues are common issues, common issues for a long time in many countries, but I think that the reality in the field favours this situation - globalization, exchanging data, exchanging samples.

The opportunity to exchange outside the regional level is also certainly very important because, again, those issues can surely be discussed at our regional level, but I think the real dimension of the problem is larger; and even at regional level, at the level of government some may agree on a certain number of principles, but all the discussion at the global level is actually providing food for thought and contributing to the general reflection. These global summits provide an opportunity for that. I think the papers that are drafted are quite useful in that respect to continue using that as a basis for reflection.

Mexico is an example of universal value of rights and cultural differences, we might have Mexico joining the group of countries having ratified the Oviedo Convention soon and it would be the first non-European country to do that.

Christiane Woopen: We have shared issues that we deal with, trying to make this world better from the perspective of bioethics and what bioethics can contribute to that; that we have a long way before us. We've already started treading that path, however there is still a lot to do. •

ROLE AND FUNCTION OF STEERING COMMITTEE: FUTURE SUMMITS

Hugh Whittall: What I would like to do is essentially two things. One is to provide you with the feedback of the discussions that took place in the Steering Committee, which is about learning from what we had seen over the last year or two and invite comments on those particular points. Secondly, we would then turn to the questions that we invited you to look at in the regional meetings yesterday evening, so that we can then bring all of those observations from your discussions on to the table.

I think it's important that we feedback from the Steering Committee, some particular things that we discussed. These were about, firstly, the terms of reference of the Steering Committee, and the second is around processes that are undertaken for the preparation of this Summit.

The terms of reference (TOR): The Steering Committee is proposing a number of changes to the TOR. The particular points that the Steering Committee felt it wanted to change were, first, about the composition of the Steering Committee. Our colleague Nicole Beaudry from Quebec had prompted us to think about reducing the size of the Steering Committee, so that was proposed. Nicole's proposal was a suitable compromise position.

The TOR considered a committee of seventeen, which consisted of two people from each of the WHO regions, plus the past hosts of the Summit, the present host of the Summit and the future host plus representatives from the WHO and the UNESCO, which made seventeen.

The final proposal considers two people on the Steering Committee each from the WHO regions, but those twelve should include past and present hosts of the Summit, so we still be twelve. We will have the WHO delegates and the UNESCO delegates, and then, once the future host is known, that person would be invited, in addition, if they are not indeed already a member of that group.

So, we effectively reduce the size of the Steering Committee and the essential point is to note that each region would be expected to have two people on the Steering Committee. They don't act as representatives of the whole region. I think that's a burden that few people could possibly bear, to represent one of six whole regions, but nevertheless, can bring a perspective from those regions. Where the past host is from a particular region, one further person from each region would be needed. This was the first point.

The second point is that the Steering Committee looked at its procedures for making significant decisions. It believed that the most important approach here would be to try to achieve consensus. Wherever possible, we would favour consensus. However, in the absence of consensus, the voting would be subject to a majority of those National Ethics Committees that are represented on the Steering Committee, so that's a kind of formality.

The third point with respect to the terms of reference of the Steering Committee and its activities: Firstly regarding the need to establish the Steering Committee as soon as possible after each Summit. We need to get the next Steering Committee initiated and in place, certainly within six months at the most. Within each region, we need to have ways to identify the members.

Secondly we need to have the process of identifying the next host so that we can have the past, present and future host as member of the Steering Committee.

The Steering Committee discussed that we would carry forward in for the establishment, the terms of reference, and the activities of the next Steering Committee, and I just invite any of my colleagues of the

Steering Committee to tell me if I missed anything or I've got anything slightly wrong, otherwise, I'll open that for comments to anybody else. I would suggest that after this meeting our colleagues of WHO would circulate this so that you have an opportunity to read it, reflect on it and come back to it.

Abha Saxena: The Steering Committee was established, as it's mentioned here, and you can read that is basically to assist with the organization of the Global Summit, both the technical and the organizational issues, and to support the host of the future Summit in developing the agenda and in ensuring that things run the way that we would like it to go. I just wanted to make that a little clear and also where to identify that sort of topics that the members of the summit are asking for the Global Summit to discuss. The Steering Committee is established to all that sort of things.

Nicole Beaudry: Oui, j'aimerais juste apporter une petite précision. Le changement de 14 membres c'était la même proposition que j'avais faite en Tunisie. Et c'était pour aider à l'organisation du Sommet. Donc ce que j'avais proposé c'était qu'il y ait 6 personnes qui viennent de différentes régions mais qui ne les représentaient pas. Je n'ai jamais dit que c'était une question de représenter les régions. La proposition de 14 membres n'était pas la mienne. J'ai repropoé les mêmes 6 personnes qui viennent des régions, le président sortant, le président de la prochaine réunion, une personne du WHO et une personne de l'UNESCO. Ce qui ferait dix personnes. L'idée derrière cette proposition là était qu'à 17 personnes pour l'organisation de ce sommet-là ça a été très compliqué pour les conférences téléphoniques à 17 personnes et pour les courriers on n'en parle pas. Je crois que j'ai deux dossiers que je pense doivent faire plein de courriers.

Donc, pour une question d'efficacité, c'était ma proposition qui n'est pas celle qui a été retenue parce que finalement on a proposé 14 membres. J'ai l'impression que dans cette proposition là on parle plus

de représentation des régions, ce qui n'était pas du tout l'objet de mon propos. L'objet était de dire «on va aider les gens qui préparent le Sommet Global».

Hugh Whittall: I apologize if you feel I misrepresented what you have proposed. I am working on that old-fashioned basis that we take silence as consent. It's not fashionable but it's effective, sometimes.

The second issue that we discussed in the Steering Groups was about processes. This is a little less specific. The first point is there was a general sense that the processes that we undertook worked well. We've learned lessons; there are things we could do better. Certainly, most of the things that happen which is about organizing, working groups, preparing papers, we could start earlier and we could deliver them earlier.

There was a sense that there was no need to fundamentally alter the manner in which the preparation of the Summit is conducted. If we think about the need to identify topics, establish working groups, encourage regions or other groups to work together, to think about processes for grants for people to attend the Summit, which was a very welcome offer that some people were able to benefit from - the need for a procedure for that, the need to maintain contact with the IAB, so that we can understand the relationship which we might or might not have with the Congress being held as well. All of these things functioned well although they could be improved. At the same time, we felt there was every reason why the new Steering Committee, with the new host in place, should be able to innovate, should also be able to bring in some new ideas, some new ways of working and of conducting the Summit, so that the character of the new host should be able to express himself upon the process as well. These were, generally, the things that we felt.

Using working groups to ensure that there was as wide a participation as possible. I think we came to the conclusion that it would also be helpful if the draft papers could be delivered to all of those participating very much earlier than they have been. It could be useful if we had received all

the papers three or even six months before the Summit. This would give us each an opportunity to discuss those within our own committees, or with our own colleagues back home, and then come into this meeting, having already had some consideration of them, so that we can engage in a different type of discussion. All of these things are contributing to identifying the content of this summit, of trying to increase participation, both in the working groups and in actively engaging being involved in parts of the Summit as it progresses, and in maintaining continuity from one summit to the next, these things add value.

Did you feel that you were well informed, that you had an opportunity to contribute, that the preparation of the papers and the quality of the papers and the way in which the Summit functioned, and was organized for you? Do you have any observations to make?

Aminu Adamu Yakubu: I'm speaking from Nigeria. I think the preparation was really excellent. I did hear some slight comments though, that the market place timing was a bit short, but apart from that I think it was excellent.

Hugh Whittall: That's a helpful observation. The market place, it seems to me, has been a really important innovation. We had this, it was very good, in Tunisia; it's been very good today. I think that geographically, the fact that it was out of sight, made it a little bit difficult that people maybe didn't go as much as they could. I think it's being a really important innovation.

Manuel H Ruiz de Chávez: Yes, I would like to comment something about the language. English was the official language, but now, in Mexico, we had to use, sometimes, Spanish, but on the other hand we had to be very polite to give the floor to respond to Nicole, in order to have the translation into French also. I think that this is a topic in which, also, we have to discuss the languages that will be used in the Global Summit.

Hugh Whittall: I think that's a very helpful comment, and I know that the translation from Spanish to English has being welcomed, but I know that more than one person has benefited from the translation into French, so that's been welcomed again.

Nicole Beaudry: Pour le Market place, c'est fait ici différemment de ce que c'est fait en Tunisie et je pense que l'expérience, ce qui s'est fait ici doit être tenu. Ces présentations-là, le temps donné à chacun de présenter, ça c'était bien. En Tunisie on a laissé ça un peu libre de tout, on avait laissé ça dans la salle à café où les gens allaient et venaient. J'ai trouvé la formule au Mexique beaucoup plus intéressante, je pense que c'est une formule qui gagne. Avec les chaises c'était bien, les gens pouvaient choisir et aller je pense que c'est une expérience gagnante.

Hugh Whittall: We keep learning from experience, that's helpful.

Now, I would like to move to the regional meetings. We had five tables, and I know that there were some interesting things discussed because the volume in the room was pretty high. What I'm going to do is take each of the questions and ask. I think that each table, because we're all experienced committee people, must have identified a rapporteur.

The first question was - How can participation of NECs in the Global Summit and between summits be increased, and how can activities be sustained between summits? Thabo, you have been identified as a rapporteur for the African Region. You have a few notes just to report back on the discussion from that group.

Thabo Molebatsi: I am from South Africa. In addressing this question, we had robust discussions. We decided that the channels of communications to provide the invitations need to be crystalized, taken into consideration that organizers of the Summit must identify the right contact channels for each country, and in particular for the National Ethics Committees. Also, we are of the view that we need to ensure that the NECs in the region are aware of the meeting.

We need to look at the existing list of NECS, taking one from the participants in the current global meeting, and also the existing data base they have. That's the first issue: combine the two, one preparing for the invitations. Then secondly, also to make sure that on the regular basis through WHO, AFRO region wants to revive and be active as a region itself, but at the moment we are saying that the current list needs to be continually updated. We suggested a continual contact of an essential regional person providing the contact, at least once in three months.

We need to revisit the data base, that's the main point. The last point is that NECS should help the region, and maybe, WHO, in trying to secure some kind of funding. I just want to be clear on this point that is not a begging bowl from our side as a region. We are saying it is our responsibility as the region, and sub-regional members, to make sure that we secure resources to come and participate in these meetings. And the region must find the way of raising some funds for those who tried and cannot do it.

Hugh Whittall: Next on my list is the European region, and I think Siobhan O'Sullivan will give us a comment or two.

Siobhan O'Sullivan: The Euro group in the main felt that the process of preparing papers between each of the Summits was actually working quite well, nevertheless we felt that it would be much more beneficial if the NECS could have the papers, perhaps, six months in advance, even three months in advance for the next Summit. This would give the various NECS the opportunity to discuss and reflect upon those papers. It would mean that we could all bring our different perspectives to the table, so we might be able to have a more interactive discussion rather than a series of presentations. If we could have the topics and the papers in time, and we could then all perhaps, commit and that each of our NECS would dedicate one meeting to discuss the various issues so that we might be in a position to bring some reflection to the meetings. This would create an extremely interesting exchange of ideas.



Suggestions have been made regarding the possibility of identifying a specific problem on which all NECs could work, and that we might be able to update each other via an Internet forum. We did all recognize that many of the NECs would already have decided their agendas for the next two years, so that might be quite challenging. We came back to this idea that, in fact, it's a good idea if we can build on the experience, on the rather successful experience; we've had with preparing papers for the last two NEC forums. If any of my colleagues in the Euro group want to add to this summary, I'm happy for them to do so.

Hugh Whittall: I think it would be valuable if you not only report back here what you discussed and what you thought, but, in addition, send you comments back into the Secretariat as well, so that we can make sure that we've gathered all of that up, so we are not missing anything here, and any other comments too. I don't know who the rapporteurs are, or if anybody has been identified for the other three regional groups, so, EMRO.

Michel Daher: Six persons met with the group of EMRO, Eastern Mediterranean Region. Currently, my colleague from Saudi Arabia and myself are representing this region. To the first question: What can be done to develop and foster regional frameworks? The answer was that participation in the global summit can be increased by encouraging a twinning mechanism, where a rich country supports the participation of the poor country. First, identify in which country National Ethics Committees exist. Second: what is their structure, status - active or inactive -, and the number of membership. Three, establish a mailing list of existing NECs in the region to remain abreast of events, and convene regional meetings of these NECs, in between Global Summits. It can be done one year from now.

Ryuichi Ida: I'm representing Japan and I would like to report back from Asia and Pacific region. We had only four countries in these two regions namely Sri Lanka, Singapore, Korea and Japan. For the first question,

we discussed four points. The first point is to increase awareness of ethical issues in the region. Efforts should be made to increase awareness and appreciation of bioethics and ethical issues in the countries. Once the countries are more aware of the bioethical issues and how it is affecting the populations, these will be more inclined to set up any National Ethics Committees. There is a need to bring in developing countries in the bioethics dialogue.

The second point is the importance of increasing the perceived value of the Global Summit to the government. One of the hindrances of participation in Global Summit is lack of funding or sponsorship by the government. For example, Australia and New Zealand did not participate this year due to lack of government funding. The Global Summit should think of how it can demonstrate to governments the value added by bioethics to the public policy discourse, so that the governments perceive the value added to it by the bioethics activities within their own countries.

The third point is the issue of funding. It should be, I think, about the increase in funds available for activities in between Global Summits and not only for each session of the summit.

Fourth point is the necessity to facilitate networking. What role do key individuals in each country? We should identify key individuals in order to foster the bioethical debate and to increase visibility of bioethics vis-a-vis policy makers. These are four points we discussed on the first question. However, we should say that these five questions are not amply discussed in detail. We have discussed some points in detail, but some other points a little, due to the lack of time; we didn't discuss all the questions in the same way.

Hugh Whittall: Let me go quickly now to the Americas. Do we have somebody to report back from the fifth group, or anybody who was there who has a recollection? Unless somebody else in the group has... I really, I think, Ryuichi has just signaled that time is such a constraint for us; this is still the case now.



Let's move on, because, we are on the second point which, some have addressed this already, which is about fostering regional networks. Is any support required and what kind of mechanisms exist? Because I think this could be a very important element of the period between summits and the maintaining continuity.

Thabo Molebatsi: From our region, we are aware of the already existing fora and some of the networks which focus mainly on research and on other issues. For example, AVREF or African Vaccine Regulatory Forum. We want to strengthen our relationship with such networks and also particularly those who are focused on research. We want to make sure that the element of ethics is actually strengthened and refocused, so when they meet, we, as we interact with them, we want to make sure that some of the focus area includes ethics.

The second point is that we are of the opinion, or we intend to revive original membership from the sub-regions. We believe that, in doing so we keep in touch with each other, we update each other with the current pending issues.

Most important is to convene an annual meeting. One of the purposes or objectives of convening such a meeting is to prepare thoroughly for the Global Summits, so that when we come we are prepared and we speak with one voice as a region.

I'm going to skip other points, in consideration of time, but two more points is that, it relates to funding which we have already spoken about or mentioned, but we as a region intend to make sure that it is our responsibility first to try and raise some funding, get some grant from ourselves so that we support each other for related matters. Also, consider issues of sustainability, self-sustainability, within the region, making sure that the sub-regions continue. We took it further that the sub-regions also need to meet on their own to discuss relevant issues, so that when there is a regional meeting, then certain relevant issues are discussed.

Siobhan O'Sullivan: In the Euro region we already have a number of platforms for exchange. That was acknowledged. In fact, many of the national ethics councils already hold bilaterals or trilaterals with other councils, and that's to be encouraged and hopefully continued. As you may be aware, there is a national ethics council forum which is funded by the European Commission, but we did recognize that since the death of the Council of Europe Group, COMEST, we are only talking about the member states of the European Union, and of course, that doesn't cover the whole Euro region, so there was a suggestion that we might look into the possibility of seeing if we could include some of those countries outside of the Union to perhaps have observer status at some of the national ethics forums. We also have an international dialogue on bioethics that's held once a year in Brussels, usually, and again, that has a much wider membership, and there's many countries invited, so that's a good opportunity for exchange. It's basically to strengthen the existing mechanisms within the Euro Area.

Michel Daher: The idea that we establish a mailing list of existing NECs in the region and to remain abreast of events, convene a regional meeting of NECs between the time of the global summits, including other relevant stakeholders in bioethics events on the regional level. We have two or three organizations that are involved in bioethics in the EMRO region, so we can invite them to join the activities of the National Ethics Committees.

Ryuichi Ida: Very briefly two ideas proposed. One is to establish a kind of regional forum on bioethics.

A regional forum on bioethics maybe organized to engage the current National Ethics Committees. However, the importance is to find the potential sponsor to organize such a forum. After the forum, the result must be followed by national workshops and consultations in order to take up the awareness of bioethical consideration in each



country. The second idea is to establish an email network, but first, for starting a regional framework, email network, is very useful and important and we should find a key person for setting the network in order to disseminate the necessity and result of the global summit.

John Tunde Bewaji: In the Caribbean we find ourselves within the Americas. We have the big brothers to the North and then we have the Latin Americans surrounding us. Consequently, the English-speaking Caribbean are dotted islands within the Caribbean. We seem to get left on. While the other regions are reporting the developments, you know, we just seem to feel as if we are nowhere.

For example, in Jamaica, over the last few years, when the Bioethics Committee was started, we've had some serious challenges. Because the ones who are committed to the bioethics issue have to procure their own resources. Let me mention one particular issue, which we would have loved, you know, to have regional discussion assistance in terms of policy formulation.

Recently, we've been going through the medical records or health records debates and, you know, the challenges are grave. We are learning from the various other regions, we heard record protection have been done, but if we could have regional inputs, it would be great.

Secondly, over the last year we've had the question of what is known as direct foreign investment, we are in particular a big international conglomerate in attempting to develop what is known as logistic hub and the particular location that is being proposed happens to protect the southern part of Jamaica. When those of us concerned about environmental, you know, ethical biodiversity raise our voice, we seem to be dwarfed, because the country needs investment and consequently it doesn't matter whether you do an environmental impact assessment or anything, nobody seems to listen. Recently, also, we've had the issue with the Caribbean native communities which relates to human sexualities, and how various agencies tend to dictate national policies regardless of what we would think. When those of us concerned about bioethical implications raise our voice, we don't seem to get any kind

of support. I don't know whether what I am trying to identify fits within the regional ethics that you are asking for, but I thought I needed to make a point.

Hugh Whittall: Your points are very well made, even if this was not precisely the area. I think there are ways in which actually the messages can carry into this question about regional networks, because obviously those networks can develop, there is an opportunity for support and, and maybe the WHO Regional Office would also be interested in conversations to help develop the kind of links that might be useful. I don't think we can answer all of your problems today, but I think that there are plenty of people who would have noted that.

Dafna Feinholz: The question was about ways of communicating in the region. Since UNESCO has already a network for National Bioethics Committees established, there was an agreement between the group that we would use, because this would be a very concrete way of starting the collaboration between WHO and UNESCO, so we will all use the already existing network of National Bioethics Committees in UNESCO.

This network has a website, they have a list of communications, so there was an agreement to start with a very concrete activity which is that each committee will send like a one page of description of what they are and how they are constituted, and that would include definitely Caribbean. I think, if we are able, we need to discuss with WHO if it's OK. Then, every committee will send to this network one page describing what's the committee doing, what's the constitution, because one of the main topics, they thought, was important to discuss is also how to build and how to achieve and what are the challenges for independence of the committees and what kind of issues they work on. They decided to start with that, and probably after that, identifying a specific topic and trying to deliberate further activities in between summits. The members of the group are here, so they can contribute. I'm not speaking as UNESCO but as member of the group.



Abha Saxena: I just want to say what happens when we go back home and that is we are inundated with our own day-to-day work and everything else and people forget it's a bilateral, the traffic is two ways. I think it would help the Secretariat immensely if we hear more from the National Ethics Committees. For example, when we did a questionnaire, we requested input from all National Ethics Committees, you get only a handful, or much less than we would have liked to do, and then we don't know if it reflects on the Secretariat, or whether it is that there are people who don't have the time, or people who don't think it's useful. There could be many reasons why we don't get back responses. I think it would be helpful for all of us to reflect that if we want us to be truly global and a truly interactive forum, conversations always happen, it's always two-way and multi-way traffic and we should all take responsibility for that.

Hugh Whittall: I think that is what we've been hearing. I think it has been an opportunity to discuss these things between the regions in a way that we've probably never have done before. If this acts through, for each to give each other some support, it makes that kind of commitment a little bit easier. I think we have to acknowledge that in six months from that our enthusiasm may be as great, but our opportunities may be diminished.

I'm going to move now to these particular questions and I think we need to keep the answers to these brief. The first is about the mechanisms to identify new members of the next Steering Committee. I don't think it is the intention of the Secretariat or of the Steering Committee to specify a process. Within each regional group - is each group content that they can find a way of identifying a NEC or two NECs who would then become a member of the next Steering Committee?

Tabho Molebatsi: In our discussions, we looked at the issue from the point of view of organizing the Steering Committee, but also with an element of regional perspective. When we started we discussed the terms of reference, at that time, we didn't have it with us. Now, that

you've supplied us with the terms of reference, what we looked at was that there's going to be, there's a need to retain some of the members. In other words, we reaffirm what you already have in the terms of reference and what you already spoke about.

We also, are of the opinion that the points, or the effect of making show that all regions are represented, we should be maintained and retained in the requirements. Thirdly, we are saying that particularly at the regional perspective, those members who are elected to be part of the Steering Committee should at least be present in the preceding Summit. For example, this current Summit we need to make sure that at least one member is present, so that there is relevance in the topics that were discussed, and the discussions which continued during the Summit.

Last two points are that we are proposing that the Steering Committee members should be representative of the NEC, or the NECs themselves, which is already what is actually happening. But, we wanted to make sure that if at a regional level we already have someone in the NEC, when there is communication, at least, there should be a member of a NEC, or at least a Secretariat, who is vested with the knowledge of how the NEC of that particular sub-region works. That person should be at least the contact person, because we will know what is actually happening in the sub-region. Relevance in this case, and linkage to the NEC of any sub-region or region is quite important, and that why we uphold.

The last thing is that at the regional level we want to make sure that other sections are also represented, i.e. the Anglophone and the Francophone, just to make sure that representativity is quite balanced.

Hugh Whittall: That's all extremely helpful and interesting. Difficult to achieve all those balances with a small number of people, but we must keep the objectives in mind.

Siobhan O'Sullivan: So, from the Euro-groups perspective, first and foremost we believe that the Committee should be convened as quickly as possible. It was discussed that it should be a process which should



be completed within weeks rather than months of the end of the current Summit. That was the first point.

We also agreed that there should be some continuity for the Euro Group. That's perhaps easier because we will only necessarily have to, if Germany is the host, we have to find one of the participants. We think the mechanisms for that should be that there would be a message sent to all of the Euro Group NECS looking for an expression of interest of who would like to participate.

Then, there was the suggestion that, if there were multiple expressions of interest, then the fairest way to do it would be by lottery. There was however another suggestion that one of the qualifying criteria to enter the lottery would be a country which hadn't served before, in order to get some sort of capacity building and get a different perspective.

Michel Daher: Well, to the question, what mechanism can the group suggest to identify new members of the next Steering Committee, the group suggested that the member should be chosen from countries who have well-established National Ethics Committees, to country that have shown commitment through their attendance, participation, contribution to the work in papers and countries that are active and engaged in the activities of the Global Summit.

Hugh Whittall: I think we all noted that membership of the Steering Committee does involve a commitment. Those people who commit to the Steering Committee recognized that there will be something that they have to do, the work.

Ernesto Luna Orosco: Bien, yo no quisiera generar alguna confusión, pero tengo varias inquietudes, después de haber escuchado muy atentamente todo lo que se ha dicho, y para mí uno de los grandes problemas es el de la representatividad

Por ejemplo, en Sudamérica se elige a los representantes para asistir a la próxima Cumbre Global o para formar parte del Comité Organizador

¿Quién elige a esas personas y por qué las elige de equis o zeta manera?

Lo mejor sería elegir con base al consenso, que cada Región, obviamente a través de sus comités nacionales de bioética, encuentre al mejor representante, porque lo que se quiere es lograr la mayor participación posible en las cumbres globales; de lo contrario, encontramos en un círculo vicioso, donde solamente participan aquellos países que tienen Comités Nacionales de Bioética bien estructurados, y se habla de bloques.

Por ejemplo, se habla del Eurogrupo; el Eurogrupo tiene la suerte de contar con Comités Nacionales de Bioética, seguramente bien subvencionados, con potencial económica, con representatividad, porque están vinculados con sus propios Estados o Gobiernos.

Esa no es la realidad del cono Sur, al menos. Y probablemente, por lo que decía el representante de Jamaica, tampoco es la realidad de Centroamérica, hay una serie de limitaciones en la América Latina, y me estoy refiriendo fundamentalmente al cono Sur y Centroamérica. México es una gran excepción, porque nos ha mostrado una fortaleza extraordinaria.

En América Latina si bien hay el movimiento bioética dentro de nuestros países, el Brasil cuenta con 500 Comités de Ética de la Investigación, y sin embargo no tiene Comité Nacional de Bioética; en Argentina sucede lo mismo.

Entonces, ¿cuál es el problema? El problema es que la bioética no está institucionalizada. Los Gobiernos, los Estados todavía no han comprendido la importancia que tiene la bioética y la necesidad que tenemos, al menos en nuestra Región, de conseguir el apoyo de nuestros Gobiernos y de nuestros Estados para potencializar los Comités de Bioética Nacionales, más allá del simple voluntarismo, y de muy pocas personas que generan actividad.

Este es un problema para poder participar. Y, desde luego, las limitaciones financieras, económicas, cuartan la posibilidad de que hubiera una mayor participación regional.



Entonces, esta es una inquietud que yo la traduzco casi como una obligación ética el poderla expresar, el poderla decir, porque hay debilidad en cuanto a Comités Nacionales de Bioética.

Si bien la UNESCO ha dado un gran apoyo, y como ya dijo Dafna, existe la red bioética latinoamericana y del Caribe, y se ha constituido la red de los Comités Nacionales de Bioética, tenemos que seguir trabajando fuertemente en lograr que se institucionalice la bioética a través de los Comités Nacionales de Bioética, con el apoyo respectivo de los Gobiernos.

Entonces, una de las conclusiones, por ejemplo, importantísima que debería tener esta Cumbre es recomendar muy respetuosamente a todos los Gobiernos la necesidad de contar en cada país con un Comité Nacional de Bioética, que tenga el respectivo apoyo, con respeto a su autonomía, porque no se trata de tener un Comité Nacional de Bioética, que es una dependencia del Estado; lo importante es que el Comité Nacional de Bioética sea una Institución autónoma y que no sea manejada políticamente, inclusive como es el peligro eterno que tenemos los países latinoamericanos.

Perdón si es que he sido quizás muy objetivo en esta mi visión, pero es un tema que creo que nos preocupa, inclusive al Delegado de Cuba, Daniel Piedra, y no sé si a algunos otros representantes de América Latina, particularmente del cono Sur

Para aclarar, ayer el Grupo tuvo una fuerte vitalidad en el intercambio de opiniones, pero no se nombró un portavoz del Grupo. Se acordó que tanto la UNESCO como la Organización Panamericana de la Salud, con Carla Sáenz, que estuvo presente, hiciera una suerte de síntesis de lo que había sido esta reunión, nos cooperara a todos, tanto la UNESCO como la OPS, en servirnos de punto focal para poder converger en ideas.

Inclusive se hicieron algunas propuestas sobre lo que debería ser el contenido temático de la próxima Cumbre, en la sede que se va a nominar a continuación.

O sea, ideas hay, potencial de querer participar hay, pero los Comités Nacionales de Bioética en el cono Sur, por lo menos, están muy débiles,

y creo que en Centroamérica también sucede algo parecido, ¿por qué? Porque nuestros Gobiernos no gastan un centavo en mandar al Delegado de Cuba o de Bolivia, no sé, no quisiera dar muchos ejemplos de lo que yo no sé, pero no podemos seguir siendo —disculpen la palabra— pedigüños eternos para que nos ayuden a participar en las Cumbres, tenemos que ver la forma de institucionalizar, de formalizar la participación de América Latina en estas Cumbres, y creo que esa es una necesidad, porque tiene que haber un equilibrio entre el potencial mundial para poder realmente converger en ideas y lograr que todos hablemos un mismo idioma, y tengamos un mismo pensamiento.

Hugh Whittall: I hesitate to respond. I don't think I'm in a position to give a comprehensive response to this. I'm sure that WHO and UNESCO both would be committed to trying to do all they can to help. Part of what we want to do here through this whole discussion is about to support those who need support and increase participation. I think, if I may take just all of your comment as a contribution to the whole discussion we have had today, I think we can all pick that up, certainly, through some of the support programs that already take place.

Abha Saxena: Just wanted to confirm that, I think, WHO is committed to work with countries where they do want support to raise their visibility, or to raise their capacity. We are willing and happy to do that.

Hugh Whittall: I have two other questions and they are very specific. The first is - which topics do we think we should bring to the next summit? This would just be, if you like, a series of statements of the topics that each group thought might be important.

Tabho Molebatsi: We have a list here. It relates to research of outlawed communities such as CSWs, or communities of sex-workers, also, MSM, "Men having sex with men", in relation to ethics, because, normally these issues are not addressed from a research point of view and looking into ethical issues. Without wasting time, we also looked at, about proposing



that further discussion should ensue in relation to bio-banking, research, material transfer, so these are biological examples. Fourth issue would be harmonization of review in multicenter studies, research and ethics of herbal medical practice, collaborative research.

A funny issue, another topic which was very close to many members in our meeting yesterday related to the ethics of authorship in general articles which are being published coming from research studies being done; there are two sides to the coin here. One relates to the people who are involved in research and when the results and the ultimate general article is written, they are left out. Also, the flip side is that some are not even involved. But when you look at the authorship list they are there, so those are issues that we looked at.

Hugh Whittall: We will gather up all of these suggestions and they will be collected within the Secretariat and the new Steering Committee will look at it together.

Siobhan O'Sullivan: We came up with four topics. The first was the interaction of NECS with media, both traditional and new. The second was something that was mentioned yesterday, the blurring boundaries between converging technologies and whether the regulations we have in bio-medicine are still fit for purpose. The third was also mentioned, is big data, but also with the caveats that we shouldn't be looking at this in a descriptive way, we have enough information as, so we need to start talking and try to draw some conclusions in respect to big data. The final one was the topic of ageing, because it's something that affects all of the regions, and how we are going to deal with those demographic challenges.

Michel Daher: We have selected four topics for the next Global Summit. First, is bio-banking; second, big data; three, coming back to reproductive medicine. Last one, issues that are related to vulnerable population with a focus on the health of refugees and immigrants.

Ryuichi Ida: Many topics were suggested, but the main topic is the globalization of biomedicine. This topic covers a wide range of different sub-topics, some of the following topics, I would say, may be included in this big topic. Our regional group may suggest this globalization of biomedicine as the main theme of the next session of the Global Summit. I must add smaller topics, I have many but I'll briefly read them out. Health services delivery, emerging health technologies, medical tourism, universalization and commodification of health care, bio-banking, governance of pharmaceutical sector, end of life, organ trade, drug-resistance disease, migration of health professions, conflict of interests, antimicrobial resistance.

Hugh Whittall: There are a few common themes coming out. Finally, the Americas.

Dafna Feinholz: Well, not the exhaustive list, but I remember that there was like a global umbrella on global justices, and then, some of the things were under it like, for example, also issues of intellectual property, also about what's the structure, what's the ethical structure of medical systems.

Ernesto Luna Orosco: Creo que se podría sintetizar lo que se dijo en el grupo de América ayer, en tres grandes temas, sin entrar en detalle: se planteó el tema del medio ambiente como algo fundamental, que le interesa al mundo entero, no solamente a una u otra región.

Se planteó también la necesidad de comenzar a establecer un diálogo más íntimo, más directo con el ciudadano común y corriente, a través de una formación ciudadana en bioética, para crear una consciencia general sobre la importancia que tiene la bioética.

Y el tercer componente que se habló, dentro de los varios, se refiere a lo que decía Dafna, ética de la organización sanitaria, donde hay muchísimos actores comprometidos para que realmente la salud logre ser de cobertura universal el día de mañana, y se consolide como un

derecho, después de todo lo que se ha hablado en las charlas de estos dos días.

Manuel H Ruiz de Chávez: Another point was palliative care. It's a big movement in Mexico. It is about end of life health care, but also in the beginning of life. These are two approaches.

Hugh Whittall: This will all be gathered up so that the Secretariat will have all of that together, it will go to the Steering Committee, so they can look at those to see where there are common themes and how continuity can be achieved between one summit and the next, so all of the factors that we've talked about.

We will also think about future venues. There will be a process for this, which we will, I think the best thing to do would be to, first, by email, signal what the process will be, if that's agreed; then, invite people to contribute to the process so that we can identify the next venue which will be in 2018. We have one proposal on the table for the venue for the Summit in 2016. I would like to invite Joachim Vetter of the Deutscher Ethikrat to hear his proposal. •

Next Venue

Joachim Vetter and Christiane Woopen: Mr. President, dear colleagues, it's a pleasure for me to have the opportunity here to give you first impression on the venue of the next Global Summit in Berlin. Berlin is in the heart of Europe, it's the capital of Germany, and one of sixteen states of Germany. Population is about 3.4 million people; that's, compared to Mexico City, maybe only a village, but compared to Europe, it's quite a big city. It's located in the North-Eastern Germany on the River Spree. It's said that Berlin has more bridges than Venice and it's the center of Berlin-Brandenburg Metropolitan Region. The German Ethics Council is seated. It's Berlin-Brandenburg Academy of Science which is the former Prussian Academy of Sciences. It is situated at the eastern center of Berlin, and I have to admit, for me, it's the most beautiful place of Berlin to go to. The Academy itself is the largest non-university research institution. There's a profile in the Humanities, in the region of Berlin-Brandenburg, and it's the biggest Academy in Humanities in Germany.

The building was originally built in 1902-1903 from the Prussian Maritime Trade Company, the later Prussian State Bank. Its historical banking hall was reconstructed for the 300th anniversary of the Academy and expanded into Conference and Events Center. It's where we have our annual meeting and also public events, we have a regular forum on bioethics where we meet with people and discuss actual themes. Here you can see the Conference and Events Centre of the Academy of Science and Humanities, spacious and also with the latest conveniences. It's primarily used for scientific conferences and lectures, so also for receptions which require prestigious setting. Basic organizational matters and catering for the center is maintained by a

professional and reliable service team with years of experience in supervising diverse events.

The travelling infrastructure of Berlin, just a map of the metro, subway, regional trains, so all the area of Berlin, which is by diameter about 60 km. It's covered by public transport. You can easily reach it by plane, by train or by public transport.

This is upper left, there's the German Parliament, the Reichstag, formally called. In the lower picture you can see the Philharmonics, the famous Berlin Philharmonics, and also the Brandenburg Gate which is in the heart of Germany. Here, Berlin was heavily destructed during the 2nd World War, but it was reconstructed also greatly after the breakdown of the Wall. Berlin is best known for its historical associations, tolerance, museums, palaces, its many cafés, bars and a lot of sights of historical interest. Just to give you an impression about the surrounding of the city, we have many lakes around it. In the lower left you can see Castle Sanssouci which was a very famous, built by Frederick II and you see the park, you can see in the right, it's right in the center of Berlin. I think it tells a lot of a city if right in the middle is really a big park where people can relax and stay outside.

Here, this is a picture from a press conference we had in the beginning of May, next to Mrs. Woopen on the right, you can see our research minister, Mrs. Wanka, and the other guy is our Health Minister, Mr. Gröhe, and the woman next to Mrs. Woopen is the person who was the head of the working group for our opinion on bioscience and freedom of research. In view of support, Mrs. Wanka said that she will support us with everything we need for the next Global Summit, so we have her on our side, and I think we will also try to support participants of lower and low income countries by offering a travel permit.

Chancellor Merkel gave a very impressive talk about the ageing society and then she stayed there for more than an hour to give answers to the questions of the Council members as well of the public. This is our Federal President in the middle, left to Mrs. Woopen. He also invited us last year for a short visit, and to have an exchange about the themes

we are working on and he also is very interested in the work of the Ethics Council.

So, I want to cordially invite you all to come to Berlin to the next Summit. Don't stay only for the city, or for the Summit, maybe you'll also have a little bit of time to stay and enjoy Berlin. Thank you very much. Hope to see you in Berlin.

Hugh Whittall: I don't think that we have in the written constitution any way of expressing our agreement or disagreement with the proposal for the next Summit, so I'll propose a mechanism which is that those who are in favour of adopting Berlin as the venue for the next Summit, and the German delegation as a host, can you please raise your hand and say, "I".

I think we call that "unanimous". Now, we have now arrived at what is, I think, the very last part of the agenda, which comes under the heading closing remarks. Manuel H Ruiz de Chávez, is my co-Chair, but I'm going to ask him to wait for a moment before he speaks, and I'm just going to, first invite Abha, on behalf of WHO, just to say a few brief words as we close.

Abha Saxena: It's been fantastic to be working for this Global Summit, and to be working with Dr. Manuel H Ruiz de Chávez, through the past year on the Summit. Some of the preparation was late, but we picked up very quickly, and in the end, we did have the hard work of the Mexican colleagues and of my own Secretariat, of my own team. We were able to put the summit back on track.

They were meetings every month through teleconference which was quite challenging, but we are quite up to the task, but without the inputs of the Steering committee, this Summit wouldn't have been what it was, so I really wish to thank all the members of the Steering Committee, for all the inputs they provided and all the help and support provided. It's very gratifying to see when your own work comes to fruition, and even more gratifying when you see that the number of participants to the



Summit is impressive. It seems like, I haven't been in previous Summits, this was the first Summit I have attended, but I'm told that this is record number, this is the largest number of member states that have attended a Summit, so I think it's thanks to the good work of the Mexicans and to the Steering Committee that I can put the credit on.

It's been good to work in collaboration, especially with the UNESCO. I think collaborations can always be improved. We've already had fruitful meetings, and I think, for the next Summit, we'll see much more our collaboration strengthened, and I want to thank Dafna for all the support and help she gave. The level of engagement at the Summit itself, the level of discussion at the Summit and the sort of discussions I saw outside of the meeting room, at the lunch tables, during the dinner, it was fantastic. I think the levels of discussions in this room were very high and I hope that we can continue to work after the Summit.

I'm a little worried by the expectation of the participants, and the work on the starting of this next Summit should begin in the next few weeks, and I'm very happy to work with Dr. Vetter and Dr. Christiane Woopen, and the rest of your team. It will be another experience, another challenge. We will continue to ask Dr. Manuel H Ruiz de Chávez for help, support, give your sane advice, and your coming influence on the whole organization. I'm really looking forward to working between the Summits and then to organize the next Summit. Thank you, everyone.

Hugh Whittall: First, our thanks to Abha and her colleagues, for the support that they give from the Secretariat, and indeed Dafna, as well, from the UNESCO, from whom we get a lot of support and this couldn't happen without them. I think the point about participation is essential, and from our point of view, to see colleagues from all parts of the world I think it's very gratifying.

To go to all parts of the world, and see this increased participation is really encouraging and gratifying. The content of this Summit, the program, the participation, the challenges, have all been as we would

hope, that they are important topics that we all can engage in. To have the opportunity to come to this great place, to have the hospitality of Dr. Manuel H Ruiz de Chávez and his colleagues, and the work that they put into it; I would just want to note our appreciation of all of that, to thank you, for everything that you and your colleagues have done in welcoming us here over these last few days. •



CLOSSING REMARKS

Manuel H Ruiz de Chávez: I would like to express my appreciation of the work of the Steering Committee and, also, I would like to say I'm very pleased with WHO and UNESCO, of course, with Dafna, and specially with Abha, who have a very strong leadership in order to bring together several pieces of this difficult organization of the Global Summit.

We are very grateful with our sponsors, mainly with the National Council for Science and Technology, as well with the Secretariat of Health. I think that without the support of these two institutions, we would not able to do any of the thing we have heard. I would like to say that the most important part of this work counting with the presence of all of you. I appreciate your being here in Mexico, and as we say in Mexico, "mi casa es tu casa", and you are always welcome, and I expect to have you more time here. The Global Summit is just an excuse, but there are other activities in which we can meet together here in Mexico. You have several friends now in Mexico. I'm pleased. Don't hesitate to call us, and I want to conclude by thanking my colleagues in the National Commission of Bioethics. Without their work, it would have been difficult to have you here. We hope that you are as pleased as we are. ●

MARKET PLACE SESSIONS

The Market Place was an initiative that was undertaken at the 9th Global Summit of National Ethics/Bioethics Committees in Tunisia in 2012. Given the success of this event, the decision was made to replicate it on June 23rd and 24th for the 10th Global Summit of National Ethics/Bioethics Committees in Mexico. The experience in Tunisia proved to be a good way of approaching themes of interest off the agenda of the Summit and has the potential to enrich the thinking about important issues and provide the participants with ideas that can enhance their work in their own countries.

The Market Place was designed to provide a privilege space in an informal environment during the breaks to facilitate the discussion among the participants of the Global Summit through poster presentations, informal chats and power point slides. The space was opened for anyone who wanted to present good practices, innovative ways of working and learnt lessons. Furthermore it provided the necessary space for Q&A and interventions from all attendees.

The Dynamic consisted of attendees to 10th Global Summit and NECS representatives sharing in a casual and friendly manner the experiences, challenges and achievements of diverse projects. This exchange of ideas favored an open and intercultural dialogue on important issues, such as: ethical aspects in biomedical research, Universal Health Coverage, spreading Bioethics among children and youngsters, informed consent, dilemmas at the end of life, biodiversity and the environment, among others.

There were three market place sessions during coffee breaks, between the Summit's work sessions, and had a total duration of 150 minutes, divided into three simultaneous work tables.



All together twenty presentations were made employing a variety of means, such as power point presentations, posters, videos, flyers, publications and oral presentations in English, French and Spanish. During the 10th Global Summit Market Place the participants were:

- Alfred M. Mwanza; The National Health Research Ethics System in Zambia
- Amadou Djibril Ba; Universal coverage disease: Senegalese system
- Ana María Millán-Velázquez; Comités de Ética en Investigación en el Estado de México
- Anoja Fernando, Sri Lanka
- Daecheong HA; The National Ethics Committee of Korea
- Francisco Javier León-Correa; Situación de las Comisiones Nacionales de Bioética en Latinoamérica, Chile
- François-Xavier Putallaz; Comité d'éthique et démocratie directe, Switzerland
- Hugh Whittall; Engaging young people in bioethics, United Kingdom
- Javier Ernesto Luna-Orosco ; Relationship between the Bolivian culture ethnicities and community consent
- Laurence Lwoff, Display of recent works and information material Council of Europe

- Lotta Erikson and Kjell Asplund; The Swedish NEC- current and future work
- Marina Montes; CONBIOÉTICA, CECOBE. México
- Michel Daher; End of Life Care in Cancer Patients, Lebanon
- Miguel Montalvo; Role of the NEC of the Dominican Republic in Bioethics and clinical trials
- Nicole Beaudry; La Commission Jeunesse, Quebec
- Patrick Gaudray; Participation of the French CCNE to the international reflection on the ethical issues about the generalized erosion of biodiversity
- Riuchi Ida, Ethical Standard of the Beginning of Life in Bio-medical Research , Japan
- Simon Langat; Establishing and Accreditation of REC in Kenya

In the words of the attendees, the market place exceeded the expectations from the last summit because the organization allowed for a greater interaction between presenters and audience. •



CONBIOÉTICA-MEXICO TRAVEL GRANT

In line with its mission to develop and promote an ethical culture at the global, regional and local level, the National Bioethics Commission of Mexico (CONBIOÉTICA) with support of the Secretary of Health offered the CONBIOÉTICA-Mexico Travel Grant to a limited number of members of National Committees of Ethics / Bioethics from around the world for attending to the 10th Global Summit of National Ethics/Bioethics Committees.

The call for the award of the CONBIOÉTICA-Mexico travel grant was issued through the official website of the 10th Global Summit (<http://bioethicsummit.mx>), and the following criteria and proceeding were established:

- The grant was extended to low and middle income countries according the World Health Organization six regions (2 grants per WHO region)
- The grant covered:
 - A economy class airfare to and from Mexico City to attend the 10th Global Summit of National Ethics Committees/Bioethics
 - The accommodation and meals at the conference venue
- Membership to a National Ethics Committees, a track of active participation in the bioethics field, besides being officially nominated by the government of his country as a representative to attend to the Summit were considered.
- A paper accepted for the Summit market place was required
- A letter stating how their participation in the 10th Global Summit of National Ethics/Bioethics Committees, benefits for future collaboration between their country and Mexico

The Selection committee conducted a review of 23 applications from 19 countries. It also found that if one of the applicants presented a paper in the meetings of the working group of the 10th Global Summit of National Ethics/Bioethics Committees, could count as participation, although the proposal does not form part of the Market Place. For the grant allocation, the selection panel considered the criterion of regional distribution

The Call stated that the grant would be awarded to two candidates per each of the six regions established by WHO. In case of not receiving enough applications per region, the remaining grants were assigned to applicants from other regions. Based on the foregoing, Bangladesh, Sri Lanka (SEARO), Moldova (EURO), Pakistan, Sudan (EMRO), Bolivia and Honduras (AMRO) were clearly identified as eligible for the grant, leaving the possibility of awarding grants to five countries in the African region (AFRO).

Regarding the eight African countries chosen for the grant, the selection committee, based on the view that individuals were clearly involved with the Committee on Ethics/Bioethics and were officially nominated as representatives of their country, decided to grant the following five countries:

- Kenya
- Senegal
- Tanzania
- Mozambique
- Togo

The selection committee identified three countries requesting granting for two people from the same country. Given this, the committee agreed that the National Bioethics Commission of Mexico to come in contact with the countries concerned, in order to determine the applicant to be granted

Some of the nominees to be granted did not attend to the Summit.

The following list shows those who receive the CONBIOÉTICA-Mexico travel grant and did attend to the Summit: •

South-East Asia Region (SEARO)
Sri Lanka (Fernando Anoja)
Eastern Mediterranean Region (EMRO)
Pakistán (Ghulam Asghar Abbasi)
Region of the Americas (AMRO)
Bolivia (Javier Luna Orosco Eduardo) Cuba (Daniel Piedra Herrera)
African Region (AFRO)
Kenya (Kirana Bhatt) Mozambique (Rassul Nala) Senegal (Amadou Djibril) Togo (Koffi N'Dakena) Zimbabwe (Paul Ndeble)

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
African Region (AFRO)		
Name	Institution	Country
Alfred Malinga Mwanza	National Health Research Ethics System in Zambia	Zambia
Amadou Djibril	Ministry of Health	Senegal
Amelia Kekeletso Ranotsi	Maluti Adventis College	Lesotho
Aminu Adamu Yakubu	National Health Research Ethics Committee	Nigeria
Elizabeth Fourn Gnansounou	Comité National Dethique pour la Recherche en Sante (CNERS)	Benin
Jeanbaptiste Mazarati	Rwanda National Ethics Committee	Rwanda
Kirana Bhatt	National Bioethics Committee	Kenya
Koffi N'Dakena	Comité Consultatif National de Bioéthique	Togo
Moussa Isseini	Ministry of Higher Education	Chad
Paul Ndebele	Medical Research Council of Zimbabwe	Zimbabwe
Rassul Mussa Nala	National Bioethics Committee	Mozambique

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
African Region (AFRO)		
Name	Institution	Country
Seni Kouanda	Burkina Faso Ethic Committee for Health Research	Burkina Faso
Simon Kipngend Langat	National Bioethics Committee	Kenya
Thabo Molebatsi	Ministry of Health	South Africa
William Kabuswe Ngosa	Ministry of Health	Zambia
Region of the Americas (AMRO)		
Christine Grady	Presidential Commission for the Study of Bioethical Issues	USA
Cristiane Alarcao Fulgencio	Brazilian Ministry of Health	Brazil
Deleury Edith	Commission de l'Éthique en Science et en Technologie	Canada
Felix Daniel Piedra Herrera	Comité Nacional Cubano de Bioética	Cuba
Francisco Javier Leon Correa	Comision Ética de Investigación en Salud	Chile
Gabriela Emperatriz Minaya Martínez	Instituto Nacional de Salud	Peru
Gabriela Marodin	Brazilian Ministry of Health	Brazil

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
Region of the Americas (AMRO)		
Name	Institution	Country
Hernan Monasterio Irazoque	Ministerio de Salud de Chile	Chile
Jaime Burrows	Ministerio de Salud de Chile	Chile
Javier Ernesto Luna Orosco Eduardo	Comité Nacional de Bioética Bolivia	Bolivia
John Bewaji	University of the West Indies	Jamaica
Jorge Jose Ferrer	Universidad Puerto Rico	Puerto Rico
Karina Castro	Ministerio de Salud del Ecuador	Ecuador
Lawrence Jaisingh	Ministry of Health	Trinidad and Tobago
Manuel Jesus Santos Alcantara	Pontificia Universidad Católica de Chile	Chile
Marcia Luz Motta	Brazilian Ministry of Health	Brazil
María del Carmen García de Luna Orosco	Ministerio de Salud	Bolivia
Miguel Montalvo	Consejo Nacional de Bioética en Salud	Dominican Republic
Nicole Beaudry	Commission de l'Ethique en Science et en Technologie	Canada

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
Region of the Americas (AMRO)		
Name	Institution	Country
Ninel Mayari Centeno Lopez	Ministerio de Salud Pública y Asistencia Social	Guatemala
Eastern Mediterranean Region (EMRO)		
Ehsan Shamsi Gooshki	Ministry of Health Education	Iran
Farhat Moazam	Center of Biomedical Ethics and Culture	Pakistan
Michel Daher	Lebanese National Ethics Committee	Lebanon
Mohamed Ben Ammar	Ministry of Health of Tunisia	Tunisia
Muhammad Asif	Health Section, Ministry of Planning, Development and Reforms	Pakistan
Muhammad Zuheir Alkawi	National Committee on Bioethics	Saudi Arabia
European Region (EURO)		
Ali Resin	Istanbul University, Istanbul Faculty of Medicine	Turkey
Anne Cathrine Beckstrom	The Norwegian National Committees for Research Ethic	Norway

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
European Region (EURO)		
Name	Institution	Country
Ansa Boco Ogu	National Health Research Ethics Committee	United Kingdom
Christiane Woopen	German Ethics Committee	Germany
Elena Baibarina	Ministry of Health of the Russian Federation	Russia
Francois Xavier Putallaz	Swiss National Advisory Commission on Biomedical Ethics	Switzerland
Grigor Hovhannissian	Embassy of Armenia in Mexico	Armenia
Hele Everaus	Estonian National Bioethics Committee	Estonia
Hilal Ilbars	Turkish Ministry of Health	Turkey
Hugh Alan Whittall	Nuffield Council on Bioethics	United Kingdom
Hulya Sirin	Public Health Institution of Turkey	Turkey
Jacob Holen	The National Committee for Medical and Health Research Ethics (NEM)	Norway
Jacob Birkler	The Danish Council	Denmark
Jeanclaude Milmeister	Commission Nationale D'Éthique	Luxembourg

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
European Region (EURO)		
Name	Institution	Country
Joachim Vetter	German Ethics Council	Germany
Josef Kostiha	Embassy of the Czech Republic in Mexico	Czech Republic
Kjell Asplund	Swedish Council on Medical Ethics	Sweden
Laura Palazzani	Italian Presidency of The Council of ministers, National Bioethics Committee	Italy
Lotta Eriksson	The Swedish National Council on Medical Ethics	Sweden
Maria do Céu Patrão Neves	National Council of Ethics for the Life Sciences	Portugal
Meral Özgüc	Bioethics Committee, Turkish National Commission for UNESCO	Turkey
Monique Lanoix	Sant Paol	Belgium
Patrick Gaudray	Comité Consultatif National d'Éthique (CCNE), Centre National de la Recherche Scientifique (CNRS)	France
Ritva Halia		Finland

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees NEC's representatives and official delegates		
European Region (EURO)		
Name	Institution	Country
Secil Ozkan	Public Health Institution of Turkey	Turkey
Siobhan O'Sullivan	European Group on Ethics	Ireland
Svetlana Axelrod	Ministry of Health of the Russian Federation	Russia
Torkild Vinther	The Norwegian National Research Ethics Committees	Norway
South-East Asia Region (SEARO)		
Anoja Fernando	Committee on Biotechnology and Bioethics	Sri Lanka
Western Pacific Region (WPRO)		
Alastair Vincent Campbell	National University of Singapore	Singapore
Atishah Ali No	Bioethics Advisory Committee	Singapore
Calvin Ho	National University of Singapore	Singapore
Daecheong Ha	Korea National Institute for Bioethics Policy	South Korea
Leonardo Doloroso De Castro	National Ethics Committee of Philippines	Philippines

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees

NEC's representatives and official delegates

Western Pacific Region (WPRO)

Name	Institution	Country
Ryuichi Ida	Expert Panel on Bioethics, Council for Science and Technology Policy	Japan
Seong D Kim	Chungang University. Healthcare System	South Korea
Youngmo Koo	University of Ulsan College of Medicine	South Korea

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees

International organizations representatives

Name	Institution
Laurence Lwoff	Council of Europe
Hans Van Delden	The Council for International Organizations of Medical Sciences (CIOMS)
Andreas Alois Reis	World Health Organization - Headquarters
Manju Rani	World Health Organization - Western Pacific Region
Carla Sáenz	World Health Organization - Americas Region
Olla Shideed	World Health Organization - Eastern Mediterranean Region
Martin Ota	World Health Organization - African Region
Jim Dratwa	The European Commission

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees

International organizations representatives

Name	Institution
Maureen Birmingham	WHO/PAHO Mexico Country Office
Najeeb Al Shorbaji	World Health Organization - Headquarters
Abha Saxena	World Health Organization - Headquarters
Dafna Feinholz	United Nations Educational, Scientific and Cultural Organization
Inez de Beaufort	The European Group on Ethics
Lynn Woodward	World Health Organization - Headquarters
Lisa Gisbert	United Nations Educational, Scientific and Cultural Organization
Janaina Sallas	World Health Organization - Americas Region
Oswaldo Artaza	WHO/PAHO Mexico Country Office
Katherine Littler	Welcome Trust Foundation

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees

Mexican institutions observers and guests

Name	Institution
Alberto Abdo Andrade	Comisión de Bioética de Tabasco
Alejandro Pacheco Gómez	Secretaria de Salud de Hidalgo
Ana Maria Millán Velázquez	Secretaria de salud del Estado de México
Carlos Benítez Pineda	Servicios de Salud de Chihuahua
Carlos Eugenio Ruiz Hernández	Secretaria de Salud/Instituto de Salud

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees

Mexican institutions observers and guests

Name	Institution
Cristal Corona Sánchez	Comisión de Bioética de Tlaxcala
Eduardo García Solís	Secretaria de Salud Campeche
Efraín Navarro Olivos	Secretaria de Salud de Guanajuato
Enrique De Gaspe Vasseur Domville	Secretaria de Salud de Oaxaca
Eréndira Natalia Calderón Guzmán	Instituto de Salud del Estado de México
Francisco Javier Madera Maldonado	Secretaria de Salud de Zacatecas
Gabriela Emperatriz Minaya Martínez	Instituto Nacional de Salud
Guillermo Ortiz Villalobos	Secretaria de Salud de San Luis Potosí
Hilda Dávila Chávez	Secretaria de Salud Federal
Jorge Charvel Ochoa	Secretaria de Salud de Coahuila de Zaragoza
José Fernando Rivas Guzmán	Comisión Estatal de Conciliación de Arbitraje Médico de Colima
Karla Lidia Margarita Pizarro Lerma	Servicios de Salud Durango
Limitzen Gabriela Trejo Ortiz	Comité Regional del Distrito Federal
Luis De León Zaragoza	Secretaria de Salud Colima
Marco Aníbal Rodríguez Vargas	Secretaria de Salud de Nuevo León
Margarita Bocanegra Olmos	Secretaria de Salud de Baja California

Attendees to the 10th Global Summit of National Ethics/Bioethics Committees	
Mexican institutions observers and guests	
Name	Institution
María Andrea Valverde Díaz	Secretaria de Salud de Veracruz
María Luisa Jiménez Ramírez	Secretaria de Salud del Gobierno Distrito Federal
Marisabel Rivera Jiménez	Instituto de Salud del Estado de México
Martha Herlinda Teliz Sánchez	Secretaria de Salud de Guerrero
Moisés Hernández Sánchez	
Octavio Márquez Mendoza	Centro de Investigación en Ciencias Médicas de la Universidad Autónoma del Estado de México
Pilar Eugenia Granja Pérez	Laboratorio Estatal de Salud Pública
Rafael Rivera Montero	Comisión de Bioética de Jalisco
Ramón José Cué González	Secretaria de Salud del Estado de Morelos
Roberto Rivera Campa	SEP Sonora
Rodolfo Ginés Martínez Fernández	Servicios de Salud del Estado de Puebla
Rodolfo Padilla Torres	Secretaria de Relaciones Exteriores
Sergio Lucio Torales	Universidad Autónoma de Aguascalientes
Víctor Manuel Pacheco Bastidas	Comisión Nacional de Bioética en Salud
Violeta Guadalupe Feria Colín	Comité Regional del Distrito Federal

Contributors	
<p>Abha Saxena Knowledge, Ethics and Research Department, World Health Organization</p>	<p>Joachim Vetter German Ethics Council</p>
<p>Alastair Campbell National University of Singapore</p>	<p>Kirana Bhatt National Bioethics Committee</p>
<p>Andreas Reis Knowledge, Ethics and Research Department, World Health Organization</p>	<p>Laura Palazzani Italian Presidency of the Council of ministers National Bioethics Committee</p>
<p>Anoja Fernando Committee on Biotechnology and Bioethics</p>	<p>Laurence Lwoff Council of Europe</p>
<p>Calvin Ho Centre for Biomedical Ethics, National University of Singapore</p>	<p>Lotta Eriksson The Swedish National Council On Medical Ethics</p>
<p>Christiane Woopen German Ethics Committee</p>	<p>Manuel H Ruiz de Chávez Council of the National Bioethics Commission of Mexico</p>
<p>Christine Grady Presidential Commission for the Study of Bioethical Issues</p>	<p>Maureen Birmingham World Health Organization - Mexico Country Office</p>
<p>Dafna Feinholz United Nations Educational, Scientific and Cultural Organization</p>	<p>Meral Özgüc Bioethics Committee, Turkish National Commission for UNESCO</p>
<p>Daniel Piedra Comité Nacional Cubano de Bioética</p>	<p>Michel Daher Lebanese National Ethics Committee</p>

Contributors	
Ernesto Luna Orosco Comité Nacional de Bioética Bolivia	Miguel Montalvo Consejo Nacional de Bioética en Salud
François-Xavier Putallaz Swiss National Advisory Commission on Biomedical Ethics	Mohamed Salah Ben Ammar Ministry of Health of Tunisia
Gabriel J. O' Shea Cuevas National Commission for Social Protection in Health, Mexico	Najeeb Mohamed Al Shorbaji Knowledge, Ethics and Research Department, World Health Organization
Hans van Delden The Council for International Organizations of Medical Sciences (CIOMS)	Nicole Beaudry Commission de l'Éthique en science et en technologie
Hele Evereus Estonian National Bioethics Committee	Norman Daniels School of Public Health, Harvard University
Hugh Whittall Nuffield Council On Bioethics	Olla Shideed World Health Organization - Easter Mediterranean Region
Isaac Morales Tenorio Secretary of Foreign Affairs, Mexico	Patrick Gaudray Comité consultatif national d'éthique (CCNE), Centre national de la recherche scientifique (CNRS)
Jim Dratwa European Commission	Ryuichi Ida Expert Panel On Bioethics, Council Four Science and Technology Policy

The National Bioethics Commission of Mexico members

The success obtained during the conduct of the Global Summit of National Ethics/Bioethics Committees would not have been possible without the commitment and dedication of every one of the people that make up this great team. Serve this space as a recognition of colleagues and peers.

Maria de los Angeles Marina Adame Gayosso	José Manuel Lozoya Pacheco
Karen Aguirre Albrecht	Alma Rosa Macedo de La Concha
Alejandra Alcocer García	Manuel Magaña Izquierdo
Carlos Alberto Alfaro Medel	Marina Montes Hernández
José Julián Álvarez Rosas	Miguel Ángel Morales Gutiérrez
Sonia Balvás Hernández	Jorge Arturo Navarrete Ruíz
Claudia Bedolla Galván	Gustavo Fernando Olaiz Barragán
Anna Flor Cadena Castillo	Aidée Orozco Pérez
Sandra Lizbeth Carrizosa Guzmán	Brenda Guadalupe Ortega Trejo
Eduardo Casillas González	Caribey Padrón de León
David Concepción Castillo Uribe	José Luis Palomares Rodríguez

Yadira Zacel Cedeño López	Sergio Pérez de Lara Choy
Juana Araceli Cruz Morales	América Nelly Pérez Manjarrez
Arturo Alejandro del Valle Muñoz	Gabriela Pineda Hernández
Santa Esmeralda Estrada Galicia	Rubén Ramírez Tlamanalco
Reynaldo Ismael Figueroa Campos	Erika Elizabeth Rocha Córdova
Andrea Fonseca Ramírez	Raúl Héctor Rodríguez Otero
Jessica García Castillo	Gerardo Roque Cruz
Edén González Roldan	Alejandro Romero Martínez
Alfonso Heredia Arriaga	Víctor Hugo Romero Sánchez
Víctor Hernández Bermejo	Carlos Alfonso Salas Gómez
María Patricia Herrera Gamboa	Graciela Sánchez Olguín
Beatriz Eugenia Herrera Pérez	Karla Gabriela Sánchez Villanueva
Raúl Huerta Martínez	Mario Patricio Silva Schütte
José Misael Jiménez Arellano	José Torres Mejía
José Gerardo Jiménez Navarro	Marisa Valdés Fernández
Raúl Jiménez Piña	Gudelia Velasco Arce
David Alejandro López Vivaldo	Juan Manuel Velázquez Balderas
	Hugo Xolalpa Galindo



10th Global Summit of National Ethics/Bioethics Committees attendees



Julia Tagueña, Christiane Wooten Isaac Morales Tenorio, Manuel H Ruiz de Chávez, Mohammed Salah Ben Ammar, Maureen Birmingham, Miguel Montalvo, Najeeb Mohamed Al Shorbaji, Dafna Feinholz y Carla Sáenz



10th Global Summit of National Ethics/Bioethics Committees official delegates



Market place session



Laurence Lwoff (Council of Europe) at a the market place session



Opening session



Role and Performance of National Ethics/Bioethics Committees session

*10th Global Summit of National Ethics/Bioethics Committees,
Finding Paths Through The World*, se terminó de imprimir
en el mes de enero de 2015 en Edamsa Impresiones S.A. de C.V.,
Av. Hidalgo 111, Col. Fracc. San Nicolás Tolentino C.P. 09850, Iztapalapa,
México D.F. Su tiraje fue de 1,000 ejemplares.



From June 22–24, 2014, Mexico City, as host for the 10th Global Summit of National Ethics/Bioethics Commission, had the privilege of welcoming delegates from National Ethics Committees, International Organizations, and distinguished experts in bioethics from all around the world.

Since Brazil, 2002, the GSNEBC returns to the American Region. During the 9th Global Summit in Tunisia, 2012, Mexico was unanimously elected to hold the next biennial meeting, as well as establishing the working agenda. It reflects Mexico's commitment to the strengthening of bioethics.

The 11th Global Summit to be held in Berlin, Germany, 2016, will continue promoting ethical analysis in the public agenda around the world.

Bioethics is a space for the convergence of different fields of knowledge –humanistic and scientific–, to reflect on the many ethical dilemmas that arise regarding health and life sciences, weighing in on the risks and benefits to populations, ensuring equitable access to interventions and promoting fairness, justice and transparency.

It shouldn't be considered a code of precepts, but an exercise of analysis, in light of the principles and criteria that guide our practice in areas of health, life sciences and research.

The National Bioethics Commission of Mexico believes this publication will make a substantial contribution in developing a deeper understanding of health and life sciences from an ethical perspective.

The book features the developments of the themes addressed on the Global Summit:

- The role and performance of NECS
- Emerging technologies and healthcare
- Universal Health Coverage
- Health research and vulnerable groups
- The role of International Organizations

