Dakar, Senegal
22-24 March 2018

12th Global Summit
of National Ethics / Bioethics Committees

Bioethics, Sustainable Development and Societies
Prepared on behalf of the Steering Committee of the 12th Global Summit by Johannes Köhler.
Welcome from the Chair of CNERS

Through my voice, the National Ethics Committee for Health Research of Senegal (CNERS) would like to express to its counterparts present in Berlin in 2016, all its gratitude for having accepted to entrust to it the organization of the 12th edition of the Global Summit National Ethics and Bioethics Committees.

This biennial summit initiated in 1996 in San Francisco, is one of the most important meetings on ethics and bioethics. So, the CNERS is honored to host this prestigious meeting and wishes you all a warm welcome. This summit, which is being held for the first time in sub-Saharan Africa, represents for us, a consecration of a sustained work of more than 15 years in the field of ethics of health research and protection of the rights of people involved in research projects.

The theme "Bioethics, Sustainable Development and Societies" is relevant and current for our sub-region. Indeed, it is an opportunity to explore sustainable development under the lens of bioethics and in taking into account the diversities and the specificities of societies around the world.

The Sustainable Development Goals set for the year 2035 objectives that are common to all nations, and States are invited to demonstrate innovation and self-engineering to achieve the objectives set.

Africa in its diversity will certainly seize this opportunity to bring its contribution to the knowledge deposit likely to enlighten the onwards march of the world towards ethical sustainable development.
The CNERS thanks all those who have mobilized to help it succeed in the organization’s challenges and its scientific contribution to this summit.

Since 2016, where the choice of our committee to host the summit has been notified to us, no effort has been spared to create the conditions for the success of this 12th edition.

The Minister of Health and Social Action was personally involved in chairing the national preparatory committee of the summit with a mobilization of all his services. This led to substantial support from the Government of Senegal but also to exceptional mobilization of partners from the health sector and bioethics.

I also thank on behalf of the CNERS, WHO and UNESCO, as well as all the members of the International Steering Committee for the outstanding work accomplished that contributed significantly to the holding of the meeting. My thanks also go to all the sponsors who subsidized the participation of members of national committees or contributed to the financing of certain activities of the Summit.

The CNERS invites you to enjoy your stay and to take the opportunity to commune with the Senegalese people and to enjoy their products.

Everything will be done to make your stay pleasant and for the summit to produce results that undeniably mark the imprint of ethics and bioethics in the conduct of world affairs.

Have an excellent summit,

May God bless you.

Papa Touré

President of the National Ethics Committee for Health Research
Welcome from the Chair of Global Summit Steering Committee

As chair of the Steering Committee of the 12th Global Summit of National Ethics and Bioethics Committees, it is my pleasure to welcome you to this important event.

Dear participants, since 1996 in San Francisco, the Global Summit brings together representatives of National Ethics and Bioethics Committees from all regions of the world every two years to exchange knowledge and lessons learned in relation to bioethical issues that have cross-border and trans-border implications.

This event stands out for its regularity and ascension over the years. Indeed, since its launch, this initiative has continuously registered more and more attendees thanks to the relevance of the topics discussed and the quality of the scientific products it generates every two years.

Rapid advances in the field of health and medical sciences and the introduction of new technologies invariably raise complex moral, legal, social and environmental issues, requiring societies and decision-makers to have an in-depth ethical analysis of the issues at stake in order to help decision-making in line with the notions of equity, justice, respect of the person.

In addition, bioethics is increasingly approached according to the original perspective of Van Ressaeler Potter where the term “Bios” was considered as “Human Life” while “Ethos” was defined as the human conduct with the resulting shift from a medical bioethics to a more inclusive bioethics. So issues like climate change, migration, disease vectors, access to water and sanitation as factors affecting Human Life are more and more considered as
integral part of bioethics adding a degree of complexity to the bioethics reflection.

The Summit offers national ethics and bioethics committees a unique space for reflection and exchange of views in order to reach a common understanding and building consensus on bioethical issues of common interest.

Keeping in mind the UNSDGs, the theme of this 12th Global Summit is “Bioethics, Sustainable Development and Societies”. This theme was chosen to bring the contribution of bioethical thinking to global sustainable development goals and to reflect the fact that the bioethical vision of sustainable development could vary across societies. Indeed, human societies could have different underlying value systems that could lead to different understanding of sustainable development and to plural responses as to how to achieve this goal.

The subthemes are i) Bioethics in electronic data era, ii) Bioethics, social justice and civil society, iii) Bioethics, Health emergencies and resilience. The discussions around these sub-themes will allow to have more specific and in-depth reflections on operational issues.

The results of the work of this 12th Summit will undoubtedly bring added value to the global bioethics movement whose objective is to create an environment conducive to the optimal development of humanity.

We hope that this Summit will be a great moment in bioethics and that it will accelerate the establishment of national ethics and bioethics committees where they are not yet present.

It will also be an opportunity for the participants to enjoy the legendary Senegalese Teranga.

Warmest regards,

Welcome, Daal leen ak jam

Aissatou Touré
Message from the Global Health Ethics Unit of World Health Organization

It is a pleasure for the World Health Organization to jointly organize this 12th Global Summit with the Comité National d’Éthique pour la Recherche en Santé (CNERS) and in close collaboration with UNESCO. Understood as a neutral broker and a trusted partner to its 194 Member States, WHO has been supporting the organization of the Summit since 2000. As the Secretariat of the Global Summit, WHO networks with existing national bioethics committees working in the areas of health and science and technology, and provides technical and logistical support to the organization of the Global Summit.

The theme of the 12th Global Summit - Bioethics, Sustainable Development and Societies resonates with the focus of the Sustainable Development Goals (SDGs) on societies and communities. The 12th Global Summit will focus attention of the global bioethics community on the contributions they can make to attaining the SDGs. The SDGs are very ambitious and without a focus on people and communities – they can be at risk. The Bioethics Committees can play a very special role in advising their governments on the ethical framework that can be used to ensure that individual values such as human dignity, and respect are promoted, and obligations are offset by responsibilities; they can advocate at a national and global level for solidarity, reciprocity, and mutual understanding amongst other values, and they can foster trust, improve transparency, and enhance accountability. The agenda of the Summit echoes some of the reflections and discussions taking place on the global stage such as the focus on health systems resilience, and the promise of the digital technology. Rightly so, the Summit also focuses on the role of civil society, and how the interactions of the bioethics community with civil society can be improved. These are exciting topics for discussion, and I look forward to hearing the plenary discussions on day 1.

The motto of the 13th Global Programme of Work (GPW) of the World Health Organization is ethically based – it is to “promote
health, keep the world safe, serve the vulnerable”. As noted in the GPW, developments at the frontier of new scientific disciplines such as genomics, epigenetics, gene editing, artificial intelligence, and big data, while posing transformational opportunities also pose risks to global health, for example through challenging countries’ capacity to provide equitable and universal access. While countries struggle to balance provision of universal health coverage in the face of new technologies, new and evolving political, economic, social and environmental realities create a more complex agenda for global health; they impact the institutions responsible for delivery and they raise new and complex ethical challenges. Consequently, many ethics committees – especially those from the low and middle income group - look to WHO for normative ethical guidance in public health and health research, and request assistance in implementing the guidance. WHO is able to assist through workshops, consultative meetings, seminars and direct interactions with the National Ethics Committees. Support is provided not only by the Global Health Ethics Unit in Geneva, but also by the responsible colleagues in the Regional Offices, and a network of Collaborating Centers which act as an extension of WHO’s technical arm. WHO also receives advice from National Ethics Committees who play a key role in advising it and shaping international policy on ethics. The bilateral and multilateral approach is a key requisite of global health governance in the 21st century. Despite the many advances in the establishment of NECs, there are many countries where they do not exist at all, or where there is very limited capacity. It is these countries which should be the focus of our attention. Much needs to be done in these countries, from supporting the establishment of NECs to raising their capacities to formulate opinions. The Global Summit is an excellent and unique opportunity for NECs to discuss, learn from each other’s experiences, and support each other, and I hope that the more than 70 NECs coming to the Summit will avail of the opportunity that the Summit offers.

I congratulate the Steering Committee, and especially its Chair Dr Aissatou Touré as well as the CNERS for its commitment and acknowledge the hard work that has gone into making the 12th Global Summit a success. The effort put together by the local organizing committee of Dakar led by Professor Papa Touré is
truly commendable and I would like to put a note of appreciation for his leadership and guidance for the success of the Summit. I look forward to what promises to be engaging and thoughtful discussions on the topics that have been identified by the various National Ethics Committees.

Dr Abha Saxena
Coordinator, Global Health Ethics
HQ/HIS/IER/REK
Recognising the importance of an ethical reflection and analysis on health-related policies, many countries have created official bodies to provide an ethics advice to their executive and legislative branches, and often to the general public. Such bodies, typically called National Ethics Committees/Bioethics Committees/Bioethics Commissions (NECs), are established as independent bodies to perform an ethical analysis on health-related policies mostly but more and more on domains beyond the scope of medical sciences, and offer conclusions and recommendations to ministries of health, of science and technology or head of states.

In the summer of 1996, the National Bioethics Advisory Commission, a body appointed by recently by President Clinton invited several countries to send delegates to an international summit meeting to be held in San Francisco in conjunction with the III World Congress of Bioethics at the end of November 1996. Delegates representing 18 nations, as well as observers from six international bodies participated in this first global meeting.

Some of the countries had specialized national commissions, others were represented by a professional association’s ethics group, and a few by a health ministry official. The delegates, from the Americas, Asia, Australia, and Europe discussed their differences in scope, sponsorship, and national cultures but found many areas of common interest in bioethics and resolved to continue their dialogue.

This was done in 1998 in Tokyo where a two-day meeting brought together Delegates and Observers from more than 30 countries and 6 international organizations. At the end of the meeting, the participants decided to formally establish the “Global Summit of National Bioethics Commissions” as an on-going organization to foster progress of the reflection on subjects of mutual interest to the national bioethics advisory bodies.

Since there, the Global Summit of National Bioethics Commissions has been held successively in London (2000), in Brasilia (2002), in

For the first time, in 2018 the Global Summit will be organized in a sub-Saharan country, in Dakar, Senegal.

The number of countries participating has progressively increased from 18 countries in San Francisco to 99 countries in Berlin.

African countries had little or no representation at the first meetings, but their participation gradually increased and will hopefully reach a peak in Dakar.

The Global Summit provides a platform for NECs to learn from each other, and to share experiences of what works and what doesn’t. This is the only event at the international level that brings together representatives of NECs especially from low and middle-income countries and offers them a platform to exchange experiences on bioethics issues that are relevant at a national level and build on each other’s progress.

Its Steering Committee comprises NEC representatives from all regions. The World Health Organization (WHO) has provided the permanent secretariat for the Global Summit since 2000, in collaboration with UNESCO.

The Summit has enabled to hear from NECs about gaps in their in-country bioethics capacity, institutional weaknesses, and difficulty translating bioethical considerations to local settings. Responding to these needs will help nations to build robust ethics infrastructures that can support societies and policymakers in carrying out ethical analysis to support decision making that is compatible with the practical, social, and political challenges raised by the burden of disease and health disparity, and those by new technologies and medical advances.

The Global Summit is also an opportunity to conduct capacity strengthening activities with representatives of NECs, and for the first time, such activities are planned in the coming summit in Dakar.
## Programme

### DAY 1 – 22 March 2018 (Thursday)

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<td>2. Research with Children – Nuffield Council</td>
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<td>3. Sharing NEC Experiences in developing ethics guidelines &amp; laws</td>
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<td>1230-1400</td>
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<td>1400 - 1450</td>
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<td></td>
<td>1. Prof. Papa Touré, President, CNERS</td>
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<td>2. Dr Aissatou Touré, Chair, Steering Committee Global Summit</td>
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<td>3. Ms. Angela Melo, Director, Policies and Programmes, UNESCO</td>
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<td>4. Dr Soumya Swaminathan, Deputy Director-General, World Health Organization</td>
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<td>5. Senegalese dignitary</td>
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<td>1450 - 1515</td>
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<td>1515 - 1545</td>
<td><strong>Keynote Address</strong>: Bioethics and sustainable development: Dr Aissatou Toure</td>
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<td>1545 – 1715</td>
<td><strong>Reporting Back</strong> – Chairs: Dr Joachim Vetter (Germany), Prof. Anta Tal Dia (Senegal)</td>
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<td>1. 11th Global Summit: Prof. Christiane Woopen</td>
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<td>2. 12th Global Summit: Dr Abha Saxena;</td>
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<td>3. 2017 Regional Summits: Dr Yoon Seong LEE; Mr. Ahmed Khitami; Dr Joana Namorado (tbc)</td>
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<td>1715 – 1845</td>
<td><strong>Report from International Organizations</strong> - Chairs: Dr Amar Jesani (India), Monsieur Camilo Manchola-Castillo (Brazil) (TBC)</td>
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<td>1. UNESCO: Dr Dafna Feinholz;</td>
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<td>2. Council of Europe: Prof. Jozef Glasa;</td>
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<td>3. WHO: Dr Carla Saenz;</td>
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<td>4. WAHO: Prof. Issiaka Sombier;</td>
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<td>5. European Commission: Dr Jim Dratwa;</td>
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<td><strong>Reception</strong></td>
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### DAY 2 – 23 March 2018 (Friday)

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<td>Welcome, and report back from Day 1</td>
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<td>0920</td>
<td>Plenary Session I: <strong>Bioethics, Health emergencies and resilience</strong> Chairs: Prof. Leonardo de Castro (Philippines) and Dr Sohel Saika (WHO)</td>
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<td>1. Resilient Health Systems – improving health - one billion at a time: Dr Soumya Swaminathan</td>
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<td>2. Embedding ethics in emergency preparedness and people-centred health services – experience of Tanzania: Dr Azma Simba</td>
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<td>3. A LEGS Framework for efficient, equitable, and quality health care delivery: Dr Joseph Mfutso-Bengo</td>
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<td>1040</td>
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<tr>
<td>1100</td>
<td>Plenary Session II: <strong>Bioethics in electronic data era</strong> Chairs: Prof. Christiane Woopen (Germany), Dr Yuko Harayama (Japan)</td>
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<td>1. Responsible innovations for health care data: design for privacy, fairness, accountability and transparency: Prof. Jeroen van den Hoeven (Video presentation)</td>
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<td>2. Data governance and role of national ethics committees: Dr Najeeb Al-Shorbajee</td>
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<td>3. Cryptology and bioethics: Prof. Mamadou Sanghare</td>
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<td>1330</td>
<td>Lunch</td>
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<td>Francophonie Networking Meeting</td>
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### 1500 – 1600

**Rapid communications (6+2 minutes each presentation)**
Chairs: Prof. David Archard (UK), Dr Marta Ascura (Paraguay)

2. Ethical issues in End-of-Life Care: Prof. Michel Daher, Lebanon
3. Ethical Responsibility for Migrants Health Care: Jordan Case: Dr Nijmeh Atiyyat, Jordan
4. Pain Relief and Palliative Care as a Human Right: Prof. Michel Daher; Lebanon
5. National Ethics Committee for health research of Senegal: Experiences and ethical problems treated: Dr Samba Cor Sarr, Senegal
6. Protection of privacy by gender in Tunisia: Ethical aspects: Prof. Hend Bouacha, Tunisia

### 1600 - 1730

**Parallel breakout discussion groups**

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<th>Bioethics, social justice and civil society Chairs: Dr Aasim Ahmed (Pakistan) &amp; Prof. Delfraissy (France)</th>
<th>Bioethics in electronic data era Chairs: Prof. Christiane Woopen (Germany), Dr Yuko Harayama (Japan)</th>
<th>Bioethics, Health emergencies and resilience Chairs: Prof. Leonardo de Castro (Philippines), Dr Sohel Saikat (WHO)</th>
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### 1730 – 1830

Reporting back to plenary by 3 session rapporteurs Chair: Hugh Whittall (UK)

### 2000-2200

*Dinner*
Global Reports:
Chairs: Prof. Christiane Druml (Austria), Prof. Oumou Bah Sow (Guinea)
1. Presentation of the IBC Report on Refugees and Health – Dr Dafna Feinholz, UNESCO
2. International Framework for Accreditation of Research Ethics Committees – Dr Andreas Reis, WHO
3. Survey of NECs – Mr Johannes Koehler, Dr Abha Saxena, WHO

Regional Meetings facilitated by WHO/UNESCO

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<tr>
<th>Time</th>
<th>AFRO</th>
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<td>1015 – 1115</td>
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1115 - 1130  Coffee break

1130 – 1200  Regional Meetings Continue

1200 - 1300  Reports from Regional Meetings
Chairs: Prof. Lucilia Nunez (Portugal), Prof. Zubairu Iliyasu (Nigeria)

1300 – 1430  Lunch break

1430 - 1600  Panel discussions: Issues, Challenges, and Country Perspectives

See following page
Bioethics and health as a human right and the role of NECs

Chairs: Prof. Mohamed Ahmed Ali Elsheikh (Sudan); Dr Tamás Kardon (Hungary)

1. Bioethics, health as a human right and the Latin American and Caribbean Regional Network of National Bioethics Committees: Dr Camilo Hernan Manchola Castillo
2. Human rights, ethics and bioethics: Prof. Samba Thiam
3. NBC – Bioethics of disasters: Prof. Luisa Borgia
4. Refugees, Migrants and Ethical Responsibility for their Health Care: Prof. Michel Daher

Discussion

Ethics guidance on Genetics/ Genomics

Chairs: Dr Ole Johan Borg (Norway); Prof. Xiaomei Zhai (China)

1. Germline intervention in the human embryo: Prof. Claudia Wiesemann
2. Use of genome editing technology for human embryo research: Dr Yuko Harayama
3. Genetic Testing in Lebanon- Role of the National Bioethics Committee: Dr Kamal Kallab

Discussion

Role of Bioethics Committees in strengthening access to reproductive & sexual health

Chairs: Dr Mahmood Uz Jahan (Bangladesh); Dr Gloria Mason (Liberia)

1. Impact of socio- cultural practices and the effects of pregnant women’s participation on clinical trials in sub Saharan Africa: Dr Jennyfer Ambe and Dr Gibril Ndow
2. L’assistance sexuelle aux personnes handicapées : une problématique pertinente pour le Comité Consultatif de Bioéthique de Belgique: Prof. Guy Lebeer
3. Role of Bioethics Committees in strengthening access to reproductive health: Prof. Christiane Druml

Discussion

1600 - 1630 Coffee Break

1630-1730 Looking ahead – Chair: Prof. Aissatou Toure

1. Adoption of the Dakar Action Statement
2. Global Summit 2020: Presentation of next venue

1730- 1800 Concluding Session

Closing Remarks and Vote of Thanks
Steering Committee Members

Please visit the Summit’s website at http://www.sommetmondial-dakar2018.gouv.sn for un-shortened biographies.

Chair Dr Aissatou Toure

Dr Aissatou Toure is a senior researcher at the Pasteur Institute in Dakar where she heads the Unit of Immunology. She graduated in Pharmacy from University Cheikh Anta Diop in Dakar Senegal then specialized in Immunology that she studied at University of Lille, France and at Pasteur Institute Paris in France.

Dr Joachim Vetter

Steering Committee Member for the WHO European Region.

Studied Biology at the Ruprecht-Karls-University of Heidelberg, Germany and obtained his PhD in Biology from the University of Cologne/Germany in 1993. Director of the German Ethics Council since 2008.
Professor Joseph Mfutso-Bengo

Professor of Bioethics and Head of Health Systems and Policy Department & Centre of Bioethics in Southern and Eastern Africa (CEBESA) at College of Medicine-University of Malawi. He heads the WHO AFRO Regional Global Summit of Nation Ethics Advisory Board and Malawi National Committee on Bioethics (NACOB).

Professor John Ayotunde (Tunde) Isola Bewaji

Professor John Ayotunde (Tunde) Isola Bewaji is the Chairman of National Bioethics Committee of Jamaica – UNESCO and he represented Jamaica and the English Speaking Caribbean at the World Humanities Forum in Liege, Belgium in August 2017.
Professor Lucília Nunes

Since 2001, Professor at School of Health, Polytechnic Institute of Setúbal, and coordinator for the Nursing Department. Member of the Ethics Committee for Health of the Hospital Center of Setubal (since 2009). Member of the IV mandate (2009-2014) and Vice President (since 2015) of the National Council of Ethics for Life Sciences.

Professor Aasim Ahmad

Is a nephrologist by training and at present he is the Dean and Chief Nephrologist at The Kidney Centre Post Graduate Training Institute and Faculty of Nephrology of the College of Physicians and Surgeons Pakistan (CPSP). He is a member of National Bioethics Committee (NBC) and chair of its Research Ethics Committee (REC).
Dr Roli Mathur

Dr Roli Mathur is presently Scientist E and Head, ICMR Bioethics Unit, at NCDIR, ICMR, Bangalore. She was based at ICMR, New Delhi between 2001-2016 before moving to Bengaluru in July 2016. Prior to joining ICMR she was at the Genetics Unit, Department of Pediatrics, New Delhi between 1994-2001 for obtaining her Ph.D in molecular human genetics.

Professor Amar Jesani

Is an independent consultant – researcher and teacher - in bioethics and public health.

Presently he is Visiting Professor, Centre for Ethics, Yenepoya University, Mangalore (since 2011); Associate Faculty, Centre for Biomedical Ethics and Culture at the Sindh Institute of Urology and Transplantation in Karachi, Pakistan (since 2010) and visiting faculty, PHFI.
**Barry Smith**

Barry Smith has an academic background in sociology, statistics and music and works in health analytics and health ethics with the Lakes District Health Board in Rotorua, New Zealand.

Associated with a number of Health Research Council of New Zealand (HRC) and Royal Society of New Zealand Marsden Fund supported projects.

**Professor Kon Oi Lian**

Professor, Duke-NUS Graduate Medical School and Honorary Professor, Department of Biochemistry, Yong Loo Lin School of Medicine, National University of Singapore. Her current research interests are in gastric cancer and cell therapy of metabolic disorders.
Dr Abha Saxena

Leads the work of the Global Health Ethics Unit at the World Health Organization – the world’s premier health institution that directs and coordinates global health through the United Nations system. She has responsibility for coordinating WHO’s work on bioethics, and public health and research ethics. Internally, she heads Secretariats of the Research Ethics Review Committee (ERC), the Public Health Ethics Consultative Group, and the Global Summit of National Bioethics Advisory Bodies (NEC).

Dr Dafna Feinholz

Since September 2009, Dafna Feinholz is the Chief of the Bioethics Section, within UNESCO Social and Human Science Sector. In this capacity, she leads different activities aiming at reinforcing capacities of Member States to manage bioethical challenges and to identify the ethical, legal and social implications of cutting-edge science, emerging technologies and their application for sustainable development.
Dr Samba Cor Sarr

Dr Samba Cor SARR PhD, health research expert in ethic in health research Coordinator of Senegalese National Ethical Committee and Chief of health research department in Ministry of Health and Prevention. Dr SARR, after his training in health research management from Laval University of Quebec, is responsible for the health research system in Senegal from 2002.

Professeur Anta TAL-DIA

Professor Anta TAL-DIA is a medical doctor and graduated from the Faculty of Medicine, Pharmacy and Odontology (FMPO) of the University Cheikh Anta Diop of Dakar (UCAD) in 1982. She is specialized in Pediatrics and Public Health, holds a DEA in Clinical Epidemiology, a diploma in Health Economics and Health and Development. She holds the Chair of Public Health at UCWO's OPCF.
Professor Christiane Woopen

Professor for Ethics and Theory of Medicine at the University of Cologne and Executive Director of the Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health (ceres).

She is former chair of the German Ethics Council, President of the 11th Global Summit of National Ethics/Bioethics Committees 2016 and amongst others member of the International Bioethics Committee of UNESCO.

Professor Mohammad Ahmed Hamdan

Advisor of the Arab Open University, Professor Hamdan is currently Senator at the Upper House of Parliament in Jordan, Vice President for Jordan Academy for Arabic Language and Vice President for The World Academy of Science/ Arab Region (TWAS), President of the Union of Arab Statisticians, he was also President and Founding Member of two public universities in Jordan: the Yarmouk University and the Hashemite University.
Professor Jean-François Delfraissy

Professor Delfraissy is a French immunologist and previously served as the head of the Department of Internal Medicine of the University Hospital of Kremlin-Bicêtre Paris-Sud. He was appointed by the president of the French Republic François Hollande as the Head of the Consultative Ethics Committee for Health and Life Sciences, a position he holds presently.

Professor Mohamed Salah Ben Ammar

Medical Doctor, Laureate of Descartes University, Paris France (1985) and Professor in Anaesthesia and Intensive Care, University El Manar, Tunis

Resilient Health Systems – improving health – one billion at a time

Dr Soumya Swaminathan, Deputy Director-General, WHO
Plenary Session I: Bioethics, Health emergencies and resilience

The recent Ebola crisis not only reminded the world that there is a genuine risk of a global pandemic but also painfully revealed the consequences of weak health systems in the face of a major public health emergency. While the 2014-2015 epidemic of ebola virus disease highlighted very starkly the importance of health security and the role that health systems can play in contributing to health security, it is equally well known that infectious diseases have threatened health security of countries since the beginning of civilisation. Equally, it has increasingly become clear that the collective health security of countries is dependent on individual health security which in turn is dependent on access of individuals to vaccines, drugs, and health services, not only during ‘peace time’ but also during periods of crises such as infectious disease outbreaks.

The UN Commission on Human Security, co-chaired by Sadako Ogata and Amartya Sen, underscored the importance of a people centred approach to security – emphasising its importance over borders, international relations, money and economics. In others words, only if health systems are able to provide health services to individuals even during periods of crisis, i.e. they are resilient enough to absorb the shocks from such external (or internal) threats can we hope to achieve health security.

What makes a health system resilient and in fact what exactly is resilience will be explored in this presentation. The presentation will link the resilience of communities and countries to UHC, and the contribution of UHC to a strong foundation for health emergency risk management. At the same time, early detection, risk assessment, information-sharing and rapid response are
essential to avoid illness, injury, death and economic losses on a large scale. The vision of the 13th Global Programme of Work of WHO to make 1 billion people safer through building resilient health systems will only be achieved if global and regional early warning and events-based surveillance systems are in place; and data is made available in a more systematic and timely manner to core partners, countries at risk, and the public. This presentation will also explore what ethical values are at stake when health systems collapse and how attention to ethics can support re-building health systems that are resilient and responsive.
Embedding ethics in emergency preparedness and people centred health services – experience of Tanzania

Dr Azma Simba, (acting) Assistant Director, Epidemiology, Ministry of Health and Social Welfare
Plenary Session I: Bioethics, Health emergencies and resilience

In February 2017, United Republic of Tanzania became the first country to develop the National Action Plan for Health Security. This process was very consultative and involved various stakeholders including Community Organizations. This process facilitated incorporation of all potential interests while at the same time ensuring a people centred approach. Participants set of core values for the plan which included among others, gender and human rights principles, equity access, shared responsibility and fostering engagement. Criteria for prioritization of key intervention areas was also developed and later subsequently followed by an open, transparency, inclusive and collective discussion which led to selection of key interventions.

The Tanzania NAPHS is really a document which advocates for a coordinated national response to public health threats. The NAPHS has identified potential discrepancies in country preparedness and response and has developed coordinated plan which will enable the country to be able to prevent, detect and respond to public health threats and prevent spread of the threats in neighboring countries. A coordinated plan will also ensure there is a strong resilient system within the country to combat public health threats, while at the same time it will ensure equal treatment for all citizens regardless of the place of origin and their legal status, basing on the policy of equity but at the same time protecting Tanzania citizens from infection by untreated individuals.
A LEGS Framework for efficient, equitable, and quality health care delivery

Dr Joseph Mfutso-Bengo, Chair, National Advisory committee on Bioethics, Malawi
Plenary Session I: Bioethics, Health emergencies and resilience

Introduction:

WHO’s framework of six building blocks recognizes; Leadership/Governance, Financing, Essential Medicines, Health Workforce, Health Information Systems and Service Delivery as guiding inputs to help a health system achieve the intended goals. This framework has worked well particularly in advanced economies with strong governance and rule of law.

Methods:

This was a desk review of selected available key literature on factors that affect health care delivery in low income countries like Malawi. Data was reviewed and analysed using thematic manual analysis.

Results:

The review identified four frequently occurring themes namely: Leadership, Ethics, Governance and Systems as the key bottlenecks in the delivery of efficient, equitable and quality health care in Malawi and Africa. The WHO framework is not flexible to accommodate other important factors like weak rule of law and integrity. Countries with weak internal controls require very strong external controls, such as; strong governance and rule of law. Likewise, weak governance and rule of law can be compensated by strong inner controls, which are integrity and moral capital. WHO Framework lacks “ethics” as a building block even though equitable access is one of its intended outcomes.

Recommendation:

The authors propose a new framework called LEGS namely: Leadership - Ethics - Governance - Systems. This new framework
identifies the above four pillars as key essential determinants for health systems strengthening. This framework is very flexible, simple to use, quick to remember and can better guide different health systems and actors to achieve intended goals by taking into consideration the contextual factors like deficits in moral capital/integrity and social determinants of health.

**Conclusion:**

The LEGS framework can complement the existing six WHO building blocks. One needs a LEG to run a resilient health System. The system building block does include other 5 five building blocks of WHO such service delivery; (iii) health workforce; (iii) health information systems; (iv) access to essential medicines; (v) financing but the WHO building block of governance has been unpacked or expanded to become three foundation building blocks of Leadership, Ethics and governance. The other WHO five building blocks have become essential elements in the building block called system of LEGS framework. Therefore LEGS BUILDING Blocks building a resilient, ethical quality and equitable health systems are namely: LEADERSHIP, ETHICS, GOVERNANCE AND SYSTEMS.
Responsible innovations for health care data: design for privacy, fairness, accountability and transparency

Professor Jeroen van den Hoven, Professor of Ethics and Technology, Delft University of Technology, the Netherlands

Plenary Session II: Bioethics in electronic data era

The digital revolution has made digital technologies ubiquitous and has given rise to numerous new, surprising and baffling moral problems. We now understand that computers are not just ‘enabling technology’, they are ‘constitutive technology’ and radically change the things to which they are applied. They do not leave things as they are. Digital technologies have also impacted health care in all of its dimensions: research & development, clinical practice, policy, innovation, entrepreneurship, insurance and financing. The moral problems we encounter here and everywhere in our digital societies have – broadly conceived - all to do with data and persons and our dealing with both of them.

I will discuss how we need to do medical ethics in the age of Big Data and AI in order to stand a chance of being effective and relevant in our ethical reflections and to innovate responsibly in health care. I argue that ‘Responsible Innovation’ as promoted by the European Commission in its H2020 R&D framework and the ‘design approach’ to applied ethics as it has recently emerged in the ethics of technology are the way forward - drawing upon my Designing in Ethics (Van den Hoven, e.a, Cambridge University Press, 2018).
Data governance and role of national ethics committees

Dr Najeeb Al-Shorbajee, free-lance Consultant, Jordan
Plenary Session II: Bioethics in electronic data era

Management of digital data substantially differ from management of analogous data as it has increased its availability and accessibility. This is due to ability for multiple access of digital data, ease of exchange, coding, networking, reuse, machine-assisted translation, formatting and reformatting, extraction, aggregation, and so on. This transformation from analogue to digital data management (collection, storage, processing and exchange) has created a number of ethical challenges. According to the Oxford Dictionary, governance, in general, suggests the act of controlling, influencing, or regulating a person, action, or course of events.

Absence of health data governance in many countries have resulted in either extreme control on data which deprived potential users from access and benefit or very relaxed control or no control that resulted in exposure and misuse of personal data by researchers, commercial entities and governments.

Data governance provides the framework to ensure knowledge and awareness of the value of health data (personal and public), stewardship of data including ownership, access rights, confidentiality and privacy and data quality. Organizations use the governance framework to manage their data and information assets to achieve results without compromising personal or institutional risks based on quality and proper use. Core component of data management is data sharing, which requires specific considerations to ensure legal and ethical compliance. Data sharing brought with it the challenge of data ownership. Data ownership by the individual vs. the enterprise dictates the way it is shared and used. The presentation will touch upon the challenges facing countries and the role of National Ethics Committees (NECs) in establishing, implementation, monitoring and evaluation of health data governance at national level.
Examples from countries that have developed such frameworks will be provided.

Countries have responsibilities to conduct health research and produce evidence that can help them in improving healthcare and medical services. With this responsibility comes additional responsibilities to ensure data protection from abuse. NECs along with other stakeholders work together develop and implement codes of conduct, legal and ethical principles that serve these purposes. The role of NECs in health data governance is integral part of its functions in supporting health research which may include setting standards, guidelines and norms, monitoring research conduct, registering and auditing of health research, adjudication and referral of complaints as appropriate.

Big data and health data analytics will be discussed in the presentation focusing on the importance of big data in health including sources and format of health data, data anonymization, coding, use and reuse. Big data has brought with it a number of challenges related to reuse of multiple data sources.
Bioethics and globalization of the health market: role and responsibility of civil society in Senegal

Professor Fatou Sarr Sow, Director of Laboratoire Genre et Recherche scientifique Université Cheikh Anta Diop, Dakar
Plenary Session III: Bioethics, social justice and civil society

Technological advances in the areas of human and animal health and the environment raise issues related to an economic and political issues.

In developed countries, there has been a shift from medically assisted procreation, in vitro fertilization, euthanasia to a gene selection issue, which no longer allows nature to determine the future of offspring with reproductive and therapeutic cloning. As for the transplants, they are no longer limited to vital functions (kidneys, liver, heart) because restorative surgery affects external organs.

All this opens the way to the commodification of health in a context of globalization. Thus, since the action of medicine could no longer obey the own interest of the patient, scientific questions should no longer be determined only by researchers. The citizen must have a right of inspection, on the construction of the questions. Thus, civil society expressing itself on behalf of citizens becomes an important player in this field.

In countries like Senegal, where the majority of the population is very far from these issues that affect or will affect their daily lives, civil society organizations (CSOs) will play a decisive role. Indeed, the biotechnology and medical activity invades the market with the creation of numerous companies in the fields of pharmacy, agri-food, chemical environment, etc.

The globalization of the health, food and beauty market, reinforced by e-commerce, will have consequences for their lives, hence the challenge of information and awareness-raising, but above all protection of the population. In the same way they have
the right to benefit from the advances of science, whose applications sometimes conflict with the systems of representation, it being understood that often these are issues that affect beliefs and religious faith in a country with 99% of Muslims and Christians.

In Senegal, the link between religious organizations and CSOs has contributed significantly to the positive management of HIV / AIDS. These organizations played an interface role between the scientific world and religious communities and contributed to the formation of public opinion. It seems important to us to start from this experience to guide the reflection on the coordination of these different types of actors for more efficiency in the appropriation of the ethical and bioethical questions by a large part of the population, and of watching in everyday on practices.

Our communication will try to open perspectives of pooling the expertise of different actors for an inclusive management and an appropriation of the new questions. But also because women are the most likely to be affected by these issues, it will be a matter of assessing their representativeness on these issues in the bodies and mechanisms of bioethical issues management, their skill levels and the potentials of which they are carriers.
Prioritising inclusiveness and sensitivity to the experiences of participants: Learning from the civil society activism on clinical trials in India

Dr Amar Jesani, Editor, Indian Journal of Medical Ethics; Consultant: Bioethics and Public Health, Mumbai, India
Plenary Session III: Bioethics, social justice and civil society

Institutional and local research ethics committees are dispersed, have scanty representation of trained patient/participant advocates and pre-occupied with review of individual protocols. Consequently, they often do not perceive as their obligation to respond and act on the new discourse and attempts at the social deliberation on the larger policy issues affecting the patients and participants in the clinical trials. A National Ethics Committee, by acting as the synthesiser of the experiences of the institutional committees and the concerns of the participants articulated by the civil society organisations (CSOs) could play a key role in the public deliberation and provide a bridge to the policy making. The presentation would use a case study of India to illustrate this point.

India does not have the NEC, but since 2005 it has opened up to the global clinical research. Next few years witnessed a massive increase in the clinical research. But that was accompanied by unhealthy competition to attract clinical research business by the Contract Research Organisations and reports of gross violation of ethics and harm to participants. The resultant public outcry, expressed thru the CSOs, Public Interest Litigation in the Supreme Court and media, created a different public discourse for the advancement of health and human rights of participants of clinical trials. In the absence of the NEC, the public deliberation was one-sided, and the regulator, under the pressure responded in a bureaucratic manner adversely affecting the clinical research.
The presentation would draw lessons from the events by arguing for the primacy of public discourse and deliberation on research ethics through a proactive National Ethics Committee providing space for the CSOs to participate in a constructive way.
Slovak Republic NEC and the Health Care System in Transition (1990 - 2018)

Professor Jozef Glasa, Ethics Committee, Ministry of Health (SR NEC) and Institute of Health Care Ethics, Slovak Medical University in Bratislava, Bratislava, Slovak Republic

Rapid communications

Established in 1990, as one of the first National Ethics Committee in the region after falling down of the “Iron Curtain” in Central, Eastern and East Southern Europe, and with great expectations to be a contributor to the humanization and improvement of quality, of the “human face” of the Slovak medicine and health care deemed deeply wounded and compromised by the heritage of more than 40 years of the totalitarian past, the Ethics Committee of the Ministry of Health (EC MH) of the Slovak Republic (SR) tried to live up, as well as it could, to these formidable prospects.

Among different activities it had been engaged into, such as to help setting up ethics committees and building the first bioethics capacities and institutions in Slovakia (e.g. Institute of Medical Ethics and Bioethics at the Postgraduate School of Medicine in Bratislava (1992)), establishing international contacts and collaborations, and initiating and supporting various bioethics educational and public outreach activities, the Committee during its history so far had been repeatedly engaged in serious legislation developments activities within the SR health care sector. This involvement was deemed appropriate in view of the Committee’s role as an advisory body to the Ministry of Health, and to other State Authorities, on ethical issues arising within the health care provision and in biomedical research realms.

Three periods of Committee’s closer involvement in the health legislation activities are worth mentioning: 1990-1992 – first major legislation changes enabling transition from the state, tightly managed socialist (communist) health care system towards a more pluralistic and open one resembling those in freer economies; 2003-2004 – participation in the most profound legislation reform of the health care system in SR since 1990-ies;
2017-present – advising Ministry of Health on major legislation changes in view of enabling necessary improvements in the SR health care sector after more than a decade of underdevelopment, as well as facing novel, serious health care, public health and biomedical research challenges.
Ethical issues in End-of-Life Care

Professor Michel Daher, National Ethics Committee Professor of Surgery, University of Balamand, Saint George Hospital, Beirut, Lebanon

Rapid communications

Introduction:

Ethics is a branch of philosophy that examines rights and wrongs, what should or ought to be done. Clinical ethics refer to application of the science and understanding of morality in the field of medicine and health sciences. The goal of clinical ethics is to improve the quality of patient care, emphasizing the commitment to the well-being of patients. Owing to technical advances in the care of critical illness, physicians, patients, and families are often confronted with ambiguous circumstances in which medical advances may inadvertently prolong suffering and the dying process rather than bring healing and recovery.

Objectives:

The objectives of this presentation are to: 1) review major principles of medical ethics relevant to the care of terminally ill patients; 2) explore further the principle of autonomy and its application to advanced directives, informed consent, and medical futility; 3) characterize the ethical differences between withholding or withdrawing life-sustaining therapies and physician-assisted death; 4) define a process for communicating bad news and negotiating decisions at the end of life; and 5) examine ethical problems specific to terminal illness in light of these principles. We will discuss how a good palliative care can be an alternative to these ethical dilemmas.

Results:

Patients and their physicians together face a number of challenging ethical issues at the end of life. Although some issues (eg, the role of physician-assisted death in addressing suffering) remain very controversial, there is much common ground based
on the application of the 4 major principles of medical ethics, nonmaleficence, beneficence, autonomy, and justice.

Conclusions:

The physician’s primary commitment must always be to the patient’s welfare and best interests, whether the physician is treating illness or helping patients to cope with illness, disability, and death. The physician must support the dignity of all persons and respect their uniqueness. When ethical dilemmas occur, Ethics Committees must be involved.
Pain Relief and Palliative Care as a Human Right

Professor Michel Daher
Rapid communications

Introduction:
For centuries, medical and surgical treatment has emphasized saving the life of the patient rather than ameliorating the patient’s pain, particularly when there were few options for the latter. Today at the dawn of the 21st century, the best available evidence indicates a major gap between an increasingly understanding of the pathophysiology of pain and widespread inadequacy of its treatment.

Objectives:
Epidemiologic evidence has proven that chronic pain is a widespread public health issue. Studies of cancer patients’ pain control consistently reveal that up to half of patients receive inadequate analgesia and 30% do not receive appropriate drugs for their pain. One response to the worldwide under treatment of pain has been to promote the concept that pain relief is a public health issue of such critical importance as to constitute an international imperative and fundamental human right.

Results:
The importance of pain relief as the core of the medical ethic is clear. Pain clinicians promote the status of pain management beyond that of appropriate clinical practice or even an ethic of good medicine. They advocate a paradigm shift in the medical professions’ perspective on pain management, from simply good practice to an imperative founded on patient rights.

There is a need to promote policies which create conditions where human beings can bear even incurable illnesses and death in a dignified manner. This must help health professionals or lay...
groups to initiate a powerful agenda to reform local statutes. The essential components of such legislation are:

1. Reasonable pain management is a right.
2. Doctors have a duty to listen to and reasonably respond to a patient’s report of pain.
3. Provision of necessary pain relief is immune from potential legal liability.
4. Doctors who are notable or willing to ensure adequate analgesia must refer to a colleague who has this expertise.
5. Pain management must be a compulsory component of continuing medical education.

**Conclusion:**

For too long, pain and its management have been prisoners of myth, irrationality, ignorance, and cultural bias. We are confident that the National Committee for Palliative Care under the auspices of the Ministry of Public Health is the main promoter of Palliative Care in Lebanon whose main goal is to relieve suffering and improve quality of life of the cancer patients, and advocate pain relief and palliative care as a human right.
Bioethics and health as a human right and the role of NECs: National Ethics Committee for health research of Senegal: Experiences and ethical problems treated:

Dr Samba Cor Sarr, Coordinator of CNERS/Senegal
Rapid communications

Context:
With the accelerated development of health research, the influence of the global movement on ethics and bioethics, the launch of the first phase of the “EDCTP” program in Dakar, the Senegalese Goverment has found it necessary to strengthen of health research and create a regulatory body for research by law 2009-17 of 9 March 2009 with Decree 2009-729 on its organization and functioning.

From 2001 to 2018, more than 800 research protocols were evaluated by the national ethics committee for health research. These protocols are examined through meetings sanctioned by minutes. Some of the validated protocols are followed up in the field. This research has touched several domains and enlisted various social groups in age, socio-economic status, types of pathology; sexual orientations, social practices.

The exploitation of these various documents made it possible to identify ethical questions on which the expertise of the members was called in order to define guidelines and express requests to the investigators. This summary aims to highlight the issues raised in these different experiences, the reflections they have inspired, the proposed solutions the issues that have not yet been answered, the challenges and perspectives.

Method:
Analysis of the National Ethics Committee for Health Research database consisting of research protocols, evaluation minutes and
supervision reports, interviews with researchers, participants and members of research committees ethics have made it possible to identify the major ethical issues that have mobilized Senegal's regulatory body for research during 15 years ago.

Results:

The dimensions explored that emerge from the analysis of the data collected are as follows:

1- Introduction of innovations through research and respect of legality in the practice of the medical profession: (Studies on the introduction of misoprostol in the community, intramuscular injection by pharmacists and their assistants, self-injection at women of childbearing age, use of antibiotics in health huts, use of mystery shoppers in observational studies.

2- Respect for the rigor of the ethical review of research protocols and the urgency of testing solutions to epidemics, as in the case of Ebola: problematic of deadlines for ethical review.

3- Respect for Cultural Values and Innovations for Improving Adolescent Sexual Health: The Problem of Adolescent Guardian Consent in a Family Planning Study versus the Liberalizing Reproductive Health Law access to contraceptive products to adolescents without parental permission.

4 - The process and materialization of consent in large-scale research (DHS, epidemiological studies) and in observational studies,

5- Risk of stigmatization, disruption of the private life of households, vitiated consent due to the advantages put in place by the research program: problems explored in the demographic and health observatories: Niakhar, Ndielmo and Ndiop.

6- Issues of serious adverse events attributable to genetic anthropology studies, and intervention studies in social change; risk of household destabilization, social injury, etc. (Genetic Anthropology Study on Household Behaviors in the Fatick Region, Household Surveys on Social Planning)
7- legality of the practice, risk of denunciation, security, breach of confidentiality, rights to health through research: Studies among MSM, PLWHA, injecting drug users, clandestine prostitutes, street children:

8- Consent in minors without identifiable legal guardian, conflicts of interest with sometimes a collision of interest between the leaders of the social group object of research and the researchers. Ex: Research centers sometimes set up facilitation groups made up of members from research populations and go through these intermediaries to provide information leading to consent.

**Conclusion:**

This exercise shows the multiplicity of cases that raise ethical problems and the need to proceed by case-by-case approaches to issue opinions that only highlight the safety of research participants.
Protection of privacy by gender in Tunisia: Ethical aspects

Professor Hend Bouacha, Tunisia
Rapid communications

Introduction:

The right to respect for private life and personal choice is universal and applicable equally to women and men. This is why debates about privacy have generally not considered gender. However, in our region, male-female relations are still dominated by prevailing patriarchal practices that grant men a privileged status and keep women in a position of inferiority. This explains the limits to respect for women’s privacy, which undermine their dignity and integrity. The authors describe the situation in Tunisia, illustrating it by some examples that touch on the private life of women in the field of health, namely,

Domestic violence against women and sexual violence:

Domestic violence against women and sexual violence are public health problems that are present in all sectors of society, in all cultures, in all countries. But, very often, battered or abused women hide their pain because they fear the consequences of their complaint. In this situation, the main issue for the doctor is that of confidentiality. There is an ethical dilemma between privacy and non-assistance to person in danger. In Tunisia, about one in two women are victims of violence (according to a survey conducted in 2010). However, thanks to the pressure of the civil society, our country has experienced a significant advance with *The promulgation of laws * Measures to raise awareness, protect and take care of victims (toll-free number ..)

Certificate of virginity and surgery of the hymen:

In several regions of Tunisia, the virginity of the bride is still surrounded by different rituals. That’s why, even today, some men require certificates of virginity from their future wives before marriage. Some doctors issue certificates of convenience to the state of distress of the young woman. This poses a real ethical
problem: many women, before marriage, resort to secretive “revirgination” interventions, namely, hymenorraphy or hymenoplasty, which concerns women of all social categories. This reconstructive surgery of the hymen is a medical aberration, and a gesture requested under pressure and not voluntary. Do we have the right to treat a woman as an object?

Respect for privacy and pregnancy interruption:

Abortion is legal in Tunisia since 1973 and is free at the woman’s request for up to three months of pregnancy. Tunisia is the only Arab country where abortion is legal, without conditions. Does the woman’s right to respect for her autonomy and her right to medical confidentiality gives her the right to request an abortion without her husband’s knowledge and, from an ethical point of view, does not the husband have the right to be informed?

Conclusion:

Even if the legal framework that establishes equality between men and women exists, women do not benefit from discrimination related to the customs and traditions of the country. This is valid in the field of health.
Defending Respect to a Dead Human Body: Slovak Republic NEC Statement on "BODY-THE-EXHIBITION" (2017)

Professor Jozef Glasa, Slovakia
Rapid communications

Following a public outcry with regard to opening the exhibition of plastinated human bodies (entitled “BODY-THE-EXHIBITION”) at the major commercial exhibition centre “Incheba” in the Slovak capital Bratislava, which had been advertised as a “family event” to include even toddlers, and following requests of the Slovak Medical Chamber, number of public personalities, Slovak Medical University’s Institute of Health Care Ethics and others directed to several Ministries of the Slovak Government, Slovak Parliament, law enforcement and customs authorities to intervene, the Ethics Committee of the Ministry of Health (EC MH, i.e. Slovak Republic NEC) was asked to examine the matter from an ethical point of view and provide the minister of health with an opinion in view of dealing with the problem in an appropriate, balanced manner.

EC MH established an ad hoc working group to produce a draft opinion. The opinion, after several rounds of comments and reviews by EC MH members, was adopted unanimously by the Committee on November 30, 2017, as the first opinion in the EC MH present mandate term. The Opinion pointed out several serious ethical issues involved, and required both the health minister and other State authorities, to act according to their legal responsibility and legal means available to them, so at least the most serious harms and risks to the vulnerable persons be reduced, and the Slovak Republic’s obligations under e.g. provisions of the Oviedo Convention (1997) (ratified by the Slovak Republic in 1998, e.g. principles of noncommercialization of human body, protection of vulnerable persons etc.) and under applicable Slovak Republic laws be appropriately honoured. The Opinion was taken into account in writing a legal motion by an initiative group of parliamentarians to pass a law on making similar future exhibitions illegal in Slovakia (e.g. by requesting that the true, documented origin of the corpses, and informed consent...
of the people whose corpses had been used for producing the plastinated “exhibits” are provided to the Slovak Competent State Authorities etc.).

The exhibition had not been closed by the authorities during its normal run, and the motion was narrowly defeated in the Parliament (mostly for “political reasons” – seen by the Parliament majority as an initiative of the opposition). The minister of health, however, made a public promise to prepare a similar legislation as a coalition proposal shortly.
International Framework for Accreditation of Research Ethics Committees

Dr Abha Saxena and Dr Andreas Reis, WHO
Global Reports

A core requirement of international guidelines on the ethics of health-related research with human participants is that an effective system of ethical oversight should exist at the institutional and national level. Such systems should ensure the prior review of proposed research by competent research ethics committees (RECs), monitoring of research to ensure that ethical requirements are actually followed, and mechanisms for ensuring accountability, transparency, and public engagement. Training and capacity building should be an integral part of the system. By now, most countries have established some sort of research ethics system (RES). Yet, while WHO standards for RESs have existed since 2011, no mechanisms exist to measure compliance with these standards. This presentation will argue for the need of developing a set of comprehensive, easy-to-use indicators for measuring compliance with the quality standards of research ethics systems.

Research ethics indicators can provide the basis for accreditation of research ethics committees, and serve to promote quality improvement efforts by providing the basis for monitoring the effectiveness of research ethics committees, identifying gaps and areas in need of improvement, establishing benchmarks against which performance is judged, and evaluating the impact of changes in the system. Having an established set of indicators can also facilitate collaborative international research through giving partners in multi-country research the confidence to defer to ethics reviews conducted in other jurisdictions, thereby avoiding unnecessary and time-consuming duplicative reviews. Finally, they can be used to inform resource allocation decisions to funders of research — through identifying where resources would be most usefully utilized and having the ability to monitor the impact of any interventions they support.
Survey of National (Bio-)Ethics Committees

Johannes Koehler, Dr Abha Saxena, WHO
Global Reports

Rapid advances in the field of health and medical sciences invariably raise complex moral, legal, social and environmental issues. Recognising the importance of an ethical reflection and analysis, many countries have created bodies, hereafter referred as National Ethics/Bioethics Committees (NECs), to advise their executive and legislative branches, and often the general public, about ethics of health and healthcare, and non-health-related matters. They may be appointed by the chief executive, minister of health or legislature to analyse ethical issues and offer conclusions and policy recommendations.

By conducting an internet-based survey, the Global Health Ethics Team at the World Health Organizations aimed to learn more about the gaps, challenges, needs and strengths of NECs around the world. The results of the study will be used to inform and improve WHO’s efforts in supporting the NECs in their roles and may help foster understanding of the needs of NECs among various stakeholders. The study consisted of a one-time online-based survey, inquiring into NECs’ activity, secretariat, membership, training, financial situation, public relations, international and national collaboration, relation to the government, independence and general challenges. The data obtained from the survey will be analysed using descriptive statistics as well as qualitative analysis.

With this survey, the Global Health Ethics Team aims to add important knowledge about NECs and hopes that the results can inform future interventions and support to the benefit of NECs around the world.
Bioethics, health as a human right and the Latin American and Caribbean Regional Network of National Bioethics Committees

Dr Camilo Hernan Manchola Castillo (Latin American and Caribbean Regional Network of National Bioethics Committees)

Panel discussions: Issues, Challenges, and Country Perspectives: Bioethics and health as a human right and the role of NECs

Access to healthcare and the conception of health as a human right have been at the center of Latin American Bioethics since its development in the early 1990s. The presence of these issues on both the agendas of the National Bioethics Committees (NBCs) of the region and the discussions held by the UNESCO’s Latin American and Caribbean Regional Network of National Bioethics Committees clearly show this circumstance.

This abstract seeks to present the UNESCO’s Latin American and Caribbean Regional Network of National Bioethics Committees experience regarding Bioethics and health as a human right, looking at the role of NBCs and the tension between health systems and individuals, taking advantage of the history of the Network, to propose an integrative analysis.

A short presentation of the Network, its purposes, objectives, current discussions and way forward will be made, highlighting its position concerning the relation between Bioethics and health as a human right. All the analysis will be contextualized in the methodological and epistemological contributions of the most important Latin American bioethicists and on the positions of the NBCs of the region.
Human rights, ethics and bioethics

Professor Samba Thiam UCAD, associated expert CNERS
Panel discussions: Issues, Challenges, and Country Perspectives: Bioethics and health as a human right and the role of NECs

The Dakar Declaration on Ethics and Bioethics of 13 July 2005 resulted in a failure to respect the value of life and dignity of the human person in Africa. How to reconcile scientific freedom, linked to social and economic development, and the fundamental rights of the human person, especially the vulnerable (disabled, children, women ...?) Reaffirming the principle of freedom of research and matching of a high sense of responsibility and greatly establishing a National Council of Ethics and Bioethics 1. The principle of freedom of research It arises from the freedom of expression, thus from the rule of law. international law, the freedom of research is well posited mainly by international sources of human rights (Universal Declaration of Human Rights of 1948, pacts of 16 December 1966, and the Universal Declaration on Bioethics and Human Rights of 19 October 2005, which invokes the great benefits of humanity.) Precisely according to Article 19 of the Covenant on Civil and Political Rights s of 16 December 1966, "Everyone has the right to freedom of expression; this right includes the freedom to search (...) ". This principle is also affirmed by Article 12.3 of the African Charter on Human and Peoples' Rights. In domestic law, in addition to the Constitution, Law 2009-17 of 9 March 2009 constitutes the Code of Ethics for Health Research, providing in Article 7 any research opportunity, respecting human dignity, physical integrity and moral of the human person.

The responsibility of the researcher or promoter. Indeed, freedom implies responsibility. To avoid an irreparable violation of the dignity of the human person, by making respect for human rights a priority, the rigorous conditions of an aptitude for research must be strengthened (Article 39 of the Code of Ethics, ministerial decree of 17 March 2004 recalling the ethical and legal principles in the field of research), by establishing a lifelong education on human rights or human rights. In particular, the existence of consent requires informed consent, a right to effective
information, including risks and possibilities of recourse, to materialize and justify the prior consent of a research useful to health. So, a simple signature is not enough to legally validate a consent. The ethical and fundamental principles relating to respect for the human person apply even after death (French Council of State of 2 July 1993, Milhaud).

For all these reasons, the institutional framework, made up of virtuous human resources, is useful for ensuring a perfect regulation of activities, as called for by the Universal Declaration on the Human Genome and Human Rights and international ethical guidelines for biomedical research. In this case, in addition to the National Committee of Ethics for Health Research, it is necessary to set up a National Council of Ethics and Bioethics (CNEB).

The indispensable setting up of a CNEB. The Council will be responsible, in particular to issue published opinions (bulletin), ensuring respect for the dignity of the human person and magnifying the genesis of bioethics in Senegal. Indeed, the existence of this Council, which will oversee the restrictions on the freedom of research established by law, can indeed be integrated, as elsewhere, into the emerging Code of Public Health.

In the same way, the latter must integrate traditional medicine reflecting the African personality, so that the Code of Ethics (Article 4) provides for it in research. In any case, if no development without research, no development without peace, says Paul VI in 1976. But no growth, no peace without an independent justice, being considered that “Justice is a need of all and every moment; as she must command respect, she must inspire confidence.”
1. In the context of the people involved in the catastrophes, it was considered necessary to expand the concept of “victim”, extending it from the classic concept of “direct victims” to that of “indirect victims”, which include those who live indirectly the trauma of people involved, like family members, friends, rescuers themselves and who suffer, due to lack of psychological resources, the so-called vicarious traumatization.

2. The topic of the management of people with disabilities in emergencies is discussed, due to the particular sensitivity that the National Bioethics Committee of Republic of San Marino has always shown on this issue, not only dedicating a specific document (The bioethical approach to people with disabilities, 2013), but also by taking up this topic in subsequent documents.

3. Equally innovative is the theme of ethical journalism, for the decision to include the communication professional among the actors involved in the catastrophes, which is responsible for the difficult choice between respect for freedom of expression and respect for private life and on which the responsibility for the protection of witnesses and sources weighs down, especially in cases of conflict, respecting the affected populations and the complex relationship of interaction with rescuers.

4. With the reflection on the rescuer nurse the importance of this professional figure is emphasized, especially in the difficult activity of triage and in the management of particular clinical situations such as pain control. This choice is the consequence of a particular attention that the Committee has dedicated to this role, starting from the drafting of the first Deontological Code of the Nurse, in collaboration with the AIS (Sammarinese Nursing Association) and to following with the document Nursing Assistance to the pain: bioethical aspects (both of 2017).
5. To hospital health personnel, with particular attention to the figure of the pharmacist, is dedicated the chapter on the management of drugs and medical devices in disasters, but for all health workers are highlighted the medical-legal responsibilities in emergency situations, as well as we address the delicate issue of acquiring consent to clinical trials in emergency situations, supported by the indications contained in the 2014 EU Regulation on the clinical testing of medicinal products for human use.

6. The most innovative and courageous theme is that dedicated to the bioethics of animals in disasters, as it proposes a reflection on the moral relevance of animals, in the dual role of victims and rescuers, while maintaining a clear distinction between values and human victims. This topic, deliberately located at the end of the document to underline its specificity, intends to open a line of bioethical reflection that, we hope, can be followed by further study.
Refugees, Migrants and Ethical Responsibility for their Health Care

Professor Michel Daher (Lebanon)

Panel discussions: Issues, Challenges, and Country Perspectives: Bioethics and health as a human right and the role of NECs

Introduction:

What is pushing people out of the source countries? They move to escape war, persecution, unemployment, poverty, and environmental degradation. What is pulling them into the destination countries? They move to find better opportunities, provide more support for their families, and build better lives.

These refugee crises happened several times during the last decades mainly in developing and less-developed countries. The health situation of these people is a major problem concerning acute malnutrition, epidemic infectious diseases, non-communication diseases which needed urgent health interventions.

Objectives:

Refugees, Migrants, legal or illegal, include men, women, children, agricultural workers, domestic workers, computer programmers, health care professionals, and many others.

Whatever they are called, their existence raises an important ethical question: Do societies have an ethical responsibility to provide health care for undocumented migrants, documented migrants, and citizens on an equal basis?

Results:

Ethical traditions of medicine and health care focus on a patient in need and do not qualify who that patient is. There is nothing in the oath of Hippocrates about excluding illegal immigrants or people without insurance: First and fundamental, our commitment to our ethical principles requires that any patient
who is sick deserves treatment, regardless of their personal characteristics or legal status.

Concerning migrants and Ethical responsibility, I will try to answer the following questions:

Does migration lead to unjustified disparities in health care? In other way, does refusal to provide healthcare to documented or undocumented migrants on terms of equality to those of citizens amounts to wrongful discrimination?

Do countries that provide universal health coverage for citizens and legal residents should provide the same health care for all refugees and migrants?

Do rich countries also have extensive moral duties to provide healthcare for noncitizens outside their territory?

Although an account of global justice needs to emphasize the duty not to harm, it also needs to include a duty to assist, because it serves human purposes well. Assistance should not aim to promote the narrow interests of the assisting country, but to promote just and decent conditions in the assisted countries. In a political account of global justice, the duty to assist is complex because it combines different ideas: the importance of social justice, the ideal of meaningful autonomy and the hope that internally just societies will be more peaceful and fair in their foreign affairs.

**Conclusion:**

I have examined the frameworks that are employed in discussions about legal, and illegal immigrants and health care. These issues should be framed in terms of professional ethics, social justice and responsibility, or even human rights. My aim is not to convince everyone of the rectitude of my account, but to shift the discussion into the realm of social justice and responsibility.

It is reasonable to think that there are some responsibilities of global justice which follows the principle of the basic equality of human beings. In any case, there appear to be a number of distinct reasons for thinking that some particularly large inequalities in health and wellbeing should be rectified.
Germline intervention in the human embryo: German Ethics Council calls for global political debate and international regulation

Professor Claudia Wiesemann, Germany
Panel discussions: Issues, Challenges, and Country Perspectives: Ethics guidance on Genetics/Genomics

The technical opportunities offered by genome editing (for example the CRISPR-Cas9 method) raise complex and fundamental ethical questions particularly where they are used to modify the human germline. Last year there was still by and large agreement – for instance at the annual conference of the German Ethics Council devoted to this topic – that there would be sufficient time for the necessary thorough and comprehensive reflection since applications in humans were still far away from actual implementation.

Recent developments, however, demonstrate that, in this particularly sensitive area, research has advanced far more quickly than expected and precedents are being created at least in some countries. As, however, this touches not only on national interests but also on the interests of mankind as a whole, there is a need for broadly-based discussion and international regulation.
Use of genome editing technology for human embryo research

Dr Yuko Harayama The Chair, Expert Panel on Bioethics, Council for Science, Technology and Innovation, Japan

Panel discussions: Issues, Challenges, and Country Perspectives: Ethics guidance on Genetics/Genomics

The Expert Panel on Bioethics at the Council for Science, Technology and Innovation (CSTI) is equivalent to the National Ethics Committee in Japan. It is a permanent committee to discuss and recommend policies and strategies for bioethical issues.

The Panel is currently discussing ethical issues regarding the use of genome editing technology for human embryo research, which would be potentially a useful research tool for assisted reproductive medicine and intractable and/or genetic diseases. The Panel, after in depth discussion of the cultural, historical and scientific dimensions and challenges around this technology, have reach to a tentative conclusion.

The conclusion was focused on the use of the technology in basic research using human embryo as a material contributing to the advancement of assisted reproductive medicine. The Recommendation was published early this year from CSTI and the Panel will continue to deepening the discussion on the bioethical issues of research using genome editing technology.
Genetic Testing in Lebanon – Role of the National Bioethics Committee

Dr Kamal Kallab (Lebanon)
Panel discussions: Issues, Challenges, and Country Perspectives: Ethics guidance on Genetics/Genomics

Introduction:

Genetics is the study of heredity and of the mechanisms by which genetic factors are transmitted from one generation to the next. Dysfunctional genes, or gene mutations, can cause illness, and can be passed from parents to children. In addition, some people have a genetic, or inherited, predisposition to certain diseases, such as cancer, diabetes, cardiovascular disease, and mental disorders. The sequencing of the human genome has been recently completed. Genomics has revolutionized the medical sciences, introducing new possibilities for diagnosis, prevention, treatment and management of both communicable and non-communicable diseases. That’s why Genetic testing is going to get more and more importance in our medical practice.

Material and Methods:

The Lebanese National Consultative Committee on Ethics (CCNLE, LNCCE) was created by the Ministry Council in 2001, Decree No: 63/2001 (15/5/2001). This committee is recognized of Public Utility; its role and objectives describe it as an “Advisory Board for Bioethics Issues: Legislation, Recommendations, Promotion, and Education”. One of its first achievements was the proposition of the Law No 574- 11/2 /2004 “Patients’ Rights and Informed Consent”. A second law followed: Law No 625 - 20 Nov 2004 about “Genetic Tests”.

Results:

In this law we refer to the “Universal Declaration on the Human Genome and Human Rights” (Unesco 1997), and the “International Declaration on Human Genetic Data” (Unesco 2003). The aims of these declarations and the Lebanese Law are: to ensure the respect of human dignity and protection of human
rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data, and of the biological samples from which they are derived, referred to hereinafter as “biological samples”. The law commends in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research. Also in January 2013, a workshop on Genetic testing and the International Declaration on Human Genetic Data was organized by the LNEC at the Lebanese American University in Beirut. An important document promoted by the Unesco and titled “Ethics and Law in Biomedicine and Genetics - An Overview of National Regulations in the Arab States” was collected and edited by Fouad Boustany, Secretary General of the LNCCE.

Conclusion:

The role of the LNCCE/ CCNLE is to contribute to the implementation of the International Declaration on Human Genetic Data (2003), and the dissemination of the principles set out therein. To educate and monitor the application of the Lebanese Law no 625 of 2004.
Impact of socio – cultural practices and the effects of pregnant women’s participation on clinical trials in sub Saharan Africa

Dr Jennyfer Ambe and Dr Gibril Ndow (Cameroon)
Panel discussions: Issues, Challenges, and Country Perspectives: Role of Bioethics Committees in strengthening access to reproductive & sexual health

Introduction:

This project aims to examine the extent to which socio-cultural practices affect the inclusion of pregnant women in clinical trials and the resulting associated ethical implications and considerations. As a result of systematic exclusion of pregnant women from clinical research and clinical trials, there is a dearth of data on the safety and efficacy of medical interventions and treatments in pregnancy. There is a deficit of data when it comes to the inclusion of pregnant women in clinical research in spite of compelling needs and the importance for the inclusion of pregnant women. It appears that some of the reasons for non-inclusion are; fear of the physiology of the pregnant woman, fear of legal issues, fear of harm to the fetus, not knowing if the pregnant woman will be willing to participate, regulations that classify pregnant women as a “vulnerable” group and other wording in regulations that may not be clear. In sub-Saharan Africa there are additional concerns that could possibly add to the non-participation of pregnant women on clinical trials such as culture, tradition as well as possibly, religion. This is an important area for research as there is no clear documentation for the reasons for exclusion. The intersecting factors behind the barriers to inclusion across different research settings, must be understood.

Method:

Focus group meetings will be held with pregnant women and semi-structured interviews with Ethics Committee Members and Institutional Review Board members and Principal Investigators
(PI). The focus groups will examine the socio-cultural beliefs of the pregnant women as well as assess their (un)willingness to participate in clinical research. The interviews with the researchers, EC and IRB board members will assess the factors that influence decisions to include or exclude pregnant women in research. The focus groups will be recorded and the interviews will be fully transcribed, anonymized and analysed using open coding and thematic content analysis. The study collaborators will use peer review verification to minimize lone researcher bias of the analysis.

**Outcome:**

This study seeks to understand psycho-socio behaviour. The outcome will be an understanding of the extent to which socio-cultural practices influence the exclusion of pregnant women in clinical trials and research in sub-Saharan Africa. It will lead to the understanding of the factors that influence women’s (un)willingness to participate in clinical research in sub-Saharan Africa and to determine the factors that influence the exclusion of pregnant women from clinical trials and clinical research. The global perspective and aim would be to promote a system that encourages research stakeholders to question the non-inclusion of pregnant women rather than simply accepting their exclusion.
L’assistance sexuelle aux personnes handicapées: une problématique pertinente pour le Comité Consultatif de Bioéthique de Belgique

Professor Guy Lebeer (Belgium)
Panel discussions: Issues, Challenges, and Country Perspectives: Role of Bioethics Committees in strengthening access to reproductive & sexual health

Le 13 novembre 2017, le Comité Consultatif de Bioéthique de Belgique rendait un avis sur la problématique de l’assistance sexuelle aux personnes handicapées. Il répondait ainsi à une demande émanant du Secrétaire d’Etat aux Personnes handicapées qui lui adressait en particulier les questions suivantes : Est-ce le rôle des pouvoirs publics de s’emparer de cette problématique ou celle-ci doit-elle rester du ressort des individus et des interactions sociales informelles ? Si ce rôle apparaît pertinent, l’assistance sexuelle doit-elle être considérée comme contribuant à la santé ? Question importante car justifiant ou non le sens même d’une saisine adressée à un comité de bioéthique. Et enfin dernières questions : Faut-il reconnaître un statut à ceux/celles qui offriraient une telle assistance ? Si oui, quel statut ? Comment serait-il distinct de celui de la prostitution et donc comment éviter le soupçon d’un Etat proxénète ? Comment éviter qu’un tel dispositif ne contribue à la répétition de situations d’exploitation d’un sexe - sous-entendu le sexe féminin - par l’autre - le sexe masculin ?

La communication rend compte des réponses que le Comité belge apporte à ces questions. Ses réponses s’inscrivent dans le droit fil du respect des droits humains, ce qui n’a pas empêché à ses travaux d’être contestés par certains pans de la société civile, parmi lesquels des organisations féministes, ceux-ci exigeant quasiment d’être auditionnés avant même qu’il n’ait rendu ses conclusions. Cette situation a suscité un certain nombre de questions sur la réponse à apporter à ces interpellations : décider d’en tenir compte ou souligner son indépendance ?
ENGLISH:
Sexual assistance for disabled persons: a relevant issue for the Belgian Advisory Committee on Bioethics.

On November 13th, 2017, the Belgian Advisory Committee on Bioethics gave its opinion on the issue of sexual assistance for disabled persons. The committee was responding to a request emanating from the Secretary of State for Persons with Disabilities, which addressed in particular the following questions: is it the role of the public authorities to deal with this problem or should it remain the responsibility of individuals as part of informal social interactions? If this role appears to be relevant, should sexual assistance be considered as contributing to health? The answer to such questions is important since it would therefore justify – or not – the appeal to a bioethics committee. And finally, some last questions: should we recognize a status for those who offer such assistance? If so, what status? In what way would it be distinct from that of prostitution? Thus, how to avoid the suspicion of a “pimp State”? How to avoid that such a service contributes to the replication of situations of exploitation of one sex – in this case the female sex – by the other – the male sex?

The communication gives an account of the answers provided by the Belgian Committee to these questions. Its answers are in line with the respect of human rights. Despite of this, and prior to their knowledge of the committee’s conclusion, certain sections of the civil society among whom feminist organizations contested the work of the Committee and even demanded to be auditioned. This situation raises question on the reaction to such protests: should the committee be ready to listen to these protests or maintain its independence?
Role of Bioethics Committees in strengthening access to reproductive health

Professor Christiane Druml, Chair of the Austrian Bioethics Commission at the Federal Chancellery

Panel discussions: Issues, Challenges, and Country Perspectives: Role of Bioethics Committees in strengthening access to reproductive & sexual health

Role of Bioethics Committees in strengthening access to reproductive health

The Austrian Bioethics Commission, established in 2001 is an advising committee for the Austrian Federal Chancellor. Its remit is to advise the Federal Chancellor from an ethical point of view on all “social, natural scientific and legal issues arising from the scientific developments in human medicine and human biology”. Its 25 members (13 men, 12 women) are experts of different disciplines like medicine, law, philosophy, theology, genetics, political science and ethics and are nominated in their personal capacity and independent.

Essential tasks of the Commission are (public) information and discussion of important advances in medicine and biology, in particular its ethical implications. This includes in recommendations for practical use and suggestions for enacting the necessary legal provisions as well as the preparation of expert opinions on specific issues. The challenges of a National Bioethics Committees in strengthening access and drawing up legislation will be demonstrated in regard to the past discussion of reproductive medicine in Austria.

The field of reproductive medicine and its ethical implications has led to various documents and an opinion of the Commission in the year 2012 referring to specific issues such as preimplantation genetic diagnosis (PGD), medically assisted reproduction outside marriage and cohabiting partnerships, the applicable legal situation and the psychological consequences of prenatal diagnosis. In December 2014 a new national law has been drafted along the recommendations of the National Austrian Bioethics Commission and agreed on in January 2015.
The presentation will focus on the ethical and emotional discourse in society relating to the beginning of life, and to the enormous social changes in the past 30 years which we have witnessed in regard to the perception of family and parenthood.

Federico de Montalvo Jääskeläinen, Vice Chair Spanish Bioethics Commission

Panel discussions: Issues, Challenges, and Country Perspectives: Role of Bioethics Committees in strengthening access to reproductive & sexual health

By the General Directorate of Public Health, Quality and Innovation of the General Secretariat of Health and Consumption of the Ministry of Health, Social Services and Equality, the Spanish Bioethics Commission was asked about the ethical dilemmas derived from the public financing of a drug, pre-exposure prophylaxis (PrEP), for the prevention of HIV transmission in people who are seronegative for HIV with a high risk of contracting the infection. In the consultation the Ministry asked three questions, in particular:

1. Is it ethical to publicly finance PrEP in Spain? (especially, when there are other priorities in health matters that are not covered)

2. Is it ethical to finance PrEP if patients do not comply with the preventive measures that should accompany it, such as the use of condoms?

3. Would it be ethical not to provide PrEP in Spain to people at high risk of infection, knowing that they will not use other preventive measures?

Considering those questions, the Spanish Bioethics Commission has faced in this Report two main ethical dilemmas: In the first place, from an ethical perspective, if pre-exposure prophylaxis (PrEP) should be publicly financed and, therefore, be provided free of charge within the public healthcare system. The dilemma is substantially motivated, according to the consultation, for two issues: first, the existence of other priorities in health that would be outside the public coverage since the resources are limited (including new treatments usually means excluding or not
include others); and, secondly, the prevention that is sought through the new drug could also be achieved through other measures that are not strictly pharmacological and with a clear lower impact on public spending, as we would understand, the abstention in the area of risky sexual behaviors or the adoption of traditional measures of prophylaxis that also reduce the possibilities of transmission of the disease (see, use of condoms and lubricants). This first dilemma is especially complex since it refers to the financing of a drug to prevent a disease that, not in all cases, but in some, can be contracted, smooth and plainly, by the individual’s own behaviour in the field of sexuality. It is a disease against which there are other options to avoid it, however, not as effective or even possible, such as suspending risk behaviour or adopting other measures of prophylaxis less expensive for the public system and without adverse effects that the taking of any medication usually entails for the subject himself (although these, in the specific case that concerns us, do not seem to be particularly relevant, as can be deduced from the consultation).

Secondly, we are also confronted with a second ethical dilemma that is no less complex than the first, and so we are asked if it is ethical to prescribe it to people who may not commit to complete their decision with the adoption of other measures of prophylaxis. The different studies have proved convenient for the preventive effects of the medication to be fully guaranteed, or they could commit to taking it regularly, which seems to significantly affect the prophylactic success of the treatment.

The question is, in this particular aspect, whether it is ethical for a person to receive the medication, with the public expense that this entails, which means limiting, excluding or not covering other health benefits, when it is not previously committed or does not subsequently comply with its commitment, or to adopt other prophylactic measures that are essential for the medicine to meet its preventive objective (see the example of barebacking), or to take it regularly.

The topic is very relevant from a Public Health perspective because HIV is again in many places of the World a problem. Currently, the social perception of the risk that HIV poses to the
health of people and the risk of transmission that is quite distorted and erroneous compared to what happened in previous eras. The very success of the treatments is shown, as in other areas of medicine, as the main enemy of the disease since this supposes a decrease in the individual and social perception of the risk. The late diagnosis is high and maintains a stable trend and, although slowed in recent years, continues the downward trend of new cases of AIDS initiated after the introduction of highly active antiretroviral treatments in the mid-1990s.
Basic Training for National Bioethics Committees

UNESCO, Angela Melo
Pre-Summit Workshops

The workshop will be chaired by Ms. Angela Melo, Director of Programs and Policies of the Human and Social Sciences Sector of UNESCO. Dafna Feinholz, chief of Bioethics and Ethics of Science and Technology Section and program specialist from UNESCO’s Africa region will also participate.

The aim of the workshop is to share with participants UNESCO’s programs and tools for training NBC members, including some practical exercises.

The second main objective is to share experiences: challenges and good practices in relation to training of current and future members of NBC in Bioethics. We all know that financial resources are always a challenge, but we would like to explore other kind of challenges and opportunities.

As an outcome of the workshop, the aim is to have a rough mapping of challenges and opportunities and concrete proposals and a roadmap in order to address these challenges, and identify how UNESCO can improve its support the committees.
In 2015 the Nuffield Council on Bioethics published a report on Children and Clinical Research: ethical issues. The purpose of this report was to address the question: how can we ethically undertake the research needed to ensure that children and young people’s healthcare services are safe and effective, given that research often involves burdens and risks?

In this workshop, the Nuffield Council report will be used to stimulate discussion on issues such as the position of children at different ages and stages of development; the role of parents; consent and assent to research participation; welfare and vulnerability; the role of ethical review; and engaging children and families in decisions about research.

The purpose of the workshop will be to encourage discussion about the ways in which children can be fully and appropriately involved in research as partners and as participants. The working premise is that it is only through this involvement, and through respecting children and young people as valued partners in research, that a proper balance between the benefits and risks of carrying out research can be found.
Bioethics meets participatory democracy in France

France, Professor Delfraissy
Pre-Summit Workshops

The Bioethics Law is reviewed and updated every eight years to ensure the legislative structure is keeping pace with changes in the society and science in France. The next review is due in fall 2018, following an extensive consultation organized by the National Consultative Ethics Committee for health and life sciences (CCNE) that brings together the scientific community, governing bodies and the general public: les États généraux de la bioéthique 2018 (“2018 General Assembly On Bioethics”).

From January to June 2018, les États généraux de la bioéthique will include 150 public debates across France along with over 100 hearings with representatives of associations, learned societies, religious bodies and industries, a dedicated website (more than 15100 contributions so far), a citizen committee of 22 people representative of the French population to assess the methodology. The consultation is very broad in scope and covers: stem cells, research on embryos, genomics, neurosciences, transplantation, artificial intelligence, health & environment, along with societal issues related to end-of-life and medically assisted reproduction.

The results of États généraux de la bioéthique are to be incorporated into a report that CCNE will submit to the government, this report will serve as a basis for the revision of bioethical laws.

Les États généraux de la bioéthique are a unique example of health democracy, and an essential exercise in a fast-paced world where scientific production increases steadily.
Indian Council of Medical Research (ICMR) is the apex body for formulation, coordination and promotion of biomedical research in India. ICMR had issued a Policy Statement related to ethical aspects of human research in 1980, drafted the ethical guidelines in 2000, and then updated them in 2006. In view of the scientific advances presenting newer ethical challenges it was decided to revise the National Ethical Guidelines and the process completed between 2015-2017. A Core Advisory Group was set up which identified the topics to be covered and appointed subcommittees of experts from variety of subject areas to prepare the initial draft. The draft document underwent one year of extensive consultation with various stakeholders from across the country including clinicians, scientists, lawyers, social scientists, civil society, patient representatives as well as public.

The document was reviewed and finalized by the Bioethics Advisory Group and the Central Ethics Committee on Human Research (CECHR) which serves as the National Ethics Committee at ICMR. Feedback was also received from Individuals, institutions, agencies, industry, associations both national and international, through public consultation, regional and national consultations. The draft guidelines were extensively discussed and the inputs and comments received were very useful in finalization. In addition a number of separate subject expert group meetings were held to obtain specific updates in areas such as human Genetics, clinical trials, new technologies etc. The guidelines have added newer topics such as public health and socio-behavioral research, research during humanitarian emergency or disaster situations and responsible conduct of research. A number of sections have been expanded such as there is a separate section on informed consent, vulnerability, bio-banking and use of
ICMR National ethical guidelines have to be followed by all researchers engaged in biomedical and health research across India and comprehensively provide guidance on a variety of relevant topics. A series of Dissemination programs are presently being organized across the country and 8 such programs have been held between Nov, 2017- till date involving participation of more than 7000 relevant stakeholders such as medical students, clinicians, researchers, ethics committee members, nurses, pharmacists and others at New Delhi, Ahmedabad, Chandigarh, Visakhapatnam, Chennai, Bhubaneswar, Kochi and Guwahati. This effort is being made in order to reach out to the masses and sensitize them about the newer updates in the revised National ethical guidelines. It is hoped that the new National Ethical Guidelines will provide guidance to researchers to conduct more relevant research and offers better protection of the rights, welfare and well-being of our persons who participate in research.
Health research has preoccupied the scientific and political authorities early on. Since independence, various initiatives have been taken to ensure the governance and development of this sector. Among these bodies we can mention the one that deals with the ethical review whose history is described.

Method:

Documentary review, interview with the actors of the health system.

Results:

In 1970: Establishment of institutional ethics committees and existence of a division of research and training attached to the Cabinet to the Minister in charge of health; Creation of an observatory by ORSTOM (now Research Institute for Development) and the Pasteur Institute of Dakar for longitudinal research on demographic and health issues.

In 1991: Creation of the National Multidisciplinary AIDS Prevention Committee Establishment by the order of doctors of a mission ethics committee for the ethical review of a vaccine trial protocol against schistosomiasis (phase 1),

In 2001: Establishment by the Ministry of Health of a national consultative body with two committees During this phase, the functioning of the ethics committee was essentially provided by a financial support of $ 5,000 per year provided by WHO.

In 2004: The two committees were merged, by ministerial decree, to constitute a body called "National Council of Research in Health" (CNRS). A contribution was requested to submissions for the conduct of ethics review sessions.

In the same period, an initiative of the National Commission of UNESCO, in connection with the Ministry of National Education and the Ministry of Health, initiated the creation of a National
Committee of Ethics of Life Sciences, with the institution of anchoring the Primature. This decree issued at the time by the Ministry of National Education never came into being for reasons not yet explained.

In 2005: The CNRS, in synergy with the network "Ethical and Health Law" of the University of Dakar and the Direction of Health organized in Dakar, the first days of bioethics for West and Central Africa, which brought together about 300 participants from more than 15 countries from the African, European and American continents. In 2006: Holding of the second days coorganized with (Panafrican Bioethics Intitative (PABIN) in Yaoundé / Cameroon,

In 2007: Organization in Lomé / Togo of the third days of bioethics In 2009: Vote of a law 2009-17 of 9 March 2009 on the code of ethics of health research was born. Decree 2009-729 on the functioning of the National Committee of Ethics for Health Research (CNERS) which was drawn up at the same time was adopted immediately after the enactment of the law.

Establishment of an organization chart and production of management tools validated by ministerial orders; Contribution to the validation of RHINNO software for submission and evaluation of protocols Contribution to the revision of declarations (CIOMS) and the development of guidance documents for AVAREF.

In 2013: Organization in Dakar of the fourth days of bioethics.

**Challenges and perspectives:**

Respond expeditiously and effectively to new life sciences inquiries; Digitalising the system of submission and evaluation of research protocols; help to set up a national bioethics committee; Contribute to the development of a national ethics review system with institutional committees accredited by the CNERS financially autonomous; Contribute to setting up a sub-regional network of functional ethics committees

**Conclusion:**

Participation in the various stages of development of the regulation of research and bioethics in Africa and in the world. This path culminated in the selection of the CNERS to organize for the first time the 12th edition of the World Summit of Ethics and Bioethics Committees in Dakar, part of Africa south of the Sahara.
Benefits:
Since the goal is protection of ethical humane society, those arms of the umbrella National Bioethics Committees that charge user fees will continue to charge such non-profit-making fees for its services, those that are funded by national budgets to perform their activities will continue to receive their votes, those which are able to attract international resources will continue to do so. But the most important benefit is oversight that is neutral, independent, robust and internationally networked. Even more significant, pulling all global and national ethical under one umbrella presents the clear advantage of uniform intersecting and energizing oversight that is recognizable, predictable and defensible.

Conclusion and Recommendation:
There is no doubt that there will be resistance from various constituencies to the proposal made here, and for various reasons with some justification. One resistance will be those who would like the status quo to remain, so that their turfs are not invaded. More significantly, the industry of ethicists would become jittery of the new and creative oversight which will hold the ethicists themselves to ethical standards. However, it is clear that the international community cannot continue along the current discordant, unsustainable and disunited fashion where monitoring and defending our common ethical values are concerned. Hence, it is a matter of time before what is proposed here become the solution to a problem that is faced as a matter of evolutionary fact of ethical society. In light of the foregoing, the overall recommendation is that the global and international bodies recognize and empower the National Bioethics Committees as the overarching organ for the supervision, monitoring and policy directive activities relating to Ethics in all countries of the world. Its advisory capacity and voluntary, individual membership quality must be reinforced and empowered to deliver on its mandate.
Biomedical Research Ethics Development (BERD) Program: Iran Experience 2013-2017

Iran, Dr Ehsan Shamsi
Pre-Summit Workshops

As any other activity of human being medical practice and research, has been the subject of ethical evaluation throughout the history of science. But at the beginning of the second half of the 20th century the medical discourse was at the center of a universal attention mainly because of those immoral researches performed by Nazi doctors on humans.

“The statements of Nuremberg” (1947), was the first international document that tried to enumerate the ethical standards for doing research on human beings. At the same time World Medical Association (WMA) issued the “Declaration of Geneva” (1948) which recounted the medical ethics standards using the traditional Hippocratic language. Later in 1964 WMA released the “Declaration of Helsinki” which represented the ethical standards for performing medical research. This document which has been revised several times until its latest revision is 2013, proposed the need for ethical evaluation of medical research proposals in “Research Ethics Committees” (RECs) for the first time.

During the following decades the issue of research ethics especially in the field of biomedical sciences has been reinforcing by international organization, mainly World Health Organization (WHO). National bodies and institutional RECs has formed in western counties to promote observation of ethical standards in biomedical research. Later this issue was discussed in the regional offices of WHO including 18’Th EM / ACHR meeting of WHO in 1995 in Riyadh, Saudi Arabia. The member states agreed that RECs should be formed in the countries of East Mediterranean region. Since then series of activities has been done in order to implement an efficient system for improving ethics of biomedical research in Iran Ministry of Health and Medical Education (MOHME).
Since 2013 such activities have been accelerated by starting a new initiative in Research Deputy of MOHME launched by the “Secretariat” of the “National Committee for Ethics in Biomedical Research” (NREC). The idea for resuscitation of biomedical research ethics system in this time is also influenced by the fact that main stakeholders and policymakers of the biomedical research recognise the importance of shifting the research improvement and development paradigm toward a system which ends in researches with higher quality, better out comes and impact from the status which lays more on the quantity of research projects and increasing the number of publications.

Therefore, research ethics is considered as one of the main and initial infrastructures for development of biomedical research in the country. While implementation of RECs in Iran was encouraged by the external international bodies mainly WHO but today the country itself is convinced that enhancing the research ethics system is a crucial step in enhancing the biomedical research of the country. In order to achieve these goals a project for “Developing a National Action Plan for Enhancing Biomedical Research Ethics Status” was done to determines goals and outline and to defines the short-term and mid-term plans of MOHME in the field of research ethics.

This study designed to assess the status of research ethics committees, which have based in the Iran’s universities of medical sciences and biomedical research centers up to the end of 2013. The main aim of this study was helping the policy-makers in the MOHME for their future activities and programs in order to improve the research ethics standards in the country biomedical science. This study was conducted based on a Gap Analysis method, in which the current status was compared with the desired situation and the intended gap that should be planned to be corrected was determined by a panel of experts. The expert panel used 10 standards defined by WHO “Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants” released in 2011.

The results of this study were analyzed in NREC secretariat and help to plan some the activities we call them “BERD” program.
The program included issues such as:

1- Accreditation of RECs across the country
2- Re-structuring of RECs according to the international standards
3- Revising national research ethics guidelines
4- Capacity building for researchers, REC members and research administrators
5- Establishing a national online system for RECs that lets NREC monitor the RECs activities
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