Introduction

From June 22-24, 2014, Mexico City will have the honour of receiving official representatives from various nations as host of the 10th Global Summit of National Ethics/Bioethics Committees. This achievement was attained through the tireless labour of the Mexican National Bioethics Commission.

The National Bioethics Commission (CONBIOÉTICA) was established in 1992, and became a deconcentrated agency of the Federal Secretariat of Health in 2005, through a presidential decree, which granted it technical and operational autonomy, as well as the specific task of promoting a bioethical culture in Mexico from a plural, secular and inclusive perspective, grounded in the respect for human rights and the protection of all living beings and the environment.

The commission is a national institution, with a plural, inclusive and secular vision. It is directed by a council integrated by a president and six board members, whom are designated carefully in order to preserve a balance of professional and gender diversity and selected for their distinction in their field of knowledge. Their essential tasks include analysing and discussing bioethical issues for public debate and expressing their opinions, and also being familiar with different points of view.

CONBIOÉTICA is the leading institution in Mexico for establishing benchmarks in bioethics. It is a consulting multidisciplinary body, entrusted with the task of formulating and expressing technical opinions, recommendations and pronouncements, regarding legislation and public policies in bioethics. Its scope of legal advice reaches the executive, legislative and judicial branches, both at federal level and local.

CONBIOÉTICA has been instrumental in solidifying the national bioethical infrastructure through local bioethics commissions, which are collegiate bodies that support the enforcement of the existing regulations in bioethics and encourage public debate around bioethical...
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CONBIOÉTICA is regarded internationally as an important actor not only in local or regional forums, but in the worldwide bioethics scene. The commission enjoys enough prestige and international recognition for establishing a dynamic communication channel with consulting organisations from different countries.

During the 9th Global Summit the participating National Ethics/Bioethics Committees unanimously decided to hold the next meeting in Mexico City in June 2014 due to the strong proposal to host the 10th Global Summit submitted by the Mexican National Bioethics Commission with the support of the National Secretariat of Health and the National Council for Science and Technology.

After more than twenty years the Global Summit will take place again in Latin America and for the first time the Global Summit will be held in Mexico. It, thus, represents a unique opportunity to secure common values and benefits in this field of knowledge in the Americas.

Thanks to the participants, the issues analysed and the results obtained so far, the Global Summit of National Ethics/Bioethics Committees is considered by participating governments to be the most important meeting worldwide in terms of its impact on ethics/bioethics and health. This event is of utmost relevance in the international bioethics scene and is considered to be a trendsetter in the development of this field and the rising of new perspectives and debates.

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The Global Summit will be a unique platform for the exchange of information about the on-going work of national ethics Advisory Boards and Commissions, and thus represents an opportunity for open, quality dialogue.

The aims of the Summit are to:

• Encourage the inclusion of bioethics in the national agendas of the nations and organizations in attendance
• Strengthen the activities developed by the commissions, as well as the guides, recommendations and guidelines issued by different organizations
• Understand the impact of the national commissions on the societies of their respective countries
• Exchange strategies and information in order to consolidate National Bioethics Commissions

issues -especially those regarding healthcare, medical research and the protection of the environment, but also to promote the foundation of Research Ethics Committees and Clinical Bioethics Committees, in accordance with the guidelines, regulations and policies established by the National Bioethics Commission.
Provide the opportunity for an open debate, focusing on specific issues such as the protection of human participants in health research, biobanking, end of life choices, public health and aging, among others. The quality of this discussion has been identified by participants as the most valuable outcome.

Contribute to updating information regarding the status and functions of national commissions.

We cannot fail to mention that the Summit will precede another important event in the field of bioethics: the International Association of Bioethics’ 12th World Congress of Bioethics. Both gatherings will be held during the week of June 22-28, 2014 in Mexico City.

The National Bioethics Commission welcomes the fact that our country will host the two most important events in the field of bioethics, making 2014 the Year of Bioethics in our country. It is our hope that Summit attendees who are interested in attending the Congress will also participate in this important event.
SESSION 1 NATIONAL ETHICS COMMITTEES

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

A two hours session about NATIONAL ETHICS COMMITTEES will take place at the Global Summit.

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

The agenda for the discussion will be:
- existing ways of nominating National Bioethics Committees members;
- main academic background;
- how often they meet and deliberate;
- process to choose Opinion’s subjects;
- average time spent to conclude an Opinion;
- how to deal with inside minorities;
- what kind of problems they have/had with the political power;
- how they interact with the media.

We believe this will constitute an important opportunity to identify the ideal profile of NECs and more deeply reflect about the actual importance and roles of National Bioethical Committees in assuring a bioethical culture at different levels. Please do join us and give us your contribution and suggestions to better plan this session.
SESSION 2 THE ETHICS OF NEW HEALTH TECHNOLOGY

(1st Report about the 2nd Plenary Session of the 10th GSNECs in Mexico)

Advances in new health technologies fascinate everyone, especially when outcomes are spectacular. The media are quick, sometimes too much so, to embrace medical advances, and increasingly patients and their family demand them.

However, what the public does not see is the difficult trek from innovation to full scientific validation and acceptance. Social justification and cost determination of new technology are necessary before they can be fully implemented. But this is complicated by many factors: health ministry technocrats and politicians who are often not interested in new technology; economists who have to measure the productivity gain resulting from technology; and industry which has a profit-driven agenda. Many principles are called on in discussion of ethics in healthcare, but for the purposes of the discussion of new health technologies, there are three central ethical aspects of modern practice that are particularly relevant:

Many principles are called on in discussion of ethics in healthcare, but for the purposes of the discussion of new health technologies, there are three central ethical aspects of modern practice that are particularly relevant:

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

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

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

In this session, we will look at how ethical considerations in health technology are likely to remain an important component of medical education, clinical practice, and the political evolution of our health systems.
SESSION 3 UNIVERSAL HEALTH COVERAGE

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

During the past decade Mexico started making significant efforts to expand and strengthen health attention services in order to reach universal coverage. This encompasses ethical dilemmas in, for instance, setting priorities, the allocation of resources, etcetera.

An ethical framework could help governments reach the best option, not only financially but also ethically speaking, for the wellbeing of populations and the sustainability of national health systems.

In this case the experience of Mexican agencies, mainly the National Bioethics Commission, and other NECs around the world should be very valuable.

At the Global Summit 22-23 June 2014, a 2 hour session will be devoted to a discussion on the ethical challenges and concerns that countries face as they roll out universal health coverage.

This session will include reflections of several NECs representing different regions on the forthcoming WHO report Making fair choices on the path to universal health coverage, which addresses key issues of fairness and equity on the path to universal health coverage.

Following a brief presentation of the WHO report by one of the authors of the report, a panel (consisting of NECs from Mexico, Bolivia, Cuba, Sri Lanka, Tunisia and Sweden) will make short presentations and comments concerning recent activities and challenges (within each NEC) with reference to universal health care coverage, and discuss the relevance and implications of the report within their work.

The objectives of the session is to emphasize the ethical questions and issues that confront national bioethics committees as they support their governments to implement universal health coverage and discuss the current and future role of NECs in this area both at a national and a global level.
The importance of ethical, professional and regulatory guidelines for biomedical research is widely recognised, although their effectiveness and relevance have been questioned, particularly where “vulnerable” populations are concerned. For instance, there is no realistic means of giving effect to potentially conflicting requirements in different guidelines.

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

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

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

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

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

In the context of these broader ethical deliberations on biomedical research involving vulnerable populations, particularly children, the Working Group will prepare a discussion paper taking an initial look at the different ways that “vulnerability” has been defined in existing guidelines and the key issues that have arisen. In addition, it will consider the feasibility of a more inclusive definition of “vulnerability” level.

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This Working Group comprises representatives from the national ethics committees (NECs) of Singapore, the United Kingdom, Uganda and Senegal. Its work will also be supported by the NECs of Austria, Estonia and Lebanon.
DEVELOPMENTS IN INTERNATIONAL ORGANIZATIONS

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

Thus, international organizations are excellent partners for NECs. Their global perspective is critical to harmonise guidelines on issues like research ethics, biobanks, etcetera.

During this session, international organizations will present their actual working agenda, perspectives and future projects, so the outcomes of this session will be very important for the 10th Global Summit.

OUR WAY OF WORKING

1. The content of each of the sessions should be as coherent as possible, but there will inevitably be some variations. The role of the Lead NEC and Working Group for each session is to identify speakers/participants for their session; to coordinate the contributions in advance to ensure a coherent approach to the topic; to ensure a background paper or abstracts are prepared in advance; and to prepare a note of the session afterwards for the final report of the Summit, which will be prepared by Mexico.

2. Working Groups and Session Chairs should bear in mind the need for discussions to seek opportunities to discuss comparative experiences and the global coverage of the Summit, but also the particular experience and perspective of Latin America.

3. The Lead NEC, Working Group, and theme of each session is as follows:

a. Review of previous summit – brief overview by Tunisia of the 2012 Summit; followed by discussion where NECs can report on recent developments in areas covered at the last summit, such as transplantation, trafficking and biobanking. Introduction by Mexico to the programme for the 10th Summit, how the sessions and themes will operate, and the Market Place activities.

b. Session 1 – NECs. This session is to examine the constitution, role, independence and operations of National Ethics Commissions, to allow comparative discussion, help identify the ideal profile of NECs, and to consider their impact in local, national and global environments. This could cover issues around their democratic role, and how they relate to ideas of global bioethics. The focus should be ‘institutionalisation’.

c. Session 2 – New Technologies. New technologies can challenge our existing approaches to bioethics, healthcare and medical research. Lebanon have proposed to discuss gene therapy, other suggested topics include caring robots, health Technology Assessment, Xenotransplantation, Big Data, Regenerative medicine (ES and iPS cells) and personalised medicine. Lead and working group members will need to develop linking theme, currently proposed as ‘impacts on autonomy’.
OUR WAY OF WORKING

d. Session 3 – UHC. The most pressing issues globally are still about social determinants of health and basic healthcare in LMIC countries. The contributors to this session can address some of the main priorities: universal healthcare (Cuba) and justice (Sweden), with persistent malaria providing a possible case study (Tunisia), but with ‘poverty and education’ as the integrating focus.

e. Session 4 – Research involving vulnerable groups. This should focus on children as a main category of ‘vulnerable’ (joint work being prepared by Singapore and UK, further contribution from Austria), and might be extended to consider other vulnerable groups, such as at end of life (Lebanon).

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