REPORT

The 10th Brazilian Congress on Bioethics

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Bioethics in Brazil

The major landmark in the implementation of bioethics in Brazil was the founding of the Brazilian Society of Bioethics (Sociedade Brasileira de Bioética – SBB) in 1995. Against the backdrop of an ethical vacuum in the healthcare sector, the SBB developed rapidly, with a special focus on the social inequalities characterising Brazilian healthcare. In addition to the focus on collective health, Brazilian legislation on human research ethics provided a regulatory benchmark which came to be recognised internationally.

Institutions besides the SBB have also been working continuously to promote bioethics, especially several Brazilian universities and the Federal Council of Medicine (Conselho Federal de Medicina – CFM). In 1993, the CFM brought out the first scientific journal on bioethics, Revista de Bioética (http://revistabioetica.cfm.org.br/index.php/ revista_bioetica), and more recently, incorporated bioethical principles, especially patient autonomy into the revised version of the 2009 Code of Medical Ethics (1). In 2005, the SBB started a second journal on bioethics (www.rbbioetica.com.br), and a third, Bioethikos, was brought out by the São Camilo University Center in São Paulo in 2007 (http://www.saocamilo-sp.br/novo/publicacoes/).

A qualitative leap was taken with regard to the study of bioethics in Brazil when, in 2004, four *stricto sensu* postgraduate programmes on bioethics were instituted (master's and doctorate) in university institutions in São Paulo, Brasilia, Rio de Janeiro and Curitiba.

The SBB is responsible for organising the Brazilian congresses on bioethics, and has already held 10 every two years since 1996. Some examples of the dynamism of Brazilian bioethics were the 6th World Congress on Bioethics in Brasilia (the country's capital), organised by the International Association of Bioethics in 2002, and the 8th International Conference on Clinical Ethics and Consultation in São Paulo in 2012. In addition, there were several meetings of the Luso-Brazilian Congress on Bioethics.

10th Brazilian Congress on Bioethics

The 10th Brazilian Congress on Bioethics was held from September 24–27, 2013 at the Baia Sul Convention Center in Florianopolis, in southern Brazil. A record number of 1186 university lecturers, bioethicists, professionals and students in the areas of health, law, human and social sciences, and philosophy were registered for the Congress. Five hundred and forty-one papers were accepted, 203 of which were talks and 338 posters. In addition, there were 25 educational videos on topics related to bioethics (unprecedented at Brazilian congresses on the subject), and 24 reports of teachers' experiences in teaching bioethics, an original feature. The guests included 101 Brazilian and 21 international speakers, among whom were Diego Gracia, José Carlos Abellán Salort, Maria do Céu Patrão Neves, Stefano Semplici, Ruth Macklin, Henk ten Have, Antonio Ugalde, Nuria Homedes, Jan H Solbakk, Johane Patenaude, Georges-Auguste Legault and Miguel Kottow. The event consisted of 29 talks, 36 round-table talks, 10 pre-congress courses, four cinema sessions with comments, and the launch of 18 books on bioethics.

The central theme of the Congress was "Bioethics: Health, Research and Education". The focus was on the most controversial issues in Brazilian bioethics, as well as key current concerns. These are dealt with below.

Use of placebo and double standard in clinical trials

Bearing in mind the imminent 64th General Assembly of the World Medical Association (WMA) to be held in Fortaleza, Brazil in October 2013, these topics were addressed on different occasions by various speakers at a three-member round-table discussion and two conferences. In the round-table talks on "Revision of the Declaration of Helsinki (DoH): interests and tendencies," the Brazilian bioethicist, Volnei Garrafa, mentioned the USA's rejection of the DoH. Ruth Macklin, the American philosopher and professor of bioethics, said that although she understood that the USA should abide by the DoH, it did not matter considering that it was of no use to researchers and ethics committees since the USA had its own standard (Good Clinical Practices).

As for the use of placebos, this researcher stated that it is not possible to use them in diseases which have their own recognised treatments, such as AIDS, hypertension and diabetes, but that they could be used in "minor conditions", such as influenza and baldness. In short, she is against the use of placebo in general; but. In exceptional diseases (Parkinson's disease or multiple sclerosis, which do not have a cure and the clinical condition oscillates), the placebo could be used under restricted conditions. The Chilean bioethicist, Miguel Kottow, who spoke on "The decline of the placebo", and took part in the round-table discussion on "Placebo: malpractice

or conflict of interests?" concluded that: (i) using a placebo is a malpractice under any circumstances since it constitutes an illegitimate invasion of the human physical territory; (ii) there is no ethical justification for using a placebo; (iii) if there is no treatment for a particular condition, one should come up with another methodological design or use nothing as a comparison; and (iv) using a placebo is an ethical transgression no matter what the circumstances are. Kottow suggested the drafting of a Decalogue on bioethics in human research, the first commandment of which would be, "Thou shalt not use a placebo in research." Miguel Jorge, who is a representative of the Brazilian Medical Association and has a vote in the assembly of the WMA, presented the background of the study group on placebo and its outcome, to be submitted for deliberation to the 64th General Assembly of the WMA. The study group's proposal was not substantially different from the 2008 DoH.

With regard to the double standard, Macklin made the controversial statement that it existed in countries where healthcare conditions were somewhat precarious (2). When speaking at the conference on "Double standards in medical research in developing countries: can they ever be justified?", Macklin said that while she was "a staunch opponent of double standards, I also believe that it is necessary to develop interventions that are suitable for use in low-resource countries or communities with a poor healthcare and medical infrastructure". Therefore, she concluded, conducting studies that use a double standard is better than leaving the people with nothing at all. In her opinion, a study would be objectionable and anti-ethical if it used a double standard when a better standard was available to all participants. She also mentioned that it was not correct to say that a study is carried out in a developed or developing country; studies may also be conducted in different regions of the same country. For this reason, she felt that "developed country" and "developing country" must be substituted by "higher-resource" or "lower-resource" areas. Also, in relation to placebo and the double standard, Jan Hellge Solbakk from the University of Oslo, on the basis of conceptual, epistemological and ethical considerations, strongly criticised the WMA's role. He said"By acting in this way, WMA is serving the interests of the most powerful players in the field of medical and health-related research, instead of speaking truth to power [sic] and defending the interest and well-being of the most vulnerable stakeholders in this play, ie individual patients and research subjects in poor and low-income countries."

At the conclusion of the Congress, the General Assembly of the SBB reiterated its position that it would not authorise the use of placebo in diseases which have a known treatment. The National Council of Health, the highest Brazilian agency in the sphere of health regulations, adopted the same stance when it approved a motion to "restrict the use of a placebo in cases where there is another effective treatment." It may also be mentioned that the ethical control system for human research in Brazil, embodied in the CNS Resolution 466/2012(3), does not allow the use of a placebo in cases for which treatment is available. Similarly, the current Brazilian Code of Medical Ethics prohibits the medical professional from "maintaining any kind of link with medical studies involving human beings, which use a placebo in their experiments, when there is effective and efficient treatment for the disease under study." Also, the double standard is inadmissible in clinical tests in Brazil. However, the text of the 2013 DoH approved in the 2013 revision in Brazil (4) retained the exceptions mentioned in this regard in the 2008 version.

Advance directives, palliative care and clinical bioethics committees (hospital)

These topics were raised at the Congress because they have been introduced to Brazil recently and are being discussed in depth, both among the general public as well as academicians and bioethicists. To help the participants improve their understanding of ethics and palliative care, a Master Conference was held on "Ethics of palliative care". The Spanish physician, Diego Gracia, introduced the clinical deliberation method. In his lecture, he emphasised the role and importance of the living will and the clinical bioethics committee. The former relates to the expression of patients' values and wishes at the end of their life, while the latter can support and steer medical decision-making to prevent useless or unnecessary treatment. Gracia stressed that "it would be very helpful if patients were to complete advance directives, making it clear what is essential for them, should they be unable to communicate." He also emphasised the need to create the so-called "patient's values history". According to Gracia, "The hospital bioethics committee represents the opportunity to discuss clinical cases, but also values and duties, reaching a moral deliberation and, with it, the settlement of value conflicts. The Spanish bioethicist emphasised that at least four values come into conflict in the decision-making process at the end of a person's life: (i) a medical contraindication (non-maleficence); (ii) therapeutic futility (beneficence); (iii) efficient management of resources (justice); and (iv) the patient's "decision" (autonomy).

In another session on "The bioethics outlook on palliative care", the Brazilian bioethicist, José Eduardo de Siqueira, mentioned that if in the first half of the 20th century, talking about sex was taboo, from the second half of the century, talking about death became taboo. As already mentioned, most physicians and a large proportion of the public in Brazil still lack awareness of issues like advance directives, palliative care and clinical bioethics committees. There is no federal government law regulating these matters, and the only existing instruments to provide physicians with ethical guidance have been drawn up by the CFM. The CFM's Resolution 1995/2012 guides physicians on the patient's wishes or advance directives, stating that "the patient's advance directives will prevail over any other non-medical opinion, including over the wishes of family members."(5). It lays down that should the patient's wishes be unknown, and if there is no appointed representative or relatives available, or if there is a lack of consensus between them, the hospital bioethics committee (if one is in existence)

shall base its decision on ethical considerations. Moreover, the CFM's Resolution 1805/2006 on orthothanasia (6) permits the physician to restrict or suspend procedures and treatments that prolong the life of a terminally ill patient, respecting the wishes of the person or his/her legal representative. Hugo Rodríguez Almada, of the Department of Legal Medicine, University of the Republic, Uruguay, stated that in Latin America, laws on advance directives have been passed only in Argentina, Uruguay, Chile and Mexico. In Brazil, there is only a regulation of the FCM. Next, the Spanish bioethicist, José Carlos Abellán Salort, spoke on "The evolution of the living will in Europe". He mentioned that currently, only a small minority of Europeans have advance directives. He said that the laws existing in some countries were not very developed, but were in the process of being organised, and added that not much was known about their use.

Finally, in his lecture on the "Clinical bioethics committee: between the real and ideal", José Eduardo de Siqueira stressed the importance of such committees, adding that there are very few in Brazil. Even in hospitals with bioethics committees, clinicians are hardly interested in consulting them. This is the result of an exaggerated focus on medical and technical training of health professionals. The training does not encourage reflection on moral conflicts relating to seriously ill patients. The Italian bioethicist, Stefano Semplici, also addressed this topic in his talk on the "Importance of bioethics committees". He emphasised the importance of such committees at the global, national and institutional levels, and elaborated on the functions that they serve at each of these levels.

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THANK YOU, REVIEWERS!

Besides the generous support of internal reviewers, the journal has also had, in 2013-14, the invaluable contribution of external peer reviewers who have been listed below. Our sincere gratitude is due to them all:

Adrian Viens, Alastair Campbell, Alireza Bagheri, Alok Sarin, Anant Phadke, Anoop Thekuveetil, Anuradha Rose, Avinash De Sousa, Bindu Desai, Bushra Shirazi, Chinu Srinivasan, David Thambu, Gagandeep Kang, Gairik Sengupta, Gauri Raje, Jagadeesh Narayan Reddy, Jissa VT, Joe Varghese, Jose Dorea, Julia Inthorn, Lopa Mehta, MR Mani, Manisha Gupte, Mariette van den Hoven, Mariam Hassan, Michael Selgelid, Monica Sakhrani, Nerges Mistry, Nikhil Govind, Nishant Alphonse Irudayadason, P Ravi Shankar, Peush Sahni, Radha Ramaswamy, Raj Vaidya, Rajan Madhok, Rajib Dasgupta, Raman Kutty, Renuka Munshi, SP Kalantri, Saima Iqbal, Salla Sariola, Samrat Sinha, Sandeep B Bavdekar, Sarojini NB, Sharada Lakshman, Soumitra Pathare, Subrata Mukherjee, Sukanya Rangamani, Sunita Simon Kurpad, Supriyo Choudhury, Unnikrishnan Payyappalli, Urmila Thatte, VR Muraleedharan, Vina Vaswani, Vrinda Marwah, Walter Vaz, William Joe, Yatin Dholakia