consent form into the local languages and its back translation into English to ensure that all participants get the same information. This is a requirement as per Schedule Y but the RECs surveyed are apparently unaware of this requirement.

Training in GCP is meant to equip REC members to conduct effective ethics review. The need for training was apparently felt by only 12(41%) of the respondents which implies that they are not completely aware of their responsibilities

4 (14%) respondents were unsure of the documents required to be provided to participants. Though the letter of approval from the Drugs Controller General of India is an essential document to be submitted to the ethics committee, 5(17%) members could not name the regulatory body for clinical trials in India.

Further, though the quality of ethics review can be affected by the workload, many members did not feel the need to restrict the number of protocols to be reviewed per meeting.

It is also a matter of concern that 41% felt that REC approval posed a hurdle in the process of clinical trials. This suggests that the critical role of RECs in the review process is not understood by all members.

The first survey on RECs was conducted by ICMR-WHO in 2003. 1,200 questionnaires were mailed to medical institutions out of which 223 responded (response rate: 18.58 %). It was observed that REC members were appointed by lobbying; many committees did not include legal experts; standard operating procedures were not followed, and records were poorly kept (5). The ICMR conducted a survey of RECs of institutions conducting clinical trials funded by the ICMR in 2006-2007 (7).The response rate was 42.5%. 64% of the committees had standard operating procedures for review, 39% had members trained in bioethics and almost all had a multidisciplinary composition as per ICMR norms. Our study had a response rate of 55 %. 52% reported training in good clinical practice. All the RECs had written standard operating procedures and met requirements for the composition of the committee.

The findings of our survey suggest that there have been some improvements in the functioning of RECs in the past decade. However, our survey was based on a small sample, was restricted to a single state, and had a poor response rate. Our study should be viewed as the first step towards collecting more systematic information on the functioning of RECs in India.

We suggest that mandatory registration, accreditation and regular audits will provide such information, in addition to performing the function of regulating RECs.

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Global Summit of National Ethics Committees: an essential tool for international dialogue and consensus-building

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Abstract

Held for the first time in 1996, the Global Summit of National Ethics Committees (NECs) is a key platform for dialogue and fostering consensus on ethical issues at a global level. At the Eighth Global Summit meeting, which took place in Singapore in July 2010, important decisions were taken to ensure the continuity of activities between the Summits. This article intends to briefly retrace the history and analyse the role and functioning of the Global Summit. It also discusses future challenges for international collaboration of NECs.

Historical background

The first national ethics committee (NEC) was established in France in 1983. Following this, an increasing number of nations have created official bodies to provide advice to their executive and legislative branches, and often to the general public, about bioethics. In 1996, the US National Bioethics Advisory Commission asked the French National Consultative Committee on Ethics to jointly invite the other NECs to attend an international summit meeting held in San Francisco in conjunction with the Third World Congress of Bioethics. Since then, eight Global Summits have taken place: San Francisco (1996), Tokyo (1998), London (2000), Brasilia (2002), Canberra (2004), Beijing (2006), Paris (2008) and Singapore (2010).

As the formal Permanent Secretariat of the Global Summit of NECs, the World Health Organization (WHO) maintains a close collaboration with NECs around the world.

Overview of the current situation of NECs

A recent web-based research (1) identified 93 countries (48.2% of WHO member states) with national ethics committees: 22 in the WHO African Region (47.8% of countries), 13 in the Region of the Americas (36.1% of countries), nine in the Eastern Mediterranean Region (42.8%), 38 in the European Region (71.7% of countries), four in the South-East Asian Region (36.4% of countries) and seven in the Western Pacific Region (25% of countries). Some of these committees are national ethics committees dealing with a broad range of ethical issues in health, while others are exclusively or predominantly research ethics committees. Sixty per cent (56) of these committees have some form of publicly accessible website, although not all of them have information in the English language. The differences in composition, goals and functions among NECs in the various regions arise from a variety of reasons that are historical, cultural and political. The diversity in mandates and missions of NECs is reflected in the range of organisational structures (2). Termed "National Commissions", "Advisory Committees", or the like, NECs can be appointed by chief executives, ministers of health, or legislatures, to analyse and offer recommendations about current issues in bioethics, or the ethics of health more generally, especially if legislative action or change in national policy is required.

International collaboration

Besides the WHO, several other international organisations have developed a wide range of activities in collaboration with NECs (3). These activities include:

a) Setting up and training new NECs (see the project "Assisting Bioethics Committees" (4) of the United Nations Educational, Scientific and Cultural Organization, UNESCO). To date, several committees, mainly in Africa, have been established under this initiative (5);

b) Facilitating dialogue on emerging issues relating to the development of science and technology (see, for instance, NEC Forum and International Dialogue (6) organised by the European Commission, and the cooperation between NEC and the Council of Europe through the European Conference of NEC, COMETH); and

c) Fostering global debate and consensus on issues of public health and research.

Using the platform of the UN Interagency Committee on Bioethics (UNIACB), WHO, UNESCO, the European Commission and the Council of Europe have over the last seven years increasingly striven to strengthen synergies and complementarities. UNESCO and WHO have also co-organised two regional summits of the NECs of the Eastern Mediterranean region, in 2007 and 2009.

In addition, the institutional development of NECs is fostered by the complementary activities and support offered by international organisations or institutions. Taking advantage of these opportunities, NECs can strengthen their national role through exchange of information and contribution to international debate.

Eighth Global Summit of National Bioethics Advisory Bodies

The Eighth Global Summit was hosted by the Bioethics Advisory Committee (BAC) and the Ministry of Health in Singapore from July 26 to 27, 2010. The meeting drew representatives from 33 countries and four regional and international organisations. The agenda was collaboratively developed by the BAC, the European Commission and the WHO.

The focus of the first day of the meeting was on ethical issues in organ, tissue and cell transplantation, research ethics committees and tuberculosis (TB) control. The WHO's three new guidance documents on these subjects were discussed. Also presented on the first day was an update on bioethical developments in Jamaica and Saudi Arabia. These developments make clear that there is considerable diversity in approaches to addressing bioethical concerns. In the light of this, a suggestion was made for an online repository to be established, with information on the NECs, their functions, work and approaches.

The session on organ, tissue and cell transplantation provided an opportunity for NECs to discuss the implementation of the guiding principles set out in the WHO's resolution (7) on the subject, which was adopted by the 63rd World Health Assembly in May 2010. In addition, NECs also discussed the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (8) that was prepared by the Transplantation Society and International Society of Nephrology, and adopted by participants at the International Summit on Transplant Tourism and Organ Trafficking in May 2008. Some of the more immediate practical concerns relating to the implementation of the guiding principles have been identified as: difficulties in recognising and removing inducement in various guises; providing longterm care for donors, and devising means of reducing reliance on living organ donors. In the long run, however, social and cultural factors (such as poverty and illiteracy) that

contribute to organ trafficking and related issues need to be better understood and addressed.

In the session on research ethics committees that followed, a standards document entitled "Standards and Guidance for Research Ethics Committees that Review Health Related Research with Human Beings" and prepared by the WHO secretariat was considered. This document served to outline key ethical requirements for the operations, functioning and governance of a research ethics committee that global stakeholders would regard as non-negotiable. These requirements include multi-disciplinary membership and clearly established terms of reference. The document was also intended to provide concrete guidance on how such committees could establish procedures to meet these international standards. While there was some consensus on operational procedures, many NECs felt that further clarification of roles and ethical expectations was required. While difficult to achieve, some level of harmonisation was generally felt to be important given the increasingly transnational nature of research.

The third WHO document that was considered and discussed by NECs was concerned with ethical guidance for programmes relating to care for and control of TB. The document, subsequently published in November 2010 (9), provides a comprehensive analysis of ethical issues and guidance to governments and other stakeholders in implementing TB care and control programmes in an ethical manner. Within the deliberative framework set out by the document, the discussion of the NECs was mainly focused on devising the appropriate balance between enabling research for public benefit and the autonomy of the patient or research subject. It was proposed that implementation issues and the role of ethics bodies be evaluated at the next Global Summit meeting.

The second day of the Eighth Global Summit comprised sessions on synthetic biology and biobanking, stem cell research and therapy, medical ethics and updates on bioethical activities of the European Commission, the Council of Europe and the WHO.

Several NECs have evaluated or are evaluating the ethical implications of synthetic biology. A document that was considered by NECs was an Opinion of the European Group on Ethics of Science and New Technologies on the ethical, legal and social implications raised by synthetic biology (10). As the Eighth Global Summit was the first occasion on which this field was discussed on a global level by NECs, it was felt that ethical concerns have to be better defined. Most immediately however, safety issues are most pressing and need to be addressed.

For biobanks to realise their full potential, international collaboration and exchange of samples and information are essential. There are numerous challenges entailed in operating and maintaining biobanks. One particular challenge is whether or not a more general form of informed consent can be ethically acceptable, given the fact that new research interest may emerge over time for which consent has not specifically been given by sample donors. The experiences of NECs in France, Austria and Greece were considered in this session.

In the session on ethical issues in stem cell research and therapy, new policies in China and Japan were considered. It was felt in both countries that a regulatory framework would have to be developed for first-in-man trials involving human pluripotent cells, whether derived from an embryo or otherwise. Denmark presented its deliberations and discussions on the use of chimeras and hybrids in research. Finally, NECs considered the Australian experience with disclosing genetic information to a person's genetic relatives; the UK's Nuffield Council's ongoing deliberations on the ethics of medical profiling and online medicine; and current debates in Switzerland on end-of-life ethics. It was agreed that the next Global Summit meeting would follow up on these important medical ethics concerns.

A brief report on the Eighth Global Summit, as well as the final agreement of participating NECs, is available at the website of the BAC (11).

Outlook for the future

Over the last 14 years, the Summits have proven to be a valuable instrument to foster international debate on ethics and health and to facilitate collaboration between national ethics committees. They offer a critical forum for identifying pertinent issues of global importance, and in respect of which international agreements and cooperation are needed.

The international community needs local ethics committees to be committed to meeting global ethical challenges in a responsible and collectively accountable manner.

There are a number of challenges ahead. The first is to increase participation of low and middle income countries in future Global Summit meetings. To achieve this as a mid-term goal, the establishment of additional NECs, particularly in Africa and Asia, is necessary. The second is to build consensus on emerging international issues, such as ethics of global research, and to empower as well as encourage NECs to implement internationally-agreed guidance. Finally, as agreed in the Eighth Global Summit, continuing collaboration among NECs from different regions is necessary. For most of the NECs, the challenge is not so much to agree on general ethical principles, but to build a global consensus on modalities for implementation in health policies.

The next Global Summit is scheduled to be hosted by the Tunisian NEC in October 2012. In addition to the priority topics identified in Singapore, the focus will also be on protection of vulnerable populations and equity of globalisation. The Ninth Global Summit will be the first time that NECs will meet on the African continent.

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Bioethics governance in Israel: an expert regime

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Abstract

This paper provides an overview of bioethics governance in Israel through an analytical description of the legal framework for the interface between individuals and biomedical practices. There is no national agency with general oversight of bioethics policy and decision making, and the rules that apply to individual usage of biomedical technologies are laid down in a multitude of different statutes, regulations and administrative directives. Expert committees play a central role in this regulatory system in two capacities: as governmental advisory bodies that recommend policy; and as decision-making bodies that resolve conflicts around patients' rights or grant individual access to biomedical technologies. This decentralised system of governance through expert committees allows for adaptation to dynamic technological developments and flexibility in accommodating creative societal usage. At the same time the experts are the agents of the state's bio-power at the expense of personal autonomy and open public deliberation.

The paper is part of a larger study investigating Israel's bioethics governance and its regime of experts, which includes an examination of the normative level of regulation, and an analysis of the composition of the expert committees. Our findings suggest that Israel has a decentralised system of governance with piecemeal regulation that has established a bioethics technocracy, governed by the ministry of health and dominated by the medical profession. The present paper is confined to a description and discussion of the legal framework of Israel's expert bioethics regime. Here, our major conclusion is that Israel has established a technocracy of official expert ethics committees, which controls life and death decisions.

Introduction

Israel has a sophisticated healthcare system with generous public funding for universal access to advanced biomedical technologies from the beginning to the end of life. It is at the forefront of research in medically assisted reproduction (MAR), and has extraordinarily high rates of consumption of repro-genetic technologies (1-5). Also at the end of life the norm is rigorous medical treatment (6: 136).

Since the mid-1990s, there has been a flurry of legislation in Israel to address the ethical challenges of new biomedical technologies. Some of these laws are known for breaking ground in the legal regulation of biomedical technologies. In 1995 Israel was the first country in the world to legalise and regulate surrogacy (7). Likewise, in 2008 it enacted a unique organ transplantation law that regulates compensation for living donors and grants donor-card holders priority in organ allocation (8).

There is no national agency with statutory powers to exercise general oversight over bioethics policy and decision-making, or to gather information and report to the public on new biomedical practices and their socio-ethical implications, as opposed to the UK or France. Nor has any public authority been mandated by statute to engage or consult the general public in deliberations on bioethical dilemmas. Instead, Israel's governance of bioethics is characterised by piecemeal regulation, and the rules that apply at the interface between individuals and biomedical practices from the beginning to the end of life are laid down in a multitude of different statutes, regulations and administrative directives.

In this paper we examine the role played by expert committees