3. Bouësseau B, Boussard H. La bioéthique dans les organisations internationales. *Bioéthique: Entre loi, morale et progrès. Revue Politique et Parlementaire*. 2009 Jan-Mar 111ème année. N°1050.: 178-83
4. United Nations Educational, Scientific and Cultural Organization. [Internet]. Assisting Bioethics Committees. Publications. [cited 2011 Jun 25]. Available from: http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/assisting-bioethics-committees/publications/
5. United Nations Educational, Scientific and Cultural Organization. [Internet]. Assisting Bioethics Committees. The present state of the ABC project. [cited 2011 Jun 25]. Available from : http://www.unesco.org/new/en/social-and-human-sciences/themes/ethics-of-science-and-technology/bioethics/assisting-bioethics-committees/present-state/
6. European Commission. Bureau of European Policy Advisors. EC international dialogue on bioethics [Internet]. 2009 Feb 19 [cited 2011 Jun 24]. Available from : http://ec.europa.eu/bepa/european-group-ethics/bepa-ethics/ec-international-dialogue-bioethics/index_en.htm
7 World Health Organization. 63rd World Assembly. *Human organ and tissue transplantation*. WHA63.22, Geneva: WHO; 2010 May 21.
8. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism. Istanbul, Turkey: 2008 Jul 5 [cited 2011 Jun 25]. Available from: http://www.declarationofistanbul.org/
9. World Health Organization. *Guidance on ethics of tuberculosis prevention, care and control*. Geneva: WHO; 2010.
10. European Group on Ethics in Science and New Technologies to the European Commission, *Opinion 25: Ethics of synthetic biology*. Brussels: European Commission; 2009 Nov 17.
11. Bioethics Advisory Committee, Ethics and Health Team, World Health Organization, Ministry of Health, Singapore. Eighth Global Summit of National Bioethics Advisory Bodies. Singapore. 2010 Jul 26-7. [cited 2011 Jun 24]. Available from: http://www.bioethics-singapore.org/gsnbab2010/

Bioethics governance in Israel: an expert regime

CARMEL SHALEV[1], YAEL HASHILONI-DOLEV[2]

[1]Adjunct Professor, Faculty of Law, Haifa University ISRAEL e-mail: cshalev@012.net.il [2] School of Government and Society, The Academic College of Tel-Aviv-Yaffo ISRAEL e-mail: yaelhash@mta.ac.il

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

in this decentralised regulatory system. We find that the mechanism of an expert committee with the power to make decisions has become a key instrument in the regulatory system that evolved, and that expert committees act in two capacities: as governmental advisory bodies to recommend policy; and, as decision-making bodies with the authority to allow otherwise forbidden practices in individual cases.

Expert advisory bodies

While there is no central bioethics regulatory agency, expert committees play a central role as governmental advisory bodies to recommend policy in relation to the use of new biomedical technologies.

As in other countries, and in accordance with the World Medical Association's Declaration of Helsinki on ethical principles for research involving human subjects, medical experiments may not be conducted unless they have undergone review and approval by a research ethics committee (REC) under public health regulations (9). In Israel RECs are called 'Helsinki' committees, because the Helsinki Declaration provides the normative content for domestic law. Most medical research in Israel takes place under the purview of hospital committees, but where the subject of the proposed research goes to "artificial" reproduction or genetics it must come before a national committee. This national Helsinki committee (NHC) was vested with advisory statutory powers under two statutes enacted by the Knesset: that which sets a moratorium on reproductive cloning and genetic manipulation of eggs and sperm (10); and that which regulates genetic testing and research (11).

In addition, in 2004 the cabinet appointed a National Bioethics Council (NBC) (12), as an advisory body to all branches of government on bioethics policy. However, the relationship between the NBC and the NHC is not clear. Furthermore, in June 2010 the minister of health appointed an ad hoc committee, called the Fertility and Reproduction Committee (FRC), with the mandate to recommend legislation on a variety of matters related to MAR, including gamete donor anonymity, pre-implantation genetic diagnosis, and extra-territorial practices of reproductive tourism. The multiplicity of advisory committees creates some overlap and confusion. For example, the subject of fertility preservation (i.e. freezing of egg cells for future use without medical indication) was included in the mandate of the FRC, but the NCB had already issued guidelines on the matter in October 2009.

The FRC was appointed following a petition to the Supreme Court to allow gay couples access to surrogate mother arrangements (13). A similar petition in 2002 to allow single women access to surrogacy (14) also led to the appointment of an ad hoc committee at the ministry of health (MoH), which recommended no change in the law (15). Indeed, most advisory expert committees have been appointed ad hoc within the MoH. Sometimes these committees are appointed subsequent to court decisions on actions brought by individuals seeking relief against infringement of their autonomy to use a biomedical technology, as in the two cases of surrogacy mentioned above. More often, committees are appointed independently to recommend legislation. For example, in 1991 a "public-professional commission" known as the Aloni Commission was appointed jointly by the minister of health and the minister of justice to recommend legislation on in vitro fertilisation, which ultimately led to enactment of Israel's surrogacy law. Likewise the Steinberg committee led to the Dying Patient Law (16). And other ad hoc committees prepared the ground for other legislation, such as the laws on organ transplantation and eggs donation.

Expert decision-making authorities

Expert committees also exercise actual decision-making powers in individual cases. Various statutes, regulations and administrative directives establish such committees and vest in their expert members the authority to allow otherwise forbidden biomedical practices, or the discretion to grant or deny individual access to a biomedical technology.

The first instance of a committee with decision-making authority in Israel's legal system is found in the law of abortion. In principle, abortion constitutes a criminal offence, but the medical profession took upon itself to self-regulate the provision of abortion as a 'therapeutic exception', by establishing hospital committees that would approve the interruption of a pregnancy on medical grounds. This practice was officially incorporated in Israel's law when the Knesset amended the Penal Law in 1977, concurrent with a world-wide trend to liberalise anti-abortion laws. The amendment allowed for legal abortion on certain statutory grounds, as an exception to the general criminal prohibition. The decision on whether or not there were grounds for legal termination of the pregnancy was vested in a hospital committee composed of two physicians and one social worker, and headed by a physician (17).

Research ethics committees might also be seen as authorised to permit an otherwise forbidden practice, since medical experiments may not take place without their approval. Of particular note is the authority of Israel's national Helsinki committee (NHC) under its anti-cloning law (section 5(a)) to permit certain exceptions to the prohibition of genetic manipulation of gametes. The NHC also acts as a decision-making body in relation to the approval of embryonic, stem cell and cloning research. Since Israel's anti-cloning law prohibits only reproductive cloning, all other matters of embryonic research are left to the discretion of the expert members of the national committee without guidance from the legislature and without public debate.

At the institutional level, besides the Helsinki committees, hospitals are supposed to establish committees under the Patient Rights Law, 1996 (18) and under the Dying Patient Law, 2005 (19). (In fact these committees are not always operative (20), but the present article analyses the policy as expressed in the law, rather than the practice.) The idea of including ethics committees in the Patient Rights Law was inspired by the voluntary practice in the USA of referring medical dilemmas to

an advisory ethics committee (21). However, the Israeli statutory committees are vested with actual authority to make decisions.

Ten years later, the Dying Patient Law also established a distinct system of institutional and national committees to resolve the special conflicts and ambiguities related to end-of-life medical care (22). These committees too have decision-making authority rather than an advisory mandate.

While these committees have statutory powers to resolve conflicts relating to doctor-patient relations, other statutes have established expert committees with the authority to grant or deny individuals access to biomedical technologies. These committees make decisions about many individual matters, including surrogacy, live organ donation, eggs donation and pre-implantation sex selection. As in the case of abortion, here too we find the model of 'forbidden but allowed', i.e., prohibiting a certain practice, but allowing it if approved by an expert committee. Thus the laws that regulate surrogate motherhood (23), organ donation (24) and eggs donation (25) all first ban the relevant practice as a matter of principle, except in accordance with the provisions of the law. Then they lay down the circumstances and conditions under which a statutory committee may approve the practice, despite the prohibition.

An outstanding example can be found in ministry of health (MoH) guidelines with respect to sex selection by means of pre-implantation genetic diagnosis (PGD) (26). The directive states that sex selection through PGD other than for medical purposes is prohibited. At the same time it may be performed "solely in extraordinary, exceptional, rare and special cases" with the approval of an expert committee, and under certain accumulative conditions. One of the conditions is that the applicants have at least four children of the same sex and do not have children of the other sex. And yet again, the expert committee has discretion to allow the procedure "in extremely rare exceptional cases" even if this condition is not fulfilled.

Discussion

Israel is often described as permissive in its approach to new biomedical technologies. But this permissiveness is not as liberal as it appears to be, because it comes hand in hand with intense regulation and control by the expert committees. We have seen that Israel has multiple committees of experts with either advisory capacity or actual decision-making authority in various matters that raise bioethical debate. At the national level the multiplicity of advisory committees creates overlap and confusion. At the hospital level too there will be no less than three committees - a research ethics committee, a patient rights ethics committee, and a dying patient committee. This means that all matters related to the protection of the rights of individuals, as either patients or participants in medical research, or to the resolution of conflicts in patient-doctor relations, are subject to the authority of expert bio-ethical fora rather than to the jurisdiction of the courts of law. This expert jurisdiction is in contrast with Germany, for example, where the power to make decisions, at least as regards end-of-life care is in the hands of legal experts. (27: 387-8).

Furthermore, a typical feature of the regulation of specific bioethics issues (abortion, surrogacy, organ donation, eggs donation and PGD sex selection) is that the practice is prohibited as a matter of principle, but allowed if approved by an expert committee. Hence individuals who wish to partake in such medical practices must receive the approval of an expert committee, which is vested with decision-making authority. The regulatory framework typically delineates what is forbidden and what is allowed in general terms, but leaves a large scope of discretion to the experts to depart from those terms. The pattern of deferring decisions to expert committees makes for a large degree of flexibility in individual cases, and is very much in line with the casuistic tradition of Jewish law. However, from the point of view of the individual, the experience may be of encountering bureaucratic barriers, which entail intrusion into privacy, humiliation, uncertainty, confusion, alienation and, above all, dependency on the appointed experts. This is at odds with the central value of personal autonomy in Israel's purportedly liberal bioethics discourse.

Different studies as well as data provided by the MoH itself indicate the power exercised by expert committees. Data from the MoH with respect to sex selection show that in the last five years less than 10% of the requests were approved by the expert committee and the vast majority of requests were dismissed (28), which amounts to restriction of personal choice and autonomy. On the other hand, despite the fact that most requests for abortion are approved, Amir (29) has argued convincingly that abortion committees are a mechanism which controls and regiments women's reproduction, and that women's experience of these committees is unnecessary intrusion into privacy and humiliation. Likewise, the surrogacy approvals committee imposes very strict screening criteria on candidates for surrogate mothers, which infringe on their privacy (30). The committee's guidelines list 15 conditions that are laid down in the law and must be met, as well as 16 additional conditions that the committee adopted in light of the experience it gained over the years. Fourteen of these additional conditions apply to the surrogate mother candidate, who must show among other things that she is able to maintain appropriate interpersonal relations; she is not in the heat of a crisis; she has a stable character, is responsible and has the ability to persevere; she has family and social support systems, and a sound parental relation with her children; and she has economic and social management capability.

While the expert regime restricts personal autonomy and privacy and comes in place of judicial review of biomedical practices, it is also worth noting the lack of any significant public engagement in making policy about bioethical issues that have broad social implications. Although the parliament provides a forum for public debate, and advisory committees typically invite comments from concerned parties, participatory practices for engaging and involving the public that are widespread in other countries are noticeably absent in Israel. This is in contrast to the United Kingdom, also a leading country in terms of new controversial medical technologies, where the Human Fertilization and Embryology Authority has conducted

multiple public consultations, since policy is based on social acceptability (31). In one exceptional case in Israel, where a public survey was conducted on the issue of sex selection, the finding was that public opinion was much more permissive than the policy (32).

Our major conclusion is that Israel has established a technocracy of official expert ethics committees, which controls life-and-death decisions. In other words, the governance of bioethics in Israel is characterised by a web of expert committees to which individuals are subjected either for approval of access to the technology or to resolve disputes with medical authorities. The experts have power not only to decide the fate of individuals but also, by so doing, to set moral boundaries demarcating good and evil, deviance and normality, insiders and outsiders (33, 34). Israel provides a clear example of the institutionalisation of expert advice in diverse official committees. In Israel experts are the legal and ethical gatekeepers (35) of new technologies which have the potential to manipulate individual life and death choices. In effect, Israel's expert bioethics committees act in the service of the state as the agents of what Foucault termed bio-power and governmentality, fabricating individuals and their bodies within a network of instruments of power (36-7)

References

1. Shalev C, Gooldin S. The uses and misuses of in-vitro fertilization in Israel: some sociological and ethical considerations. *Nashim - Journal of Jewish Women's Studies & Gender Issues*. 2006; 12: 151-76.
2. Carmeli Y S. Introduction. In: Carmeli YS, Birenbaum-Carmeli D, editors. *Kin, gene, community: reproductive technology among Jewish Israelis*. Oxford, NewYork: Berghahn Books; 2010.
3. Kahn S. *Reproducing Jews.* Durham and London: Duke University Press; 2000.
4. Hashiloni-Dolev Y, Hirsh-Yechezkel G, Boyko V, Wainstock T, Schiff E, Lerner-Geva L. Attitudes towards sex selection: a survey among potential users in Israel. *Prenatal Diagnosis*. 2010; 30(11):1019-25.
5. Sperling D. Commanding the "Be fruitful and multiply" directive: reproductive ethics, law and policy in Israel. *Camb Q Health Ethics*. 2010 19(3): 363-71.
6. Shalev C. Reclaiming the patient's voice and spirit in dying: a perspective from Israel. *Bioethics*. 2010; 24(3): 134-44.
7. Weisberg KD. *The birth of surrogacy in Israel.* Gainesville: University Press of Florida; 2005.
8. Lavee J, Ashkenazi T, Gurman G, Steinberg D. A new law for allocation of donor organs in Israel. *Lancet*. 2010. 375(9720):1131-3.
9. Public Health (medical experiments in human beings) regulations, 1980.
10. Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 1999.
11. Genetic Information Law, 2000.
12. Government of Israel Resolution no. 1219, 2004.
13. HCJ 1078/10, HCJ 1078/10 Yoav Arad Pinkas and Itai Pinkas v. The Approvals Committee for Surrogacy Agreements (unpublished decision of 2010 Jun 28).
14. HCJ 2458/01, HCJ 2458/01 New Family v. The Approvals Committee for Surrogacy Agreements P.D. 54(1) 409.
15. Ministry of Health, Israel. *Insler Committee Report. Report of the public-professional committee on the right to enter a surrogacy agreement*. Jerusalem; 2004. (Hebrew)
16. Steinberg A. A law proposal in Israel regarding the patient at the end of life - the Steinberg Committee. In: Hurwitz PJ, Picard J, Steinberg A, editors. *Jewish ethics and the care of end-of-life patients.* New-Jersey Ktav Publishing House; 2006: 99-104.
17. Penal Law, 1977, section 315.
18. Patient Rights Law, 1996.
19. Dying Patient Law, 2005.
20. Edelstein Y. Can statutory ethics committees in Israeli hospitals fulfill their designated objectives? *Journal of Health Law and Bioethics*. 2010. 3: 77-124.
21. Belkin L. *First, do no harm*. New York: Fawcett Crest; 1993.
22. Shalev C. End-of-Life Care in Israel - The Dying Patient Law, 2005. *Israel Law Review*.2009;. 42(2): 279-305
23. Surrogate Mother Agreements (approval of the agreement and status of the child) Law, 1996.
24. Organ Transplantation Law, 2008.
25. Eggs Donation Law, 2010.
26. MoH Director-General Circular 21/05, Sex selection through pre-implantation genetic diagnosis (PIGD), 9 May 2005.
27. Schicktanz S, Raz A, Shalev C. The cultural context of end-of-life ethics: a comparison of Germany and Israel. *Camb Q Healthc Ethics*. 2010. 19: 381-94.
28. Goldschmidt R. Sex selection. A background paper for the Knesset Science and Technology Committee, Knesset Center for Research and Information. 2010 May 25. (Hebrew).
29. Amir D, Biniamin O. Abortion approval as a ritual of symbolic control. In: Feinman C, editor. *The criminalization of a woman's body*. NY: Harrington Park Press; 1992: 5-16.
30. Israel Ministry of Health. Surrogacy Approvals Committee Guidelines. General Information for Appealing to the Surrogacy Approvals Committee, Appendix A
31. Franklin S, Roberts C. *Born and made - an ethnography of preimplantation genetic diagnosis* Oxfordshire. Princeton University Press; 2006.
32. Hashiloni-Dolev Y, Hirsh-Yechezkel G, Boyko V, Wainstock T, 1 Schiff E, Lerner-Geva L. Attitudes towards sex selection: a survey among potential users in Israel. *Prenatal Diagnosis* 2010 Nov;30 (11):1019-25.
33. Abbott A. *The system of professions: an essay on the division of expert labor.* Chicago: University of Chicago Press; 1988.
34. Davis N. *From crime to choice: the transformation of abortion in America.* Westport, Connecticut: Greenwood Press; 1985.
35. Petersen K. Abortion: medicalisation and legal gatekeeping. *Journal of Law and Medicine*. 2000; 7: 267.
36. Foucault M. *The history of sexuality. Vol 1: An introduction*. NY: Pantheon, 1978
37. Foucault M. Governmentality. In: Burchell G, Gordon C, Miller P, editors. *The Foucault effect: studies in governmentality*. Chicago: The University of Chicago Press; 1991: 87-104.

Endnotes

1. *The essence of the statutory function of these ethics committees is to permit exceptions from the general rules of patient rights at the request of a doctor. These exceptions pertain to the administration of non-consensual medical treatment, or the non-disclosure of personal medical information. (20)*

2. *The commentary to the bill of the Dying Patient Law explained that the duplication of ethics committees was because the patient rights committees had not been established in all the hospitals and even where they were operating, they did not answer the special needs of dying patients and their families. H.H. (Government) 5765, p. 454 (13 December 2005).*