

Assisted Human Reproduction: Lessons of the Canadian Experience

Ruth Landau

Introduction

The Canadian Assisted Human Reproduction Act, passed by the Canadian government on March 29, 2004 and effective from April 22, 2004, was passed after a long process of regulation of the complex field of assisted human reproduction (AHR).

While the field of AHR is controversial in all societies, it is certainly a sensitive issue in multicultural societies, such as Canada, the US and Israel, which absorb immigrants from a wide variety of countries. The governments of these three developed democratic societies have followed different paths in coping with the challenges of the new reproductive technologies and the choices that reflect the prevailing cultural approaches of their particular societies.

The US, with a population of over 300 million, has no federal legislation concerning AHR, reflecting the libertarian philosophy that contends that all individuals should be free to do whatever they wish so long as they respect the liberty of others. Thus, it is left to the market forces to determine whom and how some gain access to these new technologies. Despite the overall libertarian approach, one finds two federal regulations, both focusing on data collection regarding the use of the new technologies. The Fertility Clinic Success Rate and Certification Act (passed by the federal government in 1992) requires clinic-specific reporting of *in vitro* fertilization (IVF) cycles and outcomes. A 2003 ruling of the Food and Drug Administration requires all "manufacturers" of human cells, tissues and cellular and tissue-based products to register with the federal government and to provide a list of products "manufactured." While these two regulations do not cover all types of AHR, they reflect the importance the US attaches to these particular issues: the success rate of IVF by clinics and oversight over the controversial stem cell research.

Israel, a state with about 7 million residents and the world's highest *per capita* rate of *in vitro* fertilization, also lacks comprehensive legislation in the area of

AHR. Although the ministers of Health and Justice appointed a Public Professional Committee in June 1991 (Public Professional Committee Report to Examine the Issue of *In Vitro* Fertilization, 1994), which is to address matters of assisted conception treatment in Israel, most of the Committee's recommendations were not implemented. Nevertheless, the Committee's work, guided by the principle of the autonomy or freedom of the individual, congruent with the American approach, determined that there should be no interference with or limitations imposed on the right of access to assisted conception treatment. In practice, the existing regulations regarding the use of and access to the evolving technologies in human reproduction in Israel are the result of a patchwork, developed primarily as a reaction to pressure groups appealing to the Supreme Court or directly to the Ministry of Health.

The first country to introduce comprehensive legislation in the area of assisted human reproduction was the United Kingdom. Here, following the recommendations of the Warnock Committee, established as early as 1982, the UK government enacted the Human Fertilisation and Embryology Act in 1990.

Canada's AHR Act, which is to be fully implemented by 2008, was greatly influenced by the UK legislation (and, to a minor degree by Australia). According to social worker and fertility counselor Jean Haase, "the evolution of legislation in Canada has been slow and protracted, affected by political change and a lengthy consultation process between the different levels of government and stakeholder groups." As early as 1989 Canada established a Royal Commission on New Reproductive and Genetic Technologies in order to assess the impact of reproductive technology on society as a whole as well as its possible effects on specific groups such as women, children and the disabled. It is estimated that the Royal Commission's work cost CAN \$ 28,000,000, and its final report, from 1993, entitled *Proceed with Care*, laid down the basic tenets for the AHR Act in 2004. The Royal Commission consulted

over 40,000 groups and individuals, affecting subsequent debate in the Parliament and leading to the final approval of several of its early recommendations, such as the prohibition of commercialization of gamete and embryo donation and surrogacy.

Surprisingly, one finds a paucity of literature concerning important ethical issues raised by Canada's AHR Act. The present article remedies this shortcoming. I also introduce three crucial topics of concern in the field. Specifically, one must consider ethical questions that arise in the development of regulations. For instance, a single paragraph in the Act that addresses mandatory counseling services raises numerous questions. Further, because the Act prohibits the purchase of gametes and reimbursing surrogates, one must scrutinize the impact of the new legislation on recruitment of gamete donors and surrogates in Canada. Finally, the access and availability of assisted human reproduction technologies for Canadians is a crucial issue is not covered by the Act.

Considering that the AHR Act is the second comprehensive piece of legislation in the area of human reproduction in the world, the analysis of the Act is not only generally significant, but also is particularly relevant for countries themselves contemplating legislation in this area.

Canadian Assisted Human Reproduction (AHR) Act—Ethical framework

The AHR Act, enacted by the Canadian Parliament and given Royal Assent on March 29, 2004, is seventy-five paragraphs in length and divided into several sections. Briefly, the first section is a declaration of principles governing the Act; specifically, the ethical structure reflects the goal of the legislators to protect the health and safety of Canadians. The tone of the Act is both Rawlsian in giving highest priority to the protection of the health and well-being of the most vulnerable individuals affected by AHR technologies. This most vulnerable group are the children born as a result of these technologies and women, who, more than men, are directly and significantly affected by the application of the technologies. The Act also applies a Kantian approach in emphasizing the autonomy of the individuals involved in the use of human reproductive technologies. The dignity of the individual must be secured and preserved by, for instance, securing free and informed consent, and by providing equal access to assisted reproduction procedures regardless of sexual orientation or marital status.

The succeeding sections of the Act detail prohibited and controlled activities. For example, following the Kantian view that individuals are not means but ends in themselves, the Act explicitly prohibits the commercialization of the reproductive capabilities of

women and men. For the same reasons, the Act also prohibits human cloning, creating an embryo for non-reproductive research, sex selection for social purposes, commercial surrogacy, selling and purchasing gametes or embryos, germ-line alteration, and the creation of a chimera or hybrid. Another expression of the Kantian view of personal dignity in the Act, which also reflects the human rights approach, can be found in the separate and very detailed section on issues of privacy and access to information regarding those involved in AHR procedures.

Assisted Human Reproduction Agency of Canada. The Act also outlines the establishment and role of the Assisted Human Reproduction Agency of Canada (AHRAC) that is responsible for, among other tasks, licensing those performing such activities as *in vitro* fertilization, and for oversight of research involving human embryos, and for the inspection of clinics and research laboratories, collection and analysis of information from health reports and providing advice to the Minister on AHR related issues

Finally, the Act also stresses the power and authority of Canada's two Houses of Parliament in regulating each of thirty areas. Among other powers, within three years after the establishment of the AHRAC, it will undergo review by the Canadian parliament, reflecting the caution to "[proceed] with care" concerning AHR.

The Assisted Human Reproduction Implementation Office. Created for a limited period, the Assisted Human Reproduction Implementation Office (AHRIO) is to conduct policy research and consultations with a broad range of individuals and groups—such as the infertile community, persons born through AHR procedures, health care professionals in the field of infertility treatment and prevention—in order to create a regulatory framework and draft and promulgate regulations as specified in the AHR Act. Notably, this agency must request comments from the public on a paper on pre-implantation genetic diagnosis (PGD), and publish reports concerning counseling services, licensing matters, and workshops with patients or clients of AHR.

The Ethics of Mandatory Counseling

While mandated to address some of the ethical concerns raised by the Act, the Assisted Human Reproduction Agency of Canada and the Assisted Human Reproduction Implementation Office cannot resolve all ethical concerns. Professionals in the field now realize that the complex issues involved in the Act require further attention to details they did not address and perhaps did not even consider before the Act was enacted. Among the many issues to be discussed are how to implement the legislators' intention to enable

informed decision-making for users of AHR technologies by mandatory counseling services.

According to the Act (paragraph 14(2)(b),

Before accepting a donation of human reproductive material or of an *in vitro* embryo from a person or accepting health reporting information respecting a person, a licensee shall, to the extent required by the regulations, make counseling services available to the person and ensure that the person receives them.

Many questions need to be answered in order to develop the regulations in this particular area, since according to the work of the AHRIQ, professionals involved in fertility counseling were not clear what by is meant that services be "made available." The understanding of Health Canada was that licensees (the clinics) will be required to ensure that counseling services are both available to patients and received by them, but that the Act does not require that licensees themselves provide the services.

It is also unclear what is to be understood by the requirement that counseling be available "to the extent required by the regulations." Health Canada explained that receiving counseling prior to donating human reproductive material or *in vitro* embryo or providing health reporting information is mandatory, but that the regulations can provide further details on who provides the counseling and when and how. Although, according to the Report, the issue of counseling as assessment (gatekeeping) was debated, Health Canada stressed that this is not the intent of the Act.

Additional issues that have been raised also require debate: Should there be a list of issues discussed in counseling? Who should provide the mandated AHR counseling services? How should AHR counseling be provided? When and how often should AHR counseling be provided? How should AHR counseling regulations be enforced? Persons using AHR procedures involving third party donated gametes require more and a different type of counseling from those using their own gametes; a counselor should also require the licensee to complete a form stating that counseling was provided as required by the AHR Act. What types of counseling are to be offered (individual, couple, group; face to face, via telephone)? Important also are the issues to be covered in counseling, proof of documentation that counseling has occurred and that counselors are accredited. Informed decision-making requires good counseling, which includes a consideration of the significant non-medical implications, including mental health.

Of course, while some deem fertility counseling crucial, others object that mandatory counseling is coercive. Still others are concerned that, due to the shortage of fertility counselors in Canada, counseling may not be available to all who need it. Counseling itself may prove very varied: counseling provided by clinic employees might include differing information

and approach from that provided by independent practitioners; the problem of regional variation must be also considered as well as the financial costs to the patients and the clinics stemming from these decisions, and the need for developing educational and training opportunities for counselors in the field.

All these issues and probably others will be discussed during the public consultations that will lead to a revised draft of the regulations for paragraph 14(b)(2). Only then will the draft be submitted to the both Houses of Parliament for further debate. And these questions arise in just one paragraph of Canada's assisted human reproduction act.

By way of contrast, no mandatory counseling exists in the US. However, the issues of infertility and fertility have received the attention of the Mental Health Professional Group, affiliated with the American Society for Reproductive Medicine (2006). This group developed guidelines on infertility counseling as early as 1995. Since that time it has actively expanded knowledge in this area; however, the services offered by members of the group are accessible only to interested patients willing to pay for those services.

The Israeli Public Professional Committee Report to Examine the Issue of IVF (1994) recommended that women applying for fertility treatments be informed of the health risks and granted counseling services and professional support. To this end, the Committee recommended that every fertility treatment unit have an appropriately trained professional—a social worker or psychologist—to provide the women with further explanations of the information they received from the treating physician or to help them cope with the various difficulties arising in the course of treatment. However, this recommendation was never implemented.

Recruitment of Donor Gametes and Surrogate Mothers

Recruitment of donor gametes and surrogate mothers also raises questions for the new Canadian legislation. For many infertile individuals and couples the only way to become parents is the use of the sperm and also perhaps the egg of other persons and surrogate mothers. Different countries have different approaches to the recruitment of gametes and surrogates. In the US, for instance, the purchase of gametes is allowed and advertised, the gamete "donors" and surrogates are well paid, with the transactions managed by the private sector.

In contrast, Canada has consistently rejected the idea of payment for donations of organ, body tissue and blood, and the federal government has opposed commercialization of gamete and embryo donation and surrogacy. The AHR Act explicitly prohibits the purchase and advertisements of gametes, embryos and

surrogacy. While some reimbursements of expenditures in the course of donating sperm or eggs to donors may eventually be acknowledged in the regulations, in principle, by law, sperm (and egg) donation in Canada is expected to be altruistic. Further, the criteria for recruitment, screening and testing of sperm donors is the most stringent in the world, with less than 8% of the prospective donors accepted, as against about 65% in France and about 25% in the UK. Although Canadian legislators apparently expect altruistic donation of gametes, some researchers have argued that it is inherently difficult to build an altruistic system of gamete donation into a profit-making, competitive environment.

In addition, unlike blood donation that helps save lives, gamete donation aims at creating lives using the genetic material of the donating persons. But some individuals feel uncomfortable contributing to the creation of a human life without being involved in its upbringing. Others, however, may feel they are giving a significant gift to those who depend on their donation to experience the joy of parenthood. Still, since gamete donation or surrogacy are probably not perceived as normative acts, unwillingness to donate gametes might lead to a serious shortage in the supply and availability of donor gametes.

The geographical proximity of Canada to the US inevitably raises the possibility of Canadians becoming involved in "reproductive tourism." Since the Act does not specifically prohibit the importation of donor gametes, Canadians may be dependent on gamete

The geographical proximity of Canada to the US inevitably raises the possibility of Canadians becoming involved in "reproductive tourism."

donors and surrogate mothers of non-Canadian origin. Considering the different rules and policies of private agencies involved in recruiting gamete "donors" and surrogates in the US, reliance on that country may have long-term health and other implications for both the parents and the offspring resulting from these assisted conceptions.

Related concerns arise with such issues as donor screening, donor anonymity, and the number of children to be allowed to be born as a result of one sperm donor's donations. For example, when I asked a representative of a US-based sperm bank in the exhibition hall at the Canadian Fertility and Andrology Society in Ottawa in November 2006 what the limit is for the use of one donor's sperm, the answer was 40 living children. Another example of the American fertility industry may be a description of one woman's experience who "donated" eggs for US\$ 10,000. In an article titled

"Ova for Sale," the "donor," an associate editor of a respected magazine, claims that although she supports a fully open market, she finds something degrading about being lauded as a humanitarian and at the same time paid handsomely on the side.

Dating from 1994, Israel has permitted payments to both donors of eggs and sperm, not for the gametes themselves but for time, inconvenience, suffering, etc. A new bill, proposed in March 2001, added the requirement to offer insurance for any harm incurred as a result of egg donation, as well as tax exemptions for three rounds of egg donations. The bill has still not been passed, even though the Israeli Surrogacy Arrangement Act (1996), the first law of its kind in the world, was enacted in Israel in 1996 as a consequence of a legal battle. This act approved monthly payments to the surrogate mother to cover her actual expenses arising from the agreement, including expenses for legal advice and insurance fees, as well as compensation for time, loss of income, temporary inability to work, or any other reasonable ground for compensation. Considering that the current cost in Israel for surrogacy is at least US\$ 30,000, one may question whether such an amount can be viewed as reimbursement of expenses only, and whether it enables equal access to surrogacy to all Israelis.

Access and Availability of Human Reproduction Technologies

The prospect of ensuring equal access to reproductive services in Canada has also raised ethical concerns. Although the Act affirms that AHR treatments are not to be used in a manner or for purposes inconsistent with human dignity and equality, the Act does not prohibit access screening that is based directly or indirectly on social, racial, cultural or economic criteria to determine who will be able to reproduce. She feels that equal access can and should be guaranteed by federal regulations imposing strict conditions on clinic licenses and requiring that access decisions be based on legal criteria only.

Also, despite its comprehensiveness, the Act does not address the issue of funding AHR procedures in Canada. In Canada, a federation of ten provinces and three territories, the federal government is responsible for setting and administering the federal principles and standards for the health care system, and the provinces and the territories are responsible for managing and delivering health services to their residents. Yet because of their budgetary shortfalls, most of the provinces and territories have eliminated funding for assisted conception procedures. Only Ontario, with about one-third of Canada's population, has continued to fund some IVF treatments, but only for women with both Fallopian tubes blocked or absent.

Thus, in the absence of federal funding for IVF, the most effective assisted human reproduction technology is inaccessible and unavailable for most infertile couples in Canada. Since most AHR procedures are provided by the private sector, couples who cannot afford IVF turn to alternatives that are less expensive but also less effective, such as ovarian stimulation with injectable hormones, often followed by intra-uterine insemination. Financial difficulties resulted in fewer than 8,500 IVF cycles performed each year in Canada, resulting in approximately 2,000 live births.

The Canadian rate of IVF treatment cycles is probably the lowest among Western countries: in 2002 there were 283 IVF cycles per million residents, compared to 357 in the US, 580 in the UK, and 2,863 in Israel (for the year 2000). Israel's IVF cycle rate is 3.3 times higher than that of Western European countries and eight times that of the United States.

The relatively low rate of IVF cycles in the US reflects its health care system, relying on the financial ability of citizens to purchase direct health services or to have insurance coverage for these expensive treatments. In contrast to the US, while Israel also lacks

Canadians, attaching importance to democratic values, will still have to address the issues of access to and availability of IVF.

comprehensive legislation on AHR, the Israeli Health Insurance Law (Health Insurance Law, 1994) requires the health maintenance organizations (HMOs) to finance various fertility treatments, including IVF, up to the birth of two live children. Since there is no absolute limit to the number of fertility treatments to which a woman in Israel is entitled, theoretically she can start fertility treatment at any age and have six treatments a year until she reaches 51, all at public expense.

The comparison of the AHR policies in Canada, the US and Israel reveals that in both Canada and the US citizens lack equal access to AHR technologies. While Canada has nationalized health care and a comprehensive legislation on AHR, it does not fund IVF procedures. The "laissez faire" approach of the US, with no health care coverage for a considerable part of its citizens and little regulation, makes AHR inaccessible for many Americans. In contrast, while Israel does not yet have a comprehensive legislation on AHR, its national healthcare system provides public funds for assisted conception treatments, including IVF. However, providing almost unlimited funds for AHR without an appropriate and comprehensive legislation and public consultation may conflict with other health

care needs of the Israelis. The example of the cost of surrogacy in Israel also points to limits in the funding of AHR technologies even in a country that invests heavily in it.

Such challenges in access to IVF in Canada has apparently adverse and long-term effects. Studies have shown that the 25% increase in multiple births due to the use of ovulation-stimulating drugs in Canada in the last decade results from the lack of availability of IVF. Further, the well-documented risks and costs of multiple pregnancies and births could be significantly reduced were the federal government in Canada to fund at least one cycle of IVF. A one-cycle policy would also eliminate the need for aggressive treatments to induce ovulation, encourage patients to seek treatments at a younger age when success rates are higher and patients are more frequently able to undergo single rather than multiple embryo transfers. Currently, the 26.9% IVF twin rate worldwide is high. In theory, the risks of multiple births due to IVF may be reduced worldwide if the protocol of single embryo transfer is accepted as a norm.

Some experts have argued that if one IVF cycle were available to all infertile patients, a culture of altruism would develop in Canada, leading to altruistic donations of eggs and embryos. However, experience in Israel does not support this contention. Thus it seems that Canadians, attaching importance to democratic values, will still have to address the issues of access to and availability of IVF.

Conclusion

Examination into the principles of the Canadian Assisted Human Reproduction Act and comparison to the approaches of two other democratic, developed, and multicultural societies—the US and Israel—yields several valuable insights. The basic guiding values and the specific measures of the comprehensive Canadian Act are significant and laudable. True, there is still a great deal of work to be done, some at the federal level and some at the provincial and territorial level. However, this comprehensive piece of legislation reflects well the basic intentions of the legislators and therefore the will of Canadians as a whole. Surely the Act will serve as a basis for further considerations and amendments.

While presumably all three countries compared here wish to promote the autonomy and well-being of their citizens, this analysis reveals the existence of many interpretations and ways to achieve these goals. Because Canada has made clear that the dignity, safety and health of all its citizens are paramount in the legislation concerning AHR, Canada has set a fine example for all countries who hope to confront the challenging field of assisted human reproduction.

Ruth Landau
Senior Lecturer
Paul Baerwald School of Social Work and Social
Welfare
The Hebrew University of Jerusalem, Israel
mslanda@mscc.huji.ac.il

Sources: G.D. Adamson, J. de Mouzon, P. Lancaster, K.G. Nygren E. Sullivan, F. Zegers-Hochschild, *Fertility and Sterility*, vol. 85, no. 6 (2006); American Society for Reproductive Medicine (2006). <http://www.asrm.org/Professionals/PG-SIGAffiliated/Soc/MHPG/index.html> (retrieved December 15, 2006); A.N. Andersen, L. Gianaroli, and K.G. Nygren, K.G., *Assisted Reproductive Technology in Europe*, 2000 (2004). Results generated from European registers by ESHRE, *Human Reproduction*, vol. 19 no. 3; H. Bissessar, "Altruism by Law," *The Canadian Journal of Infertility Awareness* (2005); E. Blyth, "The United Kingdom: Evolution of a Statutory Regulatory Approach," in *Third Party Assisted Conception Across Cultures: Social, Legal and Ethical Perspectives*, edited by E. Blyth and R. Landau, (London and New York: Jessica Kingsley Publishers.) Also in the same volume, E. Blyth and J. Benward, "The United States of America: Regulation, Technology and the Marketplace." L. Bernier and D. Gregoire, "Reproductive and Therapeutic Cloning, Germline Therapy, and Purchase of Gametes and Embryos: Comments on Canadian Legislation Governing Reproduction Technologies," *Journal of Medical Ethics*, vol. 30, no. 6 (2004); Canadian Assisted Human Reproduction Act (2004). <http://laws.justice.gc.ca/en/A-13.4/text.html>. M. Dickens, "Legal Implications of the New Act and Regulations," Lecture at Symposium II of the 52nd Annual Meeting of the Canadian Fertility and Andrology Society, Ottawa, November 17, 2006; J. Haase, "Canada: The long Road to Regulation," In E. Blyth and R. Landau volume; J. Haase, "The Assisted Human Reproduction Act: Implications for the Provision of Counseling," Lecture at Symposium II of the 52nd Annual Meeting of the Canadian Fertility and Andrology Society, Ottawa, November 17, 2006; B. Hanck, "How Canada Plans to Secure IVF Funding, Creating Families" *Canadian Journal of Reproductive Health*. (2006); *Assisted Human Reproduction Agency of Canada*, <http://www.hc-sc.gc.ca/hl-vs/reprod/agency/index/e.html> (retrieved in

August and December 2006); *Assisted Human Reproduction Counseling Services: Workshop Report*, April 28, 2006, <http://www.hc-sc.gc.ca/hl-vs/reprod/index/e.html>. (retrieved in November 2006); *Meeting Report: Workshop with Patients/Clients*, April 7-10, <http://www.hc-sc.gc.ca/hl-vs/reprod/index/e.html>. (retrieved in December 2006); L. Hinman, *Ethics, a Pluralistic Approach to Moral Theory*, 3rd edition (Wadsworth, 2002); K. Howley, "Ova for Sale: The Art of the Deal in the Gray Market for Human Eggs," *Donor #15, Reason, Free Minds and Markets* 38 (5), (2006); R. Landau, *Assisted Conception Policy in Israel*, Paul Baerwald School of Social Work and Social Welfare, Hebrew University of Jerusalem, The Social Policy Research Group (2005); A. Lippman and J. Nisker, "Health Canada Delay Endangers Women," *Canadian Centre for Policy Alternatives. Monitor Issue* (2006); F. Manseau, Personal Communication, Ottawa, November 17, 2006; National Health Insurance Law (1994), *Book of Laws* 1469, 156 [Hebrew]; Assisted Human Reproduction (Section 8) Regulations (2005); *Canada Gazette*, vol. 139, no. 39 (September 24, 2005) National Center for Chronic Disease Prevention and Health Prevention. (2003); *Assisted Reproductive Technology Success Rates*. <http://www.cdc.gov/reproductivehealth/ART01/section1.htm>; National Health Insurance Law-1994, *Book of Law* 1467, 156; J. Nisker, "Ethical Issues in Assisted Reproduction," Lecture at Symposium II of the 52nd Annual Meeting of the Canadian Fertility and Andrology Society, Ottawa, November 17, 2006; *Public Professional Committee Report to Examine the Issue of In Vitro Fertilization* (Jerusalem: The Ministry of Justice, 1994); *Public-Professional Committee for the Examination of Egg Donations* (Jerusalem: The Ministry of Justice, 2001); C. Rasmussen, "Canada's Canadian Assisted Human Reproduction Act: Is It Scientific Censorship, or a Reasoned Approach to the Regulation of Rapidly Emerging Reproductive Technologies?," *Sask Law Rev*, 67 (2004) ; J. Rawls, *A Theory of Justice* (Cambridge, Mass: Harvard UP, 1971); Stanford Encyclopedia of Philosophy (2006), <http://plato.stanford.edu/entries/libertarianism>; Surrogacy Law—1996, *Book of Law*; L. Vandervort, "Reproductive Choice: Screening Policy and Access to the Means of Reproduction," *Human Rights Quarterly*, vol. 28, no. 2 (2006).