Building Momentum

AHRC Moving Forward

ASSISTED HUMAN REPRODUCTION CANADA

2008-2009

Annual Report

Canada

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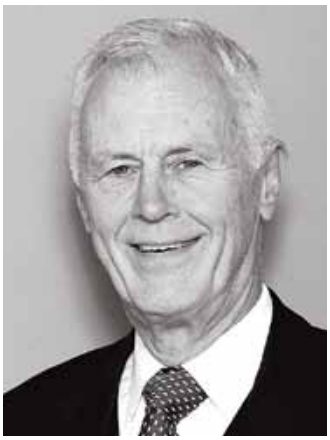


Dr. John Hamm
Chairperson, Board of Directors, AHRC

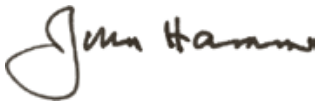
Message from the Chair

A review of the numerous initiatives launched by Assisted Human Reproduction Canada (AHRC) this past year reinforces both the value and necessity of a federal agency to oversee the safe and ethical use of assisted reproductive technologies and research. The many progressive steps taken over the previous 12 months are vital to protecting and promoting the health, safety, dignity and rights of Canadians who use or are born of assisted human reproduction technologies.

This retrospective of the Agency's accomplishments also underscores the crucial role played by the Board of Directors. I am grateful to my colleagues for their expertise, wisdom and dedication. Whatever the topic under discussion, Board Members consistently bring compassion, common sense and a deep commitment to working together in a fair, consistent and effective manner that builds understanding and consensus.

Since the Agency's formation, the Board has benefited tremendously from the contributions of past Vice-Chair, Roger Bilodeau. Mr. Bilodeau has resigned to take on another important public service role as Registrar for the Supreme Court of Canada. This position has been capably filled by Board member, Dr. Albert Chudley. He is the Medical Director of the Genetics and Metabolism Program with the Winnipeg Regional Health Authority and a professor in the Department of Paediatrics and Child Health and Department of Biochemistry and Medical Genetics at the University of Manitoba.

Of course, AHRC's ambitious agenda cannot be accomplished without the input and support of the many individuals and groups that work with us to ensure reproductive technologies are used in a manner that promotes the health and safety of Canadians. On behalf of the Board, I extend my thanks to all the committed Canadians and international colleagues who gave of their time, ideas and energy to help us achieve this shared goal.



Message from the President

Dr. Elinor Wilson
President, AHRC

Rarely a week passes without a reminder of just how important the work of Assisted Human Reproduction Canada is to Canadians. With increasing frequency, there are calls from all corners of the country for a better understanding of and access to assisted human reproductive technologies that enable numerous Canadians to build the families they so greatly desire.

I am proud to report that the Agency is growing in both size and expertise to respond to this need. AHRC has attracted skilled and experienced regulators, scientists, legal experts, policy analysts, communicators and administrators. These team members are cooperating closely with our stakeholders in the field of AHR and keeping Canadians informed of our activities through consultations and public outreach tools such as our website and newsletters. Active public engagement is essential to ensure AHRC considers and reflects the diverse needs of interested Canadians.

As we prepare to carry out our full regulatory role, we continue to enter into collaborative agreements with partners such as the Canadian Institutes of Health Research and Accreditation Canada. These arrangements are helping to establish AHRC's presence and credibility in Canada and internationally.

AHRC's global impact has already been felt, when it hosted the successful First Invitational International Forum on Cross-Border Reproductive Care: Quality and Safety. An international steering committee organized this groundbreaking working meeting in early 2009. It provided an opportunity to share best practices and build agreement among countries and organizations on the principles underpinning safe, quality care when cross-border assisted human reproduction occurs.

Whether working in partnership domestically or internationally, AHRC is committed to upholding the dignity and rights of AHR users and donor-conceived people. Based on our track record to date, I have every confidence we will succeed.

About the Agency

Assisted Human Reproduction Canada (AHRC) fulfills the 1993 recommendation by the Royal Commission on New Reproductive Technologies to establish a regulatory body to oversee permissible assisted human reproduction activities.

With the passage by Parliament of the *Assisted Human Reproduction Act* (AHR Act) in March 2004, the wheels were set in motion for the work being carried out by the Agency today. AHRC was created in 2006 to administer a comprehensive legislative and regulatory framework for assisted human reproduction consistent with the ethical principles established under the legislation. It began operations in early 2007.

AHRC is part of the federal Health Portfolio, reporting to Parliament through the Minister of Health. The Agency is headed by a President who handles day-to-day operations and governed by a Board of Directors which is responsible for its overall management. The Government of Canada may appoint up to 13 Board members with backgrounds and disciplines relevant to the Agency's objectives. The 10 current members include doctors, scientists, academics, health professionals, ethicists and a patient who bring a broad range of experiences and perspectives. They are required to meet at least twice a year.

Mandate

The Assisted Human Reproduction Agency of Canada protects and promotes the health, safety, dignity and rights of Canadians and fosters the application of ethical principles in relation to assisted human reproduction and other matters to which the *Assisted Human Reproduction Act* applies. AHRC is also a centre of expertise and a focal point of AHR information for policy makers, health professionals and Canadians.

AHRC is delivering on its responsibility to raise awareness and understanding of AHR-related matters through its public education and outreach efforts. It also has the authority to inspect AHR clinics and research laboratories across the country for compliance with the Act. For example, Section 8 of the Act and related regulations, which impose prohibitions on the use of sperm or eggs or *in vitro* embryos without a donor's "consent to use", is already in force and compliance measures are in place.

As further regulations come into force, one of AHRC's roles will be to administer the licensing framework related to AHR procedures or *in vitro* embryo research. It will also collect, manage and analyze health reporting information of donors and persons undergoing AHR procedures, respecting Canada's privacy legislation as it does so.

Health Canada is responsible for developing policy and regulations relating to assisted human reproduction. Once that work is finalized, Canada will have one of the most advanced legislative and regulatory frameworks in the world regarding reproductive technologies.

As it awaits completion of the remaining regulations, the Agency is working to promote broad understanding of and adherence to the Act. It is also building the databases and other tools to support the implementation of the licensing, inspection and registry framework. This includes developing a research agenda and compliance and enforcement strategy, consulting and communicating with individuals and organizations engaged in AHR issues, and working with the global community to address common challenges in the application of reproductive technologies for safe practice. These activities are profiled in the following pages.

The *Assisted Human Reproduction Act* prohibits activities incompatible with Canadian values and ethical standards such as human cloning, sex selection for non-medical purposes, the purchase of human reproductive material (i.e. eggs and sperm) from donors and payment for surrogacy. It ensures that assisted human reproduction activities and related research involving human embryos take place in a controlled environment. Most important, the Act includes measures to protect and promote the health, safety, dignity and rights of Canadians who use AHR to build their families, and those of the children who are born of these technologies.

Moving forward, producing results: Highlights of our second year

Protecting and promoting the health and safety of Canadians

AHRC has the responsibility and rare opportunity to implement a new regulatory system from the ground up, working in partnership with stakeholders. Agency staff has visited clinics and consulted with support groups and health professionals involved in AHR procedures. This promotes collaboration and transparency while continuing to maintain the necessary arm's length relationship required to remain accountable to Canadians.

Collaborations also help to make sure the system the Agency is implementing will fully meet public needs and expectations without being overly burdensome to service providers. Input from these individuals and organizations has informed the development of guidance documents and administrative policies. It is also providing valuable insight into how best to establish electronic tracking systems for the licensing and inspection of clinics and facilities, as well as the Personal Health Information Registry mandated under the legislation.

One example of successful collaboration involves the Canadian Fertility and Andrology Society (CFAS). The Society directs CARTR, the Canadian Assisted Reproductive Technologies Register. Fertility clinics currently provide data to CARTR on the number and type of AHR treatments they provide to patients and their outcomes.

To avoid duplication and reduce the reporting burden for clinics, AHRC established a working group with CARTR to learn how clinics currently gather and report this information so it can establish a complementary system. It is examining issues of data quality as well as indicators to inform health surveillance related to reproductive technologies. The working group is consulting with stakeholders and will make recommendations on ways to provide high quality information on AHR activities once the regulations are approved.

The *Assisted Human Reproduction Act* requires that the Agency maintain a confidential, privacy protected registry of personal health information about donors, patients and donor-conceived individuals. Once operational, the Registry will give people who undergo assisted human reproduction (AHR) and people conceived through AHR an opportunity to obtain non-identifying health information about a donor of sperm, eggs or *in vitro* embryos. However, the donor's identity may not be disclosed without the donor's written consent.

Access to this information may be vital if people conceived through AHR develop a genetically-inherited disease or other medical condition which requires knowledge of their family history. It may help prevent two individuals with the same donor from inadvertently marrying each other or having children together. Equally valuable, the registry will enable AHRC to issue reports comparing the results of various AHR procedures, which will feed into the development of treatment guidelines and policy decisions.

Collaborative arrangements are at the heart of AHRC's approach to the licensing and inspection framework, as well. The Agency has worked closely with Health Portfolio partners as it develops the tools and databases needed to support its implementation. This has been invaluable in identifying regulatory database models that can be customized to form the core of AHRC's system infrastructure.

AHRC continues to utilize the services of the Health Canada Inspectorate through a Memorandum of Understanding (MOU) to investigate allegations of violation of the AHR Act and regulations. As an example of its compliance promotion activities, AHRC is monitoring Canadian websites which deal with AHR issues to ensure compliance. The purpose of this initiative is to ensure Canadian based websites dealing with AHR subject matter are aware of the Act and regulations, and to address any findings of non-compliance appropriately.

As offences under the AHR Act could result in criminal penalties, the Agency may also engage RCMP and border agents to enforce the legislation. A training session was held with the RCMP and the Canada Border Services Agency to define the necessary processes and day-to-day interactions required to support AHRC's compliance and enforcement activities.

To advance work on its inspection framework, the Agency has been working closely with Accreditation Canada to develop a collaborative inspection/accreditation model. The objective is to reduce the administrative burden on clinics while simultaneously ensuring all necessary steps are taken to operate in accordance with the Act in order to protect public health and safety.

Enhancing our knowledge through collaboration

In a field as complex and fast-changing as assisted human reproduction, sound policy depends on reliable science. This principle has been at the core of AHRC's activities since the Agency's formation. One of its first priorities was to prepare the terrain for a progressive research agenda to ensure it possesses relevant knowledge and varied perspectives on AHR-related issues to successfully implement the regulatory regime.

In our collaborations with two institutes of the Canadian Institutes of Health Research, AHRC has taken a major step forward to achieving this goal. The Agency has entered into research partnerships with the Institute of Gender and Health and the Institute of Human Development, Child and Youth Health, two of 13 members of the Canadian Institutes of Health Research. Working together, the partners will identify and analyze

Dr. Michael Kramer, Scientific Director, Institute of Human Development, Child and Youth Health, Dr. Elinor Wilson, President AHRC, Dr. Joy Johnson, Scientific Director, Institute of Gender and Health

technological, social, economic, governmental and other opportunities and barriers related to the use of reproductive technologies.

The two research institutes along with AHRC have committed to organize workshops, consult the research community and stakeholders to facilitate the advancement of AHR research and develop strategic priorities in the field. A two-day meeting in Montreal in October 2008 drew roughly 70 delegates from across the research spectrum to develop recommendations for a Canadian AHR research agenda. Five main themes emerged as priority areas for discovery, including: Outcomes and Determinants; New Technologies; The Epidemiology of Infertility; Psychosocial Research; and, Health Economics, Policy, Services and Systems.

An important component of this collaboration is funding earmarked to solicit, encourage and enable Canadian AHR research activities. The program will provide a competitive, peer-reviewed funding stream for Canadian generated research involving assisted human reproductive technologies.

Board of Directors activities

In 2008-09, Board members met in person on three occasions. The Board was engaged in issues ranging from providing input into the development of the regulations, to cross-border reproductive care, to the impacts of multiple births on mothers and their children. On several occasions, the Board heard from stakeholder groups, such as Fertile Future. It also received updates on a number of surveys in progress, including the Canadian Community Health Survey and the Pre-Implantation Genetic Diagnosis survey, as well as presentations from organizations such as the European Society for Human Reproduction and Embryology.

Among the many topics discussed and acted on during these sessions perhaps the most important was the development of AHRC's Strategic Plan. The Plan sets future directions for the Agency and lays out a blueprint for the next phase of its work. Undertaking such an exercise is necessary to identify priority opportunities and risks in the Agency's operating environment that may impact its ability to deliver its mandate.

The Board of Directors has identified the following **Strategic Priorities for the Agency**:

- Inspections
- Personal Health Information Management
- Education
- Best Practices and Standards
- Research
- International Collaboration
- Outreach

Ethical considerations are identified as a key cross-cutting issue.

Barbara Slater

Dr. David Novak

Dr. Elinor Wilson, President

Dr. Françoise Baylis

Strategic planning is especially crucial for an organization with a mandate as unique and complex as AHRC's, which is subject to rapidly evolving scientific and technological developments as well as the resulting ethical considerations and societal concerns related to assisted human reproduction.

Board strategic planning will become a regular part of the Agency's integrated planning and reporting cycle. The Plan will feed into the Agency's operational planning, as well as the Agency's annual plans and reports to Parliament.

As important, it ensures a systematic process to ensure good planning and ongoing stewardship of resources. This guidance from the Board is invaluable to the Agency as it carries out its work.


Dr. Albert Chudley, Board Vice Chairperson


Dr. Suzanne Rosell Scorsone


Dr. John Hamm, Board Chairperson


Theresa Kennedy


Dr. Joseph Ayoub


Irene Ryll

Science leaders advance Agency's work

Hiring the Agency's Chief Science Advisor was just the first step in attracting some of this country's – and the world's – top scientists in the field of assisted human reproduction. It was quickly followed by the creation of the Board's new Science Advisory Panel (SAP).

The Panel advises the Board of Directors on current and emerging science issues surrounding reproductive technologies that may impact the Board's responsibilities. Its work focuses specifically on inter-jurisdictional and international collaboration on standards and procedures. The SAP's advice will improve AHRC's ability to identify scientific innovations and assess the implications of their application. Research is crucial to informed, evidence-based decision making and is a high priority for the Agency.

The Science Advisory Panel is chaired by Dr. John Collins, a globally respected and groundbreaking researcher on AHR. He is supported by leaders from the basic and social science fields as well as AHR clinical researchers from leading Canadian and U.S. universities. The SAP includes specialists in endocrinology, embryology, epidemiology, urology, neonatalogy, obstetrics and gynaecology, family medicine and nursing.

Dr. Collins says he and his fellow Panelists are eager to strengthen the work of AHRC. *"The chance to play a role in furthering the objectives of the Agency through our academic studies and clinical research is very rewarding to our Panel members, whatever our professional background or area of expertise. It enables us to advance our collective goal of protecting the health and safety of Canadians."*

Tripartite Committee

Members of the Tripartite Committee – composed of representatives of AHRC, the Canadian Fertility and Andrology Society (CFAS), and the Society of Obstetricians and Gynaecologists of Canada (SOGC) – continued to meet regularly to discuss matters of mutual interest, share information on emerging issues and to report on progress on several joint initiatives. Health Canada has observer status on the Committee.

The first stakeholder committee established by the Agency, the Tripartite Committee is dedicated to protecting and promoting the health, safety and values of Canadian society, families and individuals, especially women using and children born of AHR procedures. The CFAS and SOGC are developing evidence-based clinical guidelines on AHR procedures to improve the health and safety of patients. AHRC is serving as the secretariat for this work.

Apart from its own collaborative efforts, the Tripartite Committee seeks out experts and interested parties to learn about recent developments in the AHR field, both domestically and internationally. For example, Committee members heard presentations from an infectious diseases specialist as well as a community co-ordinator on the development of Pregnancy Planning Guidelines for HIV positive patients. More sophisticated drugs, together with effective management of the disease, are enabling an increasing numbers of HIV- positive patients to have children. While guidelines exist regarding the management of women during their pregnancy, there are currently no such measures for professionals or patients to follow when planning pregnancy among HIV-infected individuals. The Committee was told that a survey of 28 Canadian clinics revealed many HIV-positive patients find it difficult to access fertility treatment.

Another presentation highlighted the promising results of a new tool known as Fertiquol – a joint venture between the American Society for Reproductive Medicine, the European Society for Human Reproduction and Embryology and industry that was launched in November 2008. Fertiquol is an internationally-validated questionnaire designed to help patients and professionals gauge the level of support they require. Access to Fertiquol requires online registration, but the materials are free and available in 10 languages, with several more being planned.

One of the Tripartite Committee's key concerns revolves around AHR-related multiple births. It has assigned Committee members to a Multiple Birth Steering Committee to work with stakeholders to develop and implement a pan-Canadian strategy to prevent AHR multiple births in Canada.

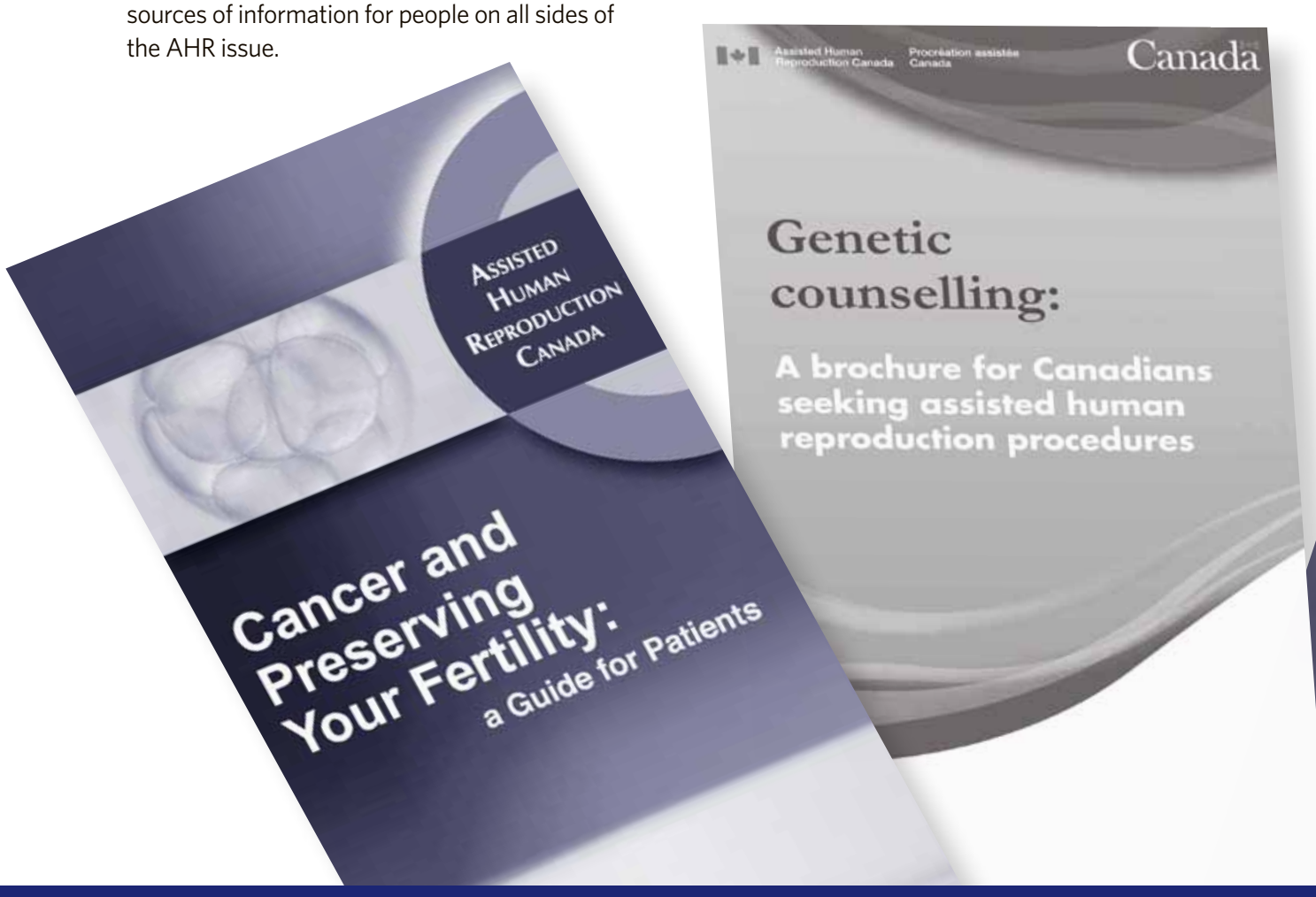
Spreading the word – Keeping Canadians informed of AHR/AHRC news

If there is a single matter that Canadians hoping to build their families through reproductive technologies require, it is a credible and up-to-date source of information about the latest developments in AHR. Meeting this need is part of AHRC's raison d'être; public outreach and education is a key component of the Agency's mandate.

AHRC is committed to being a focal point for assisted human reproduction information. The Agency is continually identifying and developing information products to satisfy various audiences. Its primary vehicle to relay the latest AHR news is the Agency's website (http://ahrc-pac.gc.ca). The site, launched in early September 2008, provides Canadians with information about the Agency's role and responsibilities, along with useful links to other sources of information for people on all sides of the AHR issue.

New information products of interest to policy makers, practitioners, researchers, patients and donor-conceived individuals are posted regularly. The user-friendly, easy-to-navigate site is a powerful communications tool that will enable AHRC to explain its mandate to implement and administer an effective AHR licensing, compliance and health information regime.

Among the other important new public outreach tools is a series of patient brochures that provide basic information on different aspects of assisted human reproduction. The brochures are available both on the website and in hard copy upon request.

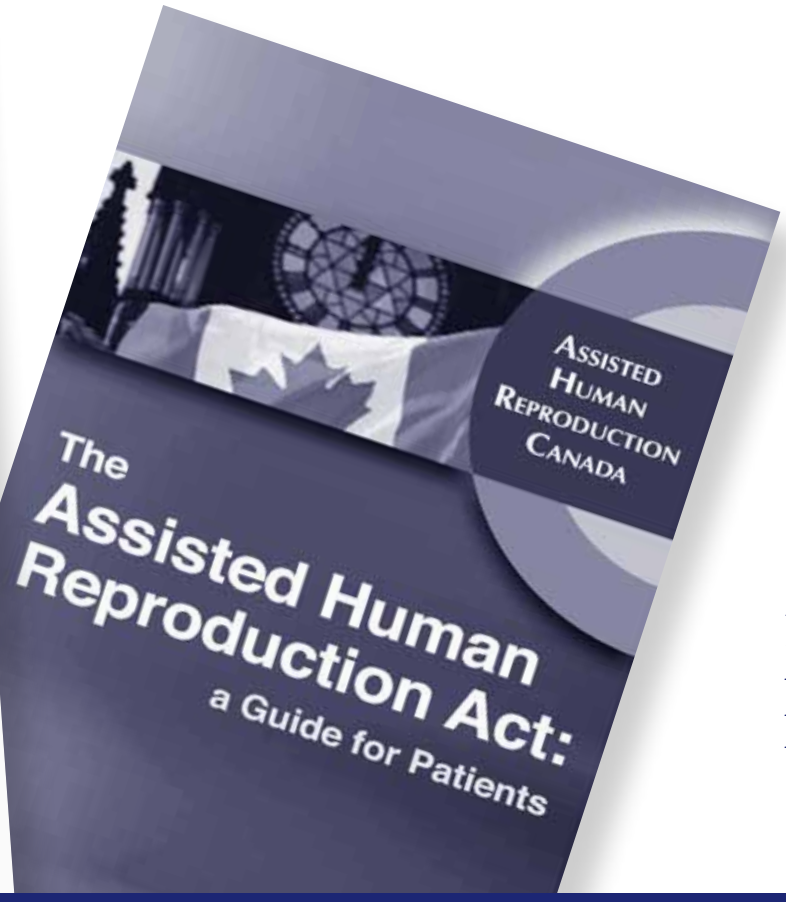


The first in the series is ***The Assisted Human Reproduction Act:* A Guide for Patients**. The brochure briefly describes why the legislation is needed, what the AHR Act covers and the role of AHRC in its administration. The document outlines how the legislation may affect patients in the immediate term, such as the Act's implications for people using sperm or egg donation or surrogate mothers.

The reproductive challenges facing Canadians with cancer is another issue covered in a new AHRC brochure. In 2005, 10,000 Canadians between the ages of 20 and 44 were diagnosed with cancer. Thankfully, the vast majority in this age group survives, however, the illness itself or cancer treatments can adversely affect fertility.

Cancer and Preserving Your Fertility: a Guide for Patients outlines the risks to one's reproductive capabilities associated with specific oncology treatments and discusses both proven and experimental fertility preservation options for individuals with cancer who are facing infertility issues.

An additional pamphlet of great interest to patients focuses on **Genetic counselling for Canadians seeking AHR procedures**. It was developed in partnership with the Canadian Association of Genetic Counsellors. This brochure covers everything from definitions of what genetic counselling means and the role of a genetic counsellor, to a step-by-step guide regarding what to expect during an appointment for genetic counselling.

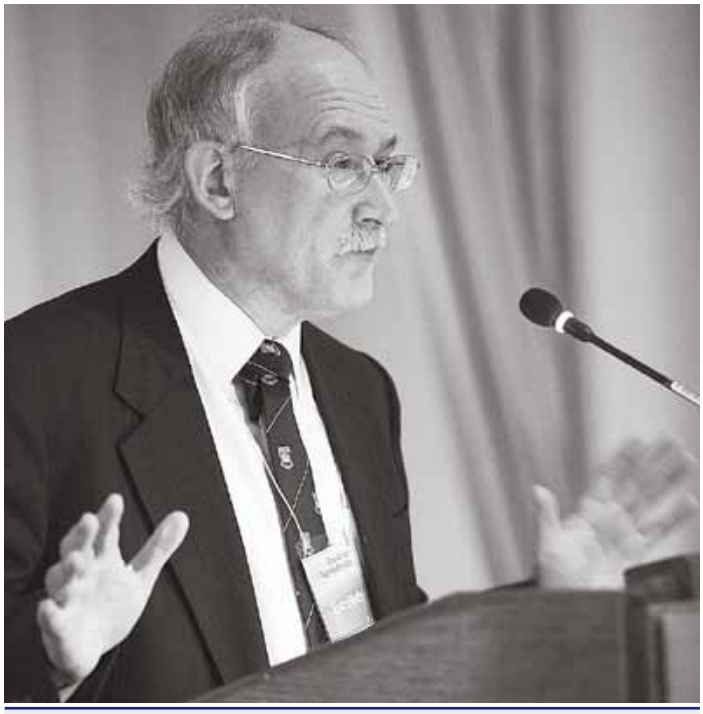


AHRC Editorial Committee

To help ensure the information provided in the brochures and on the website addresses the needs of Canadians, the Agency has established an AHRC Editorial Committee. It is composed of representatives from stakeholder groups with knowledge of AHR issues. Members include a counsellor, patient representatives, a donor-conceived person, embryologist, reproductive endocrinologist and nurse.

Safety across borders: First Invitational International Forum on Cross-Border Reproductive Care

Prospective parents sometimes seek assisted human reproduction procedures out of country. While cross-border reproductive care (CBRC) is an issue with many perspectives, there are concerns about the quality of care and patient safety when it comes to AHR activities across borders.



Dr. Eric Blyth, University of Huddersfield, England

As a result of a marked increase in CBRC activity, an international group of delegates came together for the *First Invitational International Forum on Cross-Border Reproductive Care: Quality and Safety.* AHRC hosted the groundbreaking event, which took place in mid-January 2009 in Ottawa.

The Forum was attended by more than 50 delegates from academic institutions, government bodies and patient and AHR-related organizations in over a dozen countries. Representatives came from as far afield as Germany, Japan, India and Nigeria. Both the World Health Organization and the European Commission sent delegates.

The goal of the International Forum was to exchange experiences and build agreement among countries and organizations on the principles underpinning safe, quality care when cross-border assisted human reproduction occurs. Participants focused on the importance of providing information to help patients make wise and safe choices prior to receiving AHR services abroad and to equip health practitioners in their home countries with the necessary information to provide appropriate follow-up care.

Apart from increasing understanding, the Forum produced a tangible outcome that will assist all countries dealing with CBRC. Prior to the event, the Steering Committee conducted international surveys with patients and physicians to develop "prompters" – reminder tools for patients and clinicians to support information exchange and proactive decision-making in conversations between patients and physicians.

The prompters offer a practical way to protect health and safety by empowering patients who have decided to seek cross-border care and by ensuring practitioners receive the information they need to provide quality care for patients upon their return home and for AHR-conceived children.

The Forum concluded with a joint commitment among participants to continue to work closely together to address shared challenges and capitalize on the power of the new partnerships established at the event.

"It is our job to make sure this deeply felt need for a child does not result in people putting their health at risk...My deep concern is that such people are also removing themselves from the help and protection that responsible regulation provides. We are looking closely at whether there is more we could do to protect and inform those who choose to travel abroad for fertility treatment."

Professor Lisa Jardine, Chair
U.K. Human Fertilisation and Embryology Authority

Our plans for the future

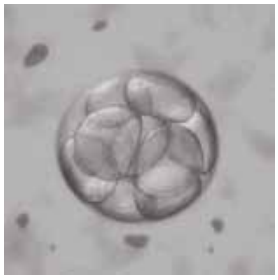
Keeping Canadians informed remains a top priority. In the coming months, the Agency will be enhancing the look and function of AHRC's website, increasing the variety and quality of information available. Beyond its existing content, such as insights into the AHR Act and the Agency's role as the federal regulator, the revamped site will include a greater range of practical information for patients, donors and donor conceived people, providing easy to understand answers to Canadians' questions about assisted human reproduction. The launch of Phase II of the website is anticipated in late 2009/early 2010.

A topic of growing interest and concern is the high level of multiple births in Canada, in great measure due to AHR procedures. While AHR makes parenthood possible for those otherwise unable to conceive, the possibility of multiple births may also pose considerable risks to the infants as well as the mother.

A catalyst in bringing groups together to discuss shared concerns, AHRC, in collaboration with the CFAS and the SOGC, is planning a Multiple Births Roundtable, scheduled for the fall of 2009.

Participants attending the Roundtable, including physicians and embryologists, are expected to examine the risks and identify potential solutions to the challenges associated with multiple births. A future meeting of allied health professions and patient groups on this topic is also in the works.

The increased reliance on assisted human reproduction reflects, in large part, another trend – rising infertility rates. To assess just how prevalent this problem is, AHRC is working with Statistics Canada, developing related questions for an upcoming Canadian Community Health Survey to capture up-to-date baseline data regarding infertility in Canada. Work is also underway to develop a brochure for patients to raise awareness of infertility risks and to identify actions individuals can take to reduce those risks. In addition, new brochures will be published with the Canadian Association of Genetic Counsellors that will assist Canadians facing reproductive challenges.



The natural rate of triplet birth is less than one (0.3) in every 1000 births .

By comparison, using in vitro fertilization:

- in 2002, 25 out of 1000 IVF births were triplets
- in 2004, 16 out of 1000 IVF births were triplets
- in 2006, 12 out of 1000 IVF births were triplets

The number of triplet pregnancies has started to decline in Canada in recent years as fewer embryos are transferred in IVF procedures.

Gunby, J. et al. IVF Directors' Goup, Canadian Fertility and Andrology Society. "Assisted reproductive technologies (ART) in Canada: ... results from the Canadian ART Register". Fertility and Sterility. Various years.

Financial statement

In 2008-2009, Assisted Human Reproduction Canada spent an estimated $5,289,000 of its approved budget of $12,418,000, which included some unspent funding carried over from previous years. The funding allocation for fiscal year 2009-2010 is forecast at $10,533,000.

AHRC continued to set up the Agency during the reporting period, hired staff and put in place the infrastructure necessary to fulfill its mandate. The Agency diligently managed its allocated funding, proceeding with the implementation of its mandate in parallel with the development of the regulations by Health Canada. The unspent portion of its 2008-09 approved funding was returned to the consolidated revenue fund of the Government of Canada.

Significant progress was made during the year on staffing, with a total of 16 full-time equivalent employees put in place of the allocation of 44 full-time equivalents, augmented by consulting resources as required.

Table 1: Financial Summary ($ thousands)

	Approved Funding	Estimated Spending	Forecast Funding
April 1 – March 31	2008-2009	2008-2009	2009-2010
Total AHRC	$12,418	$5,289	$10,533
Full Time Equivalent	44	16	44

Further details on the Financial Statements can be found at:

Departmental Performance Report 2008-2009
http://www.tbs-sct.gc.ca/dpr-rmr/2008-2009/inst/rap/raptb-eng.asp

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