



Planning the Future



ASSISTED
HUMAN
REPRODUCTION
CANADA

2009-2010

Annual Report

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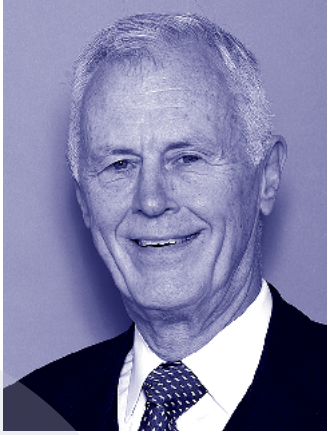
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*Dr. John Hamm
Chair, Board of
Directors, AHRC*

Message from the Chair

Assisted Human Reproduction Canada (AHRC) continues to make steady progress and the Board is pleased to be able to play a role in its ongoing evolution.

In the three years since the Agency formally began its operations, AHRC has reached numerous milestones on multiple fronts. Working in close collaboration with domestic stakeholders and its international counterparts AHRC has made strides in protecting and promoting health, safety, dignity and human rights in the area of assisted human reproduction (AHR) technologies. This past year, progress was achieved in increasing understanding of the risks of infertility and multiple births, and identifying opportunities to address these and other challenges (e.g., oncofertility and cross border reproductive care).

Despite the loss of three members, the Board remains focussed and committed. I want to thank the members of the Board of Directors whose range of perspectives and expertise provide crucial input. I also gratefully acknowledge the work of the Science Advisory Panel. The contributions of these dedicated volunteers are essential to AHRC. They help to keep us informed on both scientific and technological developments related to AHR as well as the human dimension of this work. We know from firsthand accounts from AHR users and children born using these technologies that it's important that these innovations are viewed in a respectful and dignified way.

It is a privilege for me and other members of the Board to be able to contribute to an important problem and health issue that has such a direct and meaningful impact on Canadians. The Board looks forward to a completed mandate and to ongoing progress as we plan for a future of helping affected Canadians build their families as we implement the legislation and its regulations.

A handwritten signature in blue ink that reads "John Hamm". The signature is written in a cursive, flowing style.

Message from the President

The Agency continues its work acting today and planning the future to help ensure the health and safety of Canadians who use assisted human reproduction (AHR) to build their families.

We continue to promote awareness of and monitor compliance with the *Assisted Human Reproduction Act*. We are actively enforcing the regulations under section 8 of the legislation, which deal with consent to use an individual's human reproductive material to create an embryo as well as the use of an *in vitro* embryo for any purpose. While we await the coming into force of further provisions of the regulatory regime, we have been constructing the foundations of a dynamic, accountable and highly professional organization that can deliver effective licensing, compliance and enforcement activities.

We have engaged patients, health professionals and others with an interest in reproductive technologies to better understand their perspectives and expectations in relation to our Agency's legislative and regulatory responsibilities. We have also worked to clarify the requirements of the legislation. As well, we've closely tracked technological advances and trends in assisted human reproduction, and supported valuable research that is furthering our knowledge of how to help people with reproductive challenges to have children. And we've kept Canadians informed of these developments through our various communications products and outreach activities.

Thanks to the efforts of AHRC employees, as well as those who collaborate with us to address issues of shared interest and concern, we are making measurable progress in ensuring Canadians can benefit from safe, and effective, assisted human reproduction procedures. Credit belongs, too, to our close working relationships with regulators and organizations engaged in AHR issues in other jurisdictions with which we exchange our knowledge and best practices. As a result of these activities, AHRC is increasingly viewed as a focal point for information about reproductive technologies and a credible centre of AHR expertise.

In planning the future we renew our collective commitment to promote and protect the health and safety of Canadians who use or are born of assisted human reproduction.



Dr. Elinor Wilson
President, AHRC

A handwritten signature in blue ink that reads "Elinor Wilson".



Executive summary

2009-2010 witnessed measurable progress on multiple fronts as Assisted Human Reproduction Canada (AHRC) advanced its mandate to protect and promote the health, safety, dignity and rights of Canadians in relation to assisted human reproduction.

AHRC continued to implement its compliance program to assess complaints related to alleged contraventions of the *Assisted Human Reproduction Act* and regulations currently in force. The report highlights the tools and outreach activities employed by the Agency to increase awareness of and monitor compliance with the legislation. As part of these measures, the Agency continually monitors websites to verify adherence to the Act's provisions and responds to complaints related to alleged contraventions of the legislation.

The Agency also gained momentum building – and transferring – knowledge necessary to protect public health and safety in relation to reproductive technologies. AHRC supported the development of the 2009 Inventory of Health Surveillance Databases which collects information related to the health outcomes of assisted human reproduction (AHR) procedures. This information assists policy makers and health practitioners in gauging the safety and effectiveness of various AHR options. In addition, the Agency helped to increase understanding of the incidence of infertility among the Canadian population by asking Statistics Canada to include questions related to the issue in its 2009 Canadian Community Health Survey. This is the largest survey sample of its kind in roughly two decades, since the Royal Commission on New Reproductive Technologies.

AHRC put the spotlight on cancer and fertility by sponsoring a symposium on oncofertility in Canada and helped to establish new networks among researchers, medical practitioners and patient advocates to encourage further research in this field. As well, it helped to bring together domestic and international researchers, clinicians and infertility experts at a Scientific Roundtable on the Prevention of Multiple Births Associated with Infertility Treatments to explore the challenges associated with AHR and multiple births. These efforts culminated in the development of a Canadian framework to prevent multiple births associated with infertility treatments. The annual report outlines follow-up steps to this achievement, including the creation of a Multiple Births Patient Committee made up of representatives from numerous stakeholder groups to provide consumer input as well as a Healthy Singleton Committee, composed of AHR and other specialists, which will identify ways to meet the goals agreed upon in the Multiple Births Framework.

Both AHRC's domestic and international activities were carried out collaboratively with its partners in the Tripartite Committee, members of the research community, health providers, patient groups and other governments engaged in these issues. Much of this work was informed by the activities of the Board of Directors' Science Advisory Panel as well as the Agency's in-house policy analysts and research experts. AHRC benefits, as well, from information exchanges with its international counterparts in Europe, Australia, New Zealand and the United States. The report notes several important global AHR initiatives in which AHRC took part.

A regular feature of AHRC annual reports, the 2009-2010 edition outlines key meetings of the Board of Directors and the Tripartite Committee. As well, it profiles some of the promising new research endeavours being monitored by the Science Advisory Panel (SAP).

All of these developments have been shared with Canadians through the Agency's outreach and communications activities. AHRC continued to develop new information products to keep the public apprised of the latest technological innovations as well as some of the issues prospective parents need to be aware of when considering assisted human reproduction. The Agency's newest brochures, reports and other materials of interest have been posted to the AHRC website, which continues to undergo improvements to better serve Canadians.

The financial statement discloses the costs associated with these activities and notes that the Agency returned nearly half of its budget for the fiscal year 2009-2010 to the consolidated revenue fund of the Government of Canada.

Looking forward, the report outlines AHRC's plans and priorities for the coming year. AHRC will continue to facilitate important research in priority areas such as the epidemiology of infertility, to psychosocial research, to an examination of environmental health and reproduction. A planned best practices workshop in this field will explore the impacts of a wide range of chemicals prevalent throughout society on reproductive health.

Enhanced information offerings in 2010-2011 will continue, including the launch of Phase II of AHRC's website to keep Canadians better informed about the agency's activities and AHR generally.

About the Agency

Assisted Human Reproduction Canada (AHRC) responds to the 1993 recommendation by the Royal Commission on New Reproductive Technologies to establish a regulatory body to oversee permissible assisted human reproduction activities. The federal regulatory agency was established in 2006 to protect and promote the health, safety, dignity and rights of Canadians who use or are born of assisted human reproduction technologies. It opened its doors in 2007 and the Agency's mandate and responsibilities are set out in the *Assisted Human Reproduction Act*. These activities are overseen by the Board of Directors of the Agency.

AHRC promotes an environment in which ethical principles are applied in all matters related to assisted human reproduction (AHR), while supporting scientific advances that benefit Canadians. The Agency is also a centre of AHR expertise for policy makers, health professionals and Canadians.

The *Assisted Human Reproduction Act* promotes the health and safety of individuals using reproductive technologies in Canada and the children born from such technologies, while reflecting the social and ethical values of Canadians.

The Act prohibits a number of assisted human reproduction procedures 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, the purchase or sale of *in vitro* embryos and payment for surrogacy. It also seeks to regulate certain activities, such as *in vitro* fertilization, through licensing and compliance activities.

The legislation provides for the establishment of Assisted Human Reproduction Canada (AHRC), a federal agency under the authority of the Minister of Health, which is responsible for the issuance and review of licenses, the collection of health reporting information, inspections and the enforcement of the AHR Act.

What is the Agency's mandate?

AHRC:

- Carries out inspections and enforcement related to activities prohibited or controlled under the AHR Act and provides clarifications to clinics about the Act's requirements
- Collects and analyzes information relating to AHR
- Transfers knowledge to health professionals and provides information to the public on AHR and associated matters, including risk factors associated with infertility
- Consults and collaborates with organizations within Canada and internationally involved in AHR issues to monitor and evaluate AHR developments domestically and globally
- Provides advice to the Minister of Health on matters relating to assisted human reproduction
- Provides internal support services in accordance with governmental policies and regulations

What is AHRC doing, as a regulatory agency, in the absence of regulations?

As Health Canada works towards finalizing the licensing, health information and other regulations, Assisted Human Reproduction Canada is developing the systems, policies and procedures necessary to implement the appropriate frameworks. This includes putting in place the infrastructure and networks necessary to safeguard the health and safety of Canadians building their families through reproductive technologies.

Once the licensing regulations come into force, AHRC is prepared to begin accepting and processing licence applications. With the coming into force of the health information regulations AHRC will begin collecting information on donors, persons undergoing assisted reproduction procedures, and persons conceived by means of these procedures. This information will be maintained, by AHRC, in a Personal Health Information Registry. Such information will help inform interested parties and the public on AHR related matters in accordance with the legislation and regulations. In the interim, AHRC continues to focus its compliance activities on promoting, monitoring and

enforcing the AHR Act and Section 8 Consent to Use Regulations. The Agency collects information on alleged contraventions to the Act or regulations, and takes appropriate action.

The Agency continues to fulfill its statutory mandate to monitor and evaluate developments within Canada and internationally in assisted human reproduction, and to generate and provide information to the public and the professions regarding AHR issues.

The Agency engages health professionals, patients, researchers and other key stakeholders, within and outside of government, to better understand their issues and expectations in relation to the Agency's regulatory responsibilities.

In addition, the Agency has also collaborated with key stakeholders to address issues of particular concern: health and safety of cross-border reproductive care and the high level of multiple births in Canada, due to AHR.

Constitutional Reference – Supreme Court of Canada

The ***Assisted Human Reproduction (AHR) Act*** received Royal Assent on March 29, 2004. On December 15, 2004, the Government of Quebec filed a reference with the Quebec Court of Appeal (QCA), seeking the opinion of the Court with respect to the constitutional validity of sections 8-19, 40-53, 60, 61 and 68 of the AHR Act. The Quebec Court of Appeal rendered its opinion on June 19, 2008, that all challenged provisions were unconstitutional.

An appeal to the Supreme Court of Canada was filed by the Attorney General of Canada on August 19, 2008. The Supreme Court of Canada heard the case on April 24, 2009. Its opinion had not been rendered at the time of publication of this annual report.

Making a difference

Inspections and enforcement

The Agency has an active compliance program to increase awareness of and ensure compliance with the *Assisted Human Reproduction Act* as well as to assess complaints related to alleged contraventions of the Act and its associated regulations currently in force.

AHRC promotes compliance through a variety of means, including direct mailings, speaking at clinics and conferences, hosting workshops and via the information available on its website. The Agency's regulatory and compliance staff have received and responded to hundreds of questions from clinics, the public and other organizations regarding the AHR Act and its regulations. AHRC's central email (info.arhc-pac@hc-sc.gc.ca) and its toll free number (1-866-467-1853) are valuable, well used regulatory communication tools.

The Agency has developed extensive materials for both professionals and patients on the Section 8 Consent to Use Regulations. Continual monitoring of media reports and websites for adherence to the legislation – particularly those related to payment for the purchase of gametes and the services of a surrogate mother – is another of the many ongoing compliance activities undertaken by the Agency. It has recently initiated a website monitoring project to monitor and promote compliance with sections 6 & 7 of the Act (payment for surrogacy / purchase of gametes).

AHRC has a formal process in place to assess allegations of violations of the Act or regulations. The Agency collects information, assesses the facts and contacts the relevant parties in order to promote compliance with the Act. Usually, this is all the action that needs to occur. To date, the Agency has received several reports of violations, including a number of serious allegations relating to the purchase of gametes from donors and to payment and advertising for surrogacy. Each has been fully investigated and appropriate measures taken.

Monitoring the marketplace

Building the necessary knowledge to protect public health and safety in relation to AHR is one of AHRC's most important roles in delivering its mandate. It is essential that health policymakers and practitioners have adequate information to plan for and appropriately resource health programs and to confirm that they produce the intended results.

One of the means to accomplish this is through relevant and effective monitoring of health outcomes, an area that AHRC is actively advancing. Health researchers across the country collected and collated information on databases relevant to assisted human reproduction, as well as reproductive, perinatal, infant and children's health. The 2009 *Inventory of Health Surveillance Databases*, which was produced based on this information, is an important resource for researchers, health professionals and governments (http://www.ahrc-pac.gc.ca/aux_files/Inventory%20of%20Health%20Surveillance%20Databases%202009%20eng.pdf).

Improved and additional information related to reproductive technology has been identified as a priority by patients, fertility centres and researchers. There is currently little data on the long-term outcomes of various AHR options, in large part because many countries do not monitor national AHR data.

One of the key recommendations from a 2008 research workshop related to AHR, co-hosted by AHRC and the Canadian Institutes for Health Research (CIHR), was enhanced data related to AHR. The Canadian Fertility and Andrology Society (CFAS) has also recognized the importance of data availability for clinics. It began collecting relevant data in 1999.

Despite these efforts, there is currently no national system of outcome measurement related to reproductive technology in Canada. At the moment, the only available information comes from the Canadian Assisted Reproduction Technologies Register (CARTR), which is maintained by clinics' *in vitro* fertilization directors and managed by CFAS. Databases provide vital information about the effects of AHR on maternal, child and family outcomes. Such information stimulates further research required to optimize patient care and improve results for mothers, babies and families. This information also enables policy makers to monitor the health and welfare of the population, to observe trends in infertility and demographics, and to predict and respond to demand for AHR services.

Accordingly, in addition to information AHRC will collect once health information regulations are in place, the Agency is working with the Canadian Fertility and Andrology Society and other experts to

Risks of infertility

Factors affecting infertility include public health risks such as smoking and alcohol use, obesity, chronic disease, pharmaceuticals and other drugs, sexually transmitted infections, environmental contaminants and delayed child-bearing.

Reproductive technologies may be used to overcome infertility with varying success. Fertility preservation techniques and clinical management varies dramatically depending on patient age, sex, diagnosis and treatment regimen.

Source:

Lifestyle factors in people seeking infertility treatment – A review.
Anderson K, Nisenblatt V, Norman R. Aust N Z J Obstet Gynaecol. 2010 Feb;50(1):8-20.

find ways to provide more timely data on this important topic. The group is exploring potential models around the measurement of outcomes.

Increasing understanding of infertility

In the last decade, the incidence, causes and treatment of infertility have become matters of international concern. To underscore this point, the World Health Organization recently identified infertility as a disease that demands worldwide attention¹ due to its social, economic and psychological consequences.

The precise number of Canadians confronting infertility and seeking treatment is unknown, as there is no current Canadian data available. The Royal Commission on New Reproductive Technologies (<http://www.dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/MR/mr124-e.htm>) estimated in 1993 that about 8.5% of Canadian couples were infertile.

¹ **WHO Releases Glossary of Terminology in Assisted Reproduction, Defines Infertility as a Disease.**
<http://www.asrm.org/news/article.aspx?id=3029>, http://www.who.int/reproductivehealth/publications/infertility/art_terminology2.pdf

While not all people using AHR face infertility challenges, the growing number of Canadians turning to reproductive technologies to build their families reinforces the need to promote and protect their health and safety, as well as their dignity and rights.

To gain a better understanding of both the extent and causes of infertility among Canadians, AHRC asked Statistics Canada to add questions related to infertility to its 2009 Canadian Community Health Survey (See Moving Forward).

Focus on cancer and fertility

Each year, more than 2,000 new cancer cases are diagnosed in young adults in Canada and their prognosis has never been better. Thanks to advances in detection and treatment, the overall survival rate is now 83%.² With the promise of a long healthy life often comes the desire to have families, an option sometimes compromised since some life-saving cancer therapies can adversely affect fertility. In fact, up to 70% of survivors may have reduced fertility rates.

Fertility preservation options are available both for cancer patients facing oncology treatment and for those who have already completed their treatment. To determine how readily available such services are in Canada, AHRC built on a survey which identified scientific innovations in fertility preservation relevant to young cancer patients.

Fertility clinic websites within Canada were surveyed for information specific to oncofertility and the various preservation options available. It revealed that there are opportunities to increase connections

between oncology teams and fertility clinics that allow for timely interventions that give cancer patients a chance to preserve their fertility.

To raise awareness of advances in reproductive technologies that can increase the chances of conception among cancer survivors, the Agency commissioned a brochure on cancer and fertility, posted on AHRC's website (<http://www.ahrc-pac.gc.ca/doc.php?did=25&lang=eng>).

Most notable, in March 2010, AHRC worked with the Canadian Partnership Against Cancer (CPAC) as part of a symposium focused on Adolescent and Young Adult (AYA) cancer issues. Sessions with CPAC's internationally-renowned speakers on survivorship issues in AYA cancer cases were invited to the AHRC symposium titled "Oncofertility in Canada: Building Connections for the Improvement of Fertility Preservation Options." AHRC's Oncofertility symposium was planned with the assistance of a volunteer, expert committee, including Fertile Future, an organization focussed on educating Canadian patients around their options. The symposium was designed to facilitate knowledge transfer among reproductive scientists, oncology staff, fertility preservation specialists and patient advocates, and to encourage research collaboration. As well as increasing understanding, the event has prompted additional research efforts among participants – a further step in generating increased opportunities for cancer survivors to build families (*Report of symposium - available on AHRC website*).

² **CANADIAN CANCER SOCIETY'S STEERING COMMITTEE. Canadian Cancer Statistics 2009. Special Topic: Cancer in Adolescents and Young Adults.** Toronto: Canadian Cancer Society, 2009.

Minimizing multiple births

Prior to the birth of the first Canadian child conceived of *in vitro* fertilization (IVF) in 1982, the natural rate of multiple births in Canada was 1.8%. That number has since risen to about 3%, in part due to multiple embryo transfer practices associated with IVF.

Until recently, it was common in IVF treatment to implant several embryos to improve a woman's odds of conceiving – often at the request of patients, given their deep desire to conceive. Increasingly, however, women undergoing IVF are being advised by their doctors to use single embryo transfers for their own, and their offspring's, health and safety. Multiple births are the single greatest health risk for women and their children following IVF treatment. As one example, gestational diabetes, a risk associated with multiple births, can cause the death of an unborn child or newborn baby. Early and late miscarriages are also more common among women carrying more than one foetus.³

Aside from subjecting mothers and babies to avoidable risks, multiple births also pose significant costs for the health system. Canada's multiple birth rates are among the highest of comparable countries. According to the Canadian Institute for Health Information, ante- and neo-natal as well as pregnancy complications were among Canada's top 15 most expensive health conditions in 2005.⁴

An increased rate of twin births represents IVF's biggest risk for mothers and babies because they significantly raise the chances of mortality, prematurity, low birth weight and cerebral palsy for babies. It can also cause life-long term problems for children and risks to mothers, including preeclampsia, diabetes and heart disease.

Source:
Human Fertilisation Embryology Authority, U.K.

The risks and costs associated with multiple births in relation to AHR can be reduced by transferring fewer embryos. However, single embryo transfers (SET) accounted for only 4% of fresh embryo transfers in Canada in 2007⁵. Establishing a standard single embryo transfer policy for appropriate patients at fertility clinics is the goal of a growing number of health practitioners and scientists.

The health and well-being of children born through the use of assisted human reproductive technologies must be given priority in all decisions respecting their use, according to one of the principles of the *Assisted Human Reproduction Act*.

3 **BISSONNETTE F, COHEN J, COLLINS J, AND AL. Incidence and complications of multiple gestation in Canada: Proceedings of an expert meeting.** Reproductive Biomedicine Online 2007;14:773-90.

4 **CIHI. The Cost of Acute Care Hospital Stays by Medical Condition in Canada 2004-2005.** Ottawa: Canadian Institute for Health Information, 2008.

5 **GUNBY J, BISSONNETTE F, LIBRACH C, COWAN L. Assisted reproductive technologies (ART) in Canada: 2007 results from the Canadian ART Register.** Fertility and Sterility; In Press, Corrected Proof.



Multiple Births Speakers: Dr. Albert Yuzpe, Dr. Catherine Racowsky (USA), Dr. Andre van Steirteghem (Belgium), Dr. Anuja Dokras (USA), Dr. Jason Min, Dr. Sarah McDonald and Dr. Tony Rutherford (United Kingdom).

In November 2009, approximately 75 researchers, clinicians and other infertility experts from across Canada and around the world met in Montreal for a scientific roundtable on the issue of multiple births. “Prevention of Multiple Births Associated with Infertility Treatments in Canada: Building A Canadian Framework”, was hosted by the Canadian Fertility and Andrology Society (CFAS), the Society of Obstetricians and Gynaecologists of Canada (SOGC) and AHRC and coordinated by the Multiple Births Roundtable Steering Committee.

The purpose of the meeting was to develop a framework to prevent multiple births in Canada associated with infertility treatments and to support the framework’s implementation across the country (*Framework available on AHRC website*). Given that Canada’s multiple birth rates are among the highest of comparable countries, delegates agreed that a change in AHR practices is needed to improve outcomes for patients and their families. Various speakers updated participants on the latest research and trends, current guidelines, as well as legislation and policy development related to infertility-treatment related multiple births, both in Canada and internationally.

The roundtable culminated in a draft Canadian framework, including timelines and targets, to reduce the contribution of infertility treatments – both *in vitro* fertilization and non-IVF – to the annual number of multiple births in Canada. Delegates committed to building a Canadian and international community of experts working to decrease the number of multiple births associated with infertility treatments and to educating AHR clients about the risks involved.

One of the key pillars of the Framework to Prevent Multiple Births due to fertility treatments is a focus on patients – their knowledge and decision making. A Multiple Births Patient Committee made up of representatives from the National Patient organizations, along with a counsellor and the One At A Time Program from the UK is exploring the development of a tool to assist patients with their decision making around the number of embryos to transfer.

The Healthy Singletons Committee, a continuation of the Multiple Births Roundtable steering committee, was established following the November conference. It is tasked with identifying tangible and achievable targets and

Framework to prevent multiple births

By the close of the Multiple Births Roundtable, participants had updated their knowledge of international policies on embryo transfer and agreed on targets to improve the health of Canadians using AHR clinics for infertility treatment.

Embryology and fertility specialists agreed that improvements in three key areas are required: Professional Education; Patient Education; and, Data Collection and Analysis. With specific action plans to address these areas, AHR professionals recognized the need to:

1. Decrease the twin rate per fertility clinic by 10%
2. Increase the use of elective single embryo transfers
3. Eliminate higher-order multiples due to AHR
4. Develop and implement educational tools for patients
5. Develop and implement training and practice updates for professionals

actions that will help the professionals (REI physicians and embryologists) to meet the goals they agreed upon in the Multiple Births Framework.

Staying on top of emerging trends

Nothing better cements AHRC's credibility and reputation as a trusted source of AHR information and best practice than knowledge of the latest scientific trends – an area where the Agency is garnering global attention. The Science Advisory Panel (SAP), which provides information and guidance to the Board of Directors, has earned international notice for the calibre of its members and the quality of the work they do.

For instance, the Panel Chair has been invited to sit on the prestigious scientific horizon scanning body of the UK's Human Fertility and Embryology Authority. The organization is recognized worldwide for its cutting edge work in research and

technology development. This participation will enable AHRC – to keep abreast of the latest scientific breakthroughs in research and development as well as emerging challenges associated with reproductive technologies. Being current with the most recent trends will help to ensure the Agency has a solid science foundation on which to base its policy and program decisions. As valuable, it will create stronger linkages with other regulatory agencies grappling with many of these same issues.

As well, panelists defined processes for SAP work, including reviewing scientific update documents. The Panel has developed criteria for evidence assessment and horizon scanning, and defined a spectrum for evidence. It has also co-authored a number of documents on topics such as innovative practices that have been accepted by the Board of Directors for their use. Access to such research is crucial to informed, evidence-based decision making and is a high priority for Board members.

International collaboration

No country can work in isolation in a field as complex and fast-changing as reproductive technology. Recognizing the importance of staying abreast of global developments and sharing knowledge, the Agency has been enhancing its relationships with regulators and AHR-related organizations in other countries in order to exchange information and best practices.

Over the past year, a number of meetings and exchanges took place – either to bring in outside expertise or to share AHRC's knowledge with others in the AHR community. For instance, representatives from the Donor Network of the U.K. met with AHRC to offer insight and advice on how best to address public inquiries about reproductive technologies and issues associated with them. Another presentation related to altruistic donations was made for the benefit of AHRC by the U.K. based National Gamete Donation Trust.

In addition, meetings were held with the Chairperson of the New Zealand Advisory Committee on Assisted Reproductive Technology, as well as with a number of key staff at the UK's Human Fertility and Embryology Authority (HFEA). Recently, the Infertility Treatment Authority in the Australian state of Victoria invited AHRC to sit on one of its advisory bodies by teleconference, which will provide another key way to share information among regulators.

Cross Border Reproductive Care

Quality and safety in cross-border reproductive care (CBRC) is of significant concern to all those involved: patients, physicians, gamete and embryo donors,

surrogates, and the regulators in the home country and abroad. From a regulatory perspective, Professor Lisa Jardine, the Chair of the UK's Human Fertilization and Embryology Authority, has summed up the concerns well: "that 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."

As a result of these concerns and on behalf of an international steering committee, AHRC hosted the First International Forum on CBRC: Quality and Safety in January 2009. Major concerns raised throughout the Forum were: the lack of data on those choosing to access CBRC, the procedures involved and the health outcomes from them; the need for good quality, reliable, up-to-date and easily accessible information; and the need to encourage patients, surrogates, donors and others to access and use such information in their decision-making. It was noted that a lack of information on CBRC itself is a barrier to informed decision-making by health authorities, professional bodies and others concerned with promoting safe, quality CBRC when it occurs.

One early outcome of this strengthened relationship was the decision to ask the International Committee Monitoring Assisted Reproductive Technology (ICMART) to include questions regarding international travel for AHR services. At its fall 2009 meeting, ICMART agreed to develop CBRC-related questions for inclusion in its next survey. This improved information should increase understanding of current practices and potential challenges among regulators and health professionals, enabling them to better address issues of safety and quality of care.

Key meetings

Board of Directors

Board members held two formal, in-person meetings in 2009-2010, in addition to numerous formal and informal teleconferences. These meetings allowed the Board to provide direction to the Agency as it continues planning for the future as well as input to Health Canada on regulatory development.

As part of its oversight responsibilities, the Board approved the Agency's goals, operational policies and annual budget. It also continued to oversee the Agency's longer-term plans moving forward.

Strategic planning is 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. The Board of Directors has identified a number of priorities for the Agency as it prepares to assume its regulatory responsibilities. They include inspections, personal health information management, education, best practices and standards,

research, international collaboration and outreach. Ethical considerations are identified as a key cross-cutting issue. Action in these areas will help to ensure that AHRC has the capacity to safeguard patients, donors, and children born of reproductive technologies and to establish the Agency as an internationally recognized leader in the application of AHR technologies for safe practice (*Strategic plan available on AHRC website*).

Tripartite Committee

Since its inception, AHRC has worked actively to build networks with key organizations immersed in AHR issues in Canada. One of the best examples of this is the Tripartite Committee, which brings the perspectives and expertise of the Canadian Fertility and Andrology Society (CFAS) and the Society for Obstetricians and Gynaecologists of Canada (SOGC) to the work of the Agency. Committee members from the three organizations meet twice annually to discuss issues and projects of common interest. Among these topics are concerns surrounding multiple births, noted earlier in this report.



Other activities

AHRC has also been working with the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynecologists of Canada to facilitate the development of joint clinical practice guidelines. As a result, the Joint Clinical Practice Guidelines Committee has co-ordinated the process for production of a joint guidelines entitled “Elective Single Embryo Transfer following IVF”, which has been published in the Journal of Obstetrics and Gynecology of Canada (http://www.sogc.org/jogc/abstracts/201004_SOGCClinicalPracticeGuidelines_3.pdf).

The Joint Clinical Practice Guidelines Committee is continuing to catalyze the development of other guidelines, including guidelines for the diagnosis and treatment of Ovarian Hyperstimulation Syndrome (OHSS), Obesity and Infertility and Oncofertility. These guidelines are anticipated to be published in 2011.

In a related activity, AHRC has also provided the opportunity for the CFAS Nurses Special Interest Group, to develop a series of Position Statements regarding the professional scope and responsibilities of nurses in the care of patients. Opportunities have also been provided to the CFAS ART Lab and Counsellors Special Interest Groups. The Lab Special Interest Group is exploring the development of a certification framework for embryologists and andrologists and requirements for training and continuing education, and the Counsellors Group has recently produced guidelines for ‘Best Practice Counselling’ in compendium format (<http://www.cfas.ca>).

Advancing AHR knowledge

Science Advisory Panel

The Science Advisory Panel's primary role is to provide timely scientific advice to the Agency and the Board of Directors on current and emerging science issues related to AHR. It focuses specifically on the quality, safety, efficacy and effectiveness of AHR diagnostic and treatment options.

To advance this objective, the Panel has established a process for Horizon Scanning, a process that involves the systematic identification and assessment of new scientific innovations and best practices in the area of AHR. As the Panel identifies items of interest, brief reviews of the current state of the innovation or best practice are prepared, and one or more SAP members “adopt” the issue for continuous monitoring. The SAP members update the group on their selected areas at each meeting, at which point the topic is re-evaluated for its status and potential for use in clinical practice.

Some of the topics currently being continuously monitored by SAP members include:

- Gamete and embryo culture conditions and their effect on long-term health
- Creation of hybrid embryos for basic science and clinical research
- *In vitro* maturation of immature oocytes
- Preservation of fertility in cases of young adult cancer or other disease
- Use of preimplantation genetic diagnosis and screening in Canada and internationally

- Transplantation of oocyte cytoplasm for the avoidance of mitochondrial disease transmission
- Genomics, proteomics and metabolomics: Non-invasive embryo evaluation methods
- Innovative treatments for male factor infertility

In addition, the Panel conducts reviews of pertinent scientific issues. This provides the Agency with the necessary evidence base to identify knowledge gaps. Reviews have been prepared by the volunteer SAP members since the group's inception in 2008. Papers have been prepared on the following research topics including:

- Complementary and alternative medicine use in AHR treatment
- Culture media: What makes the best environment for gametes and embryos?
- Culture media manipulations: Long-term effects
- Embryo assessment
- Free fetal DNA in maternal circulation
- Hybrid embryos
- Innovations in the diagnosis and treatment of male factor infertility
- *In vitro* maturation of oocytes
- 'Omics: Non-invasive assessment of embryo and gamete quality
- Oncofertility: Preservation of fertility in young cancer patients
- Ooplasm transfer: Prevention of mitochondrial disease transmission
- Outcomes after assisted reproductive technologies
- Preimplantation genetic diagnosis

SAP will continue its efforts advising the Board of Directors and the Agency by monitoring AHR diagnostic and treatment options, and reviewing pertinent AHR scientific issues.

Sharing our knowledge with Canadians

From its earliest days, AHRC has reached out to *all* Canadians interested in AHR issues to keep them informed of the Agency's activities and to provide information on issues and developments related to its mandate. The Agency is continually developing new information products and services to share news about assisted human reproduction as well as the latest technological developments with Canadians.

A selection of information publications:

The Assisted Human Reproduction Act: A Guide for Patients http://www.ahrc-pac.gc.ca/aux_bin.php?auxid=29

Counselling and Assisted Human Reproduction: A Guide for Patients http://www.ahrc-pac.gc.ca/aux_files/Counselling-and-assisted-human-reproduction.pdf

Genetic Counselling: A brochure for Canadians seeking assisted human reproduction procedures in association with Canadian Association with Genetic Counsellors (CAGC) http://www.ahrc-pac.gc.ca/aux_bin.php?auxid=35

Reproductive genetic testing and screening options: A brochure for Canadians seeking assisted human reproduction procedures in association with Canadian Association with Genetic Counsellors (CAGC) http://www.ahrc-pac.gc.ca/aux_files/Reproductive-genetic-testing-and-screening-options.pdf

Cancer and Preserving Your Fertility: a Guide for Patients http://www.ahrc-pac.gc.ca/aux_files/Cancer%20and%20Preserving%20Your%20Fertility%20-%20English.pdf

These brochures are just the latest in a series of publications produced by AHRC to assist practitioners, researchers, patients and donor-conceived individuals in understanding the many complex issues surrounding reproductive technologies. The Agency's website publishes information documents for professionals and patients on AHR related issues. Work continues on the next phase of the website to further improve its information offerings.

In addition, the Agency supported the production of a DVD **'Considering Your Options for Embryo Transfer: Understanding the Issues'** and is available upon request.

AHRC Editorial Committee

The development of all communications products benefits from the input of AHRC Editorial Committee members. They review draft text prior to publication and make recommendations for changes to better reflect and respond to the needs of Canadians seeking information about assisted human reproduction. The Committee is composed of representatives from organizations with knowledge of AHR issues, including a counsellor, a patient, a donor-conceived person, as well as an embryologist, gynaecologist and nurse.

Moving Forward

Assisted Human Reproduction Canada will continue to enhance and expand AHR awareness and knowledge. Chief among these efforts, the Agency will continue to consult patient groups in 2010 to discuss strategies regarding multiple births and further engage patients and professionals.

AHRC will also capitalize on new data generated by the 2009 Canadian Community Health Survey which, for the first time, will include questions on infertility. This survey collects information on the health status, health care utilization and health determinants for the Canadian population. The 2009 questionnaire presents the largest sample of Canadians surveyed about infertility in almost twenty years, since the work of the Royal Commission. It provides a unique opportunity to study and shed light on the health-related aspects of infertility trends in Canada by providing a current measure of the prevalence of infertility in Canada.

Equally valuable, it could show a relationship between factors such as obesity, smoking, sexually transmitted infections and other factors that influence fertility levels.

It is anticipated that the survey data will be available for analysis in fall 2010. Studies based on the survey results will complement other research efforts into outcomes, interactions and implications along with best practices associated with reproductive technologies. This will further enhance public health awareness of infertility prevention and treatment approaches and foster evidence-based decision making in the field of AHR.

AHRC will continue to facilitate important research in priority areas such as the epidemiology of infertility to psychosocial research. The Agency will carry on its work with Statistics Canada and the Canadian Institutes of Health Research to develop the evidence base required to support policy and decision-making. A further objective for the coming year is the development of a strategy to inform Canadians about the risk factors for infertility.

Another area of upcoming exploration is the Environmental Health and Reproduction project, which will examine the impacts of a wide range of chemicals prevalent throughout society on reproductive health. People are exposed to an increasing number of chemicals on a regular basis. While basic toxicity testing on new or existing chemicals is required, their 'silent' and synergistic

effects are largely unknown. Evidence indicates reproductive health and the health of offspring can be adversely affected by exposure to environmental toxins⁶. In 2010, the Agency will host a Best Practices Workshop on Environmental Health and Reproduction.

Enhanced information offerings on the broad range of AHR-related issues of interest to all Canadians remains a key priority for the Agency. In addition to preparing relevant information on numerous topics, AHRC will launch an updated version of its website to keep Canadians better informed about our activities and AHR generally.

A positive course has been set for the Agency's ongoing success in the future as momentum builds and measurable progress is made.

Financial statement

Assisted Human Reproduction Canada spent \$5,191,530 during fiscal year 2009-2010. The funding allocated for the fiscal year (April 1, 2009 to March 31, 2010) was \$10,521,000. The unspent portion of the annual appropriation by Parliament for the operating year 2009-2010 was returned to the consolidated revenue fund of the Government of Canada.

The Agency continues to build a sustainable organization through creation and staffing of indeterminate positions, commensurate with the release of the regulations.

**Table 1: Financial Summary
(\$ in thousands)**

	Approved Funding	Estimated Spending	Forecast Spending
April 1 – March 31	2009-2010	2009-2010	2010-2011
Total AHRC	\$10,521	\$5,191	\$10,521

Further details on the Financial Statements can be found at:

Departmental Report on Plans and Priorities for 2009-2010

<http://www.tbs-sct.gc.ca/rpp/2009-2010/inst/rap/rap-eng.pdf>

⁶ LUOMA J. *Challenged Conceptions: Environmental chemicals and fertility*. Bolinas CA: Collaborative on Health and the Environment, 2005.

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View our publications:

Annual Reports

- Annual Report – 2008-2009 http://www.ahrc-pac.gc.ca/aux_files/AHRC-AR-en%202009.pdf
- Annual Report – 2007-2008 http://www.ahrc-pac.gc.ca/aux_bin.php?auxid=33

Newsletters

- 2009 Winter Newsletter http://www.ahrc-pac.gc.ca/aux_files/AHRC-Newsletter-winter-e-WEB.pdf
- 2008 Summer Newsletter http://www.ahrc-pac.gc.ca/aux_bin.php?auxid=26
- 2008 Winter Newsletter http://www.ahrc-pac.gc.ca/aux_files/AHRC-Newsletter-Winter-e.pdf

Other Reports

- 2009 Inventory of Health Surveillance Databases http://www.ahrc-pac.gc.ca/aux_files/Inventory%20of%20Health%20Surveillance%20Databases%202009%20eng.pdf
- 2008 AHRC / CIHR Workshop <http://www.ahrc-pac.gc.ca/doc.php?did=22&sls=1&lang=eng>
- 2008 National Consultation on AHR Oversight <http://www.ahrc-pac.gc.ca/doc.php?did=18&lang=eng>