Hope, Health and Safety

Assisted Human Reproduction Canada

2007-2008
Annual Report

Canada

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Minister of Health

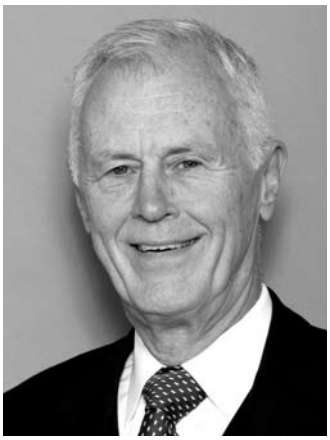
The Honourable Tony Clement
Minister of Health

I am proud to present this first annual report of Assisted Human Reproduction Canada (AHRC) for 2007–08, a period of steady progress.

The federal regulatory agency, AHRC, was created to protect and promote the health, safety, dignity and rights of Canadians who use or are born of assisted human reproduction technologies, and to foster the application of ethical principles in their use and development.

The importance of the Agency's work for the thousands of Canadians across the country who need help in having the children they want cannot be understated. AHRC works to ensure that the gift of life made possible by assisted reproductive technologies happens in a safe, healthy and dignified way.

The Agency continues to build a strong organization in which all Canadians can take pride.



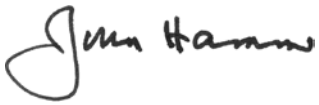
Dr. John Hamm
Chairperson, Board of Directors, AHRC

Chair, Board of Directors

As a family physician I often encountered patients frustrated by their inability to conceive and have children. I have witnessed the personal pain and suffering of individuals living with infertility, and the health and social consequences both for them and for society at large. So it is a great privilege to chair the Board of Directors of AHRC, a group of individuals with great knowledge, experience and compassion who share my commitment to enabling Canadians to create the families and futures they want.

Our priority is ensuring that AHRC will both safeguard patients, donors, and children born of reproductive technologies and serve as a welcome resource for all Canadians affected directly or indirectly by AHR-related research and science. We are equally determined to see the Agency recognized internationally as a leader in the application of AHR technologies for safe practice.

Most of all, we are committed to fostering ethical principles in relation to assisted human reproduction. Under our watch, AHRC will administer regulations flowing from the *Assisted Human Reproduction Act* in a fair, transparent, inclusive, consistent and effective manner that leaves no doubt about Canada's commitment to the dignity and rights of AHR users and offspring.



President, AHRC

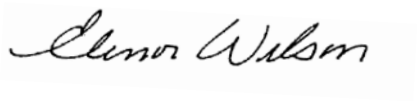
Dr. Elinor Wilson
President, AHRC

The inability to have a family affects thousands of Canadians in communities big and small, in every corner of the country. For many, the challenge is infertility, a condition of reproductive systems that afflicts roughly one in eight Canadians and affects men and woman equally. For others, the issue isn't infertility but the need to build a family through AHR procedures.

Whatever the cause, the issues that surround the inability to procreate are generally viewed as a private matter, to be borne in stoic silence. In reality, they are a serious public health challenge. Assisted human reproduction is a complex field that challenges our very understanding of what it is to be human, and poses risks and opportunities for individuals and communities. Beyond the health and safety considerations associated with these technologies, AHR touches on issues related to the dignity and rights of Canadians.

To effectively regulate this complex area requires the full engagement, involvement and commitment of all parties with a role to play in these vitally important issues. With this in mind, a major focus of our Agency's work is reaching out to all Canadians who want to contribute to these matters.

AHRC is committed to working closely with Canadians to build a strong and open relationship based on doing what is right for the health, safety, rights and dignity of individuals who turn to AHR to produce the children they desire.



Who we are

The Assisted Human Reproduction Agency of Canada (Assisted Human Reproduction Canada, or AHRC) was created in January 2006. However, its genesis dates back to the 1993 recommendations of the Royal Commission on New Reproductive Technologies. The commissioners spent four years examining assisted human reproduction (AHR) activities in Canada. They heard from 40,000 Canadians, including doctors, medical organizations and ordinary citizens, before issuing their final report, *Proceed with Care*. The report called on the Government of Canada to ban activities such as human cloning, payment for sperm or eggs, and commercial surrogacy, and recommended that the Government establish an independent regulatory body to govern permissible assisted human reproduction activities.

Mission

Assisted Human Reproduction Canada protects and promotes the health and safety of donors, patients and offspring born of AHR technologies by being the centre of expertise in administering a comprehensive legislative and regulatory framework.

Assisted Human Reproduction Canada was created to fill this need. The Agency was established under the *Assisted Human Reproduction Act* (AHR Act), enacted by Parliament in March 2004 to provide a safe and ethical framework for AHR activities and related research in Canada. The Act prohibits human cloning and other unacceptable activities (such as sex selection for non-medical purposes and the purchase of human reproductive material) which Parliament has determined to be incompatible with Canadian values and ethical standards. It also ensures that AHR activities and related research involving the *in vitro* human embryo take place in a controlled environment. The Government of Canada takes these matters very seriously: there are criminal sanctions under the Act for contraventions of the legislation.

Most important, the Act provides measures for the protection and promotion of 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. Once the regulation regime is in place, Canada will have one of the most comprehensive legislative frameworks in the world regarding assisted reproductive technologies.

As part of the Government of Canada Health Portfolio, AHRC reports to Parliament through the Minister of Health. The Agency is headed by a President and governed by a Board of Directors charged with developing corporate plans, priorities, operational policies and procedures.

The Board is currently composed of 11 members who reflect a broad range of backgrounds and disciplines to ensure relevant knowledge and varied perspectives on AHR-related issues and research.

Dr. Elinor Wilson
33rd annual D.A. Boyes Society Meeting, Vancouver, B.C., 2007

Barbara Slater

Dr. David Novak

Dr. Albert Chudley

Dr. Suzanne Rosell Scorsone

Dr. John Hamm, Board Chairperson

About the Board

AHRC Board members include doctors, scientists, academics, health professionals, ethicists and a patient who bring broad-based experience and expertise to their work. Directors were appointed by the Governor in Council following a public call for expressions of interest. The legislation requires the Board to meet at least twice annually. It also stipulates that no member can hold a licence under the Act, including a commercial interest in an AHR clinic.

Dr. Elinor Wilson, President

Roger Bilodeau, Board Vice Chairperson

Dr. Françoise Baylis

Theresa Kennedy

Dr. Joseph Ayoub

Irene Ryll

What we do

Mandate

The Assisted Human Reproduction Agency of Canada (AHRC) 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.

The Agency administers the *Assisted Human Reproduction Act*. Once the Act's regulations (currently being developed by Health Canada) come into force, the Agency will be responsible for licensing, inspecting and enforcing activities and facilities controlled under the legislation. Specifically, it will:

- Issue, renew, amend, suspend or revoke licences for AHR procedures or research using *in vitro* embryos;
- Inspect AHR clinics and research laboratories for compliance with the Act;
- Collect, manage and analyze health reporting information related to controlled activities; and
- Designate inspectors and analysts to enforce the Act.

Preparing the terrain

In the interim, AHRC is laying the groundwork and building the capacity vital for the successful implementation of the regulations. It is performing key developmental functions, including:

- Providing support and advice to the AHRC Board of Directors and to the Minister of Health;
- Developing the implementation plan for the licensing framework for controlled activities, including AHR procedures and related research;
- Developing an inspection strategy to ensure compliance with the *Assisted Human Reproduction Act* and its regulations;
- Creating a national personal health information registry that obtains and maintains secure information on donors, recipients and those born of AHR;
- Developing a research agenda to inform policy;
- Consulting and communicating with interested individuals and organizations engaged in AHR issues to raise awareness of both AHR technologies and the role of the Agency;
- Becoming a centre of expertise on AHR by monitoring and evaluating national and international developments related to assisted reproductive health and working with the global community to share concerns; and
- Building a strong foundation for these functions through relevant planning and administration.

Who's who

There are several important partners at the federal level with differing responsibilities under the *Assisted Human Reproduction Act* (AHR Act). AHRC's role in overseeing the use of reproductive technology in Canada is not to be confused with that of Health Canada. Health Canada is responsible for setting policy and developing the regulations stemming from the Act, whereas Assisted Human Reproduction Canada's role is to administer the new regulations once they are finalized. Although it reports to Parliament through the Minister of Health, the Agency is separate from the federal Department of Health. It was established as a Departmental Corporation under Schedule II of the *Financial Administration Act*.

Why it matters

It has been 30 years since the world awoke to the news that parenthood no longer depended solely on biology, with the birth of the first "test tube baby"—a revolutionary event that redefined our understanding of "conception". Ever since, countries around the globe have been grappling with important scientific, medical, legal and ethical questions associated with these transformative technologies.

The moral, economic and social repercussions continue to reverberate as a new generation of citizens conceived through these technologies claim their place in contemporary society. Over the past three decades, more than 1.5 million people[1] have been born as a result of these innovative methods of producing children, including some 3,500 newborns in Canada each year whose lives have been made possible by assisted reproductive technologies.[2]

Meeting of the Board of Directors

While it might be tempting to presume that these are private matters that affect only the children and families involved, in fact AHR is a public health challenge. It directly affects about one in eight Canadian couples struggling with infertility, as well as individuals who are dependent on non-conventional methods to build a family. It also has indirect consequences for all Canadians.

The inability to have a child or build a family can cause considerable distress and even despair. This health challenge is largely hidden from public view as it is a topic that is still frequently taboo, even in open societies like ours. The resulting social isolation can take a terrible toll. In some cases, individuals and couples experience anxiety, depression, reduced job performance and relationship stress.

There are other costs as well. For example, the number of multiple births in this country has increased significantly, in part because of AHR. Assisted reproductive technologies—such as *in vitro* fertilization (IVF) and other techniques designed to help couples conceive—often use ovulation-stimulating medications to produce multiple eggs which are then fertilized and returned to the uterus to develop. [3]

Multiple births have much higher rates of complications for both mothers and newborns, including pre-term labour and birth, pregnancy-induced hypertension, anemia, caesarean delivery, post-partum hemorrhage, miscarriages and birth defects. Multiple birth babies have about twice the risk of congenital (present at birth) abnormalities, including spina bifida and gastrointestinal and heart abnormalities.[4]

Declining fertility rates, coupled with Canada's aging population, are a further issue of concern to society at large. In 2001, one in eight Canadians was 65 or older. By 2026, this figure will be one in five. Population aging is a complex issue affecting health, labour markets and public financing.[5] If fertility remains at the current level, deaths are expected to exceed births in Canada within the next few decades.[6]

[1] World Medical Association, *Statement on Assisted Reproductive Technologies*, October 2006, http://www.wma.net/e/policy/r3.htm

[2] Canadian clinics reporting data to the Canadian Assisted Reproductive Technologies Register (CARTR) for 2005.

[3] University of Virginia Health System. http://www.healthsystem.virginia.edu/uvahealth/peds_hrpregnant/multiple.cfm

[4] Ibid.

[5] Health Canada, *Canada's Aging Population*, 2002. http://www.phac-aspc.gc.ca/seniors-aines/pubs/fed_paper/pdfs/fedpager_e.pdf

[6] Statistics Canada, *Trends in Canadian and American Fertility*, 2002. http://www.statscan.ca/Daily/English/020703/d020703a.htm

Results in our first year

Getting AHRC up and running

The first order of business in 2007 was to build AHRC from the ground up. In the initial months, this entailed everything from locating office space and installing telephone and Internet connections, to hiring a strong team of in-house professionals and outside consultants, to organizing Board meetings.

With the core team in place, the Agency has focused on establishing a compliance and enforcement framework so it can deliver effective licensing, and verification services once Canada's new AHR regulatory regime comes into force. Equally important has been the development of the necessary tools to disseminate information to Canadians and to ensure AHRC becomes a centre of expertise on assisted human reproduction.

Encouraging constructive dialogue

The strength of AHRC will be the strength of its relationship with stakeholders, because regulations can be effectively administered only when the individuals and organizations affected by them are fully engaged and informed and when oversight is a collective effort. AHRC has been actively consulting with patient groups, AHR providers, health professionals and other partners within and outside of government, both in Canada and abroad. The objective of these discussions has been to gain a better understanding of emerging trends, stakeholders' issues and expectations. Just as important, the Agency is working to ensure that everyone involved is well briefed about the purpose of the regulations and the principles behind them.

Building productive partnerships

The Board Chair and the President have been reaching out to communities across the country to build networks that will guide the work of AHRC. Discussions have been held with the CEOs and Presidents of the Canadian Fertility and Andrology Society (CFAS), the Society of Obstetricians and Gynaecologists of Canada (SOGC), the Canadian Medical Association (CMA), and the College of Family Physicians of Canada (CFPC). This strong working relationship will enable AHRC to liaise with physicians on their AHR-related activities.

Among the most significant developments has been the creation of a Tripartite Committee made up of representatives of AHRC, CFAS and SOGC. The Committee provides a forum for discussion on matters of mutual interest, to share information on emerging issues, and to make recommendations on future initiatives such as clinical practice guidelines.

The Agency will provide regular briefings to and seek advice from the Committee on issues of mutual interest. The Tripartite Committee typically meets face-to-face on a quarterly basis.

The President and Board members have visited clinics and consulted with support groups and health professionals involved in AHR procedures, to develop a strong working relationship with the people the Agency serves. In March 2008 a meeting was held with three key patient groups—the Infertility Awareness Association of Canada, the Infertility Network, and the Lesbian, Gay, Bisexual and Trans (LGBT) Parenting Network—to build partnerships and assess how these organizations and AHRC can best work together.

During its first year of operations, the Agency met with an array of organizations and participated in or hosted several conferences, including:

Domestic

- May 2007 – Nobody's Child, Everybody's Children (international conference)
- September 2007 – Meeting with patient group, London Health Sciences Centre
- September 2007 - Annual general meeting of the Canadian Fertility and Andrology Society
- October 2007 - Vital Statistics Council of Canada
- November 2007 - 33rd annual D.A. Boyes Society Meeting (provincial obstetrics and gynecology)
- November 2007 – Healthy Embryo Conference
- January 2008 – National invitational meeting to consult with partners on collaborative approaches to oversight of AHR in Canada to create a licensing framework
- March 2008 – Meeting with patient groups

International

- June 2007 - 23rd annual meeting of the European Society of Human Reproduction and Embryology
- June 2007 - Human Fertilisation and Embryology Authority
- October 2007 - American Society for Reproductive Medicine Congress

Dr. Ed Hughes (Past-President of CFAS), Dr. Elinor Wilson, (President of AHRC) and Dr. Scott Farrell (President Elect of the SOGC) Tripartite Committee meeting, 2007

The Agency is also collaborating with AHR regulatory bodies in other countries to learn from their experiences and to develop joint solutions to shared challenges. Thanks to these efforts, the Agency has acquired valuable insights into best practices and opportunities associated with managing assisted human reproduction.

Creating the necessary infrastructure

AHRC is awaiting the regulations necessary to give effect to the elements of the *Assisted Human Reproduction Act* that will authorize the Agency to implement and enforce the legislation's provisions. In the short term, the Agency has entered into Memoranda of Understanding (MOU) with other federal partners that can help AHRC discharge its duties.

For instance, the Agency has signed an MOU with Health Canada's Health Products and Food Branch Inspectorate. Under its terms, Health Canada will provide inspection, compliance and enforcement services for the *Assisted Human Reproduction Act* under the direction of AHRC. This arrangement will address the need to respond to issues raised by AHR users and providers.

Where a breach of the AHR Act is alleged, AHRC has an agreement with the RCMP, the federal authority that may assist in investigating such complaints. If, for example, an offer to buy an egg or pay for a surrogate mother's services (both activities prohibited under the Act) were reported and an individual or business were deemed to be in violation of the Act, the case might be turned over to the RCMP for investigation.

Another key piece of the Agency's infrastructure is the Personal Health Information Registry. The information to be supplied will be set out in the regulations, currently being developed by Health Canada. This information is confidential and can only be disclosed under specific circumstances: for example, where an individual conceived by AHR wishes to obtain the health reporting information (such as medical history) of their donor, or where two individuals wish to know if they were conceived from the same donor. In this regard, the aim of the registry is to allow people conceived through donation to obtain information about their genetic background in order to make informed decisions in such matters as medical treatment, marriage and having children. However, AHRC cannot disclose a donor's identity without the donor's written consent.

AHRC has visited fertility clinics across the country to document what information is currently being gathered, how and by whom, and how it is stored. It is working with clinics and other partners to develop the Personal Health Information Registry in ways that protect the privacy and information security of all involved. The Agency is also working with stakeholders to identify the types of data that may be released on AHR outcomes in order to monitor trends and developments that could improve the safety, efficacy and efficiency of AHR procedures in Canada.

Implementing the Regulations – "Consent to Use"

The first set of regulations developed by Health Canada came into force on December 1, 2007. These regulations fulfill legislative requirements under Section 8 of the *Assisted Human Reproduction Act.*

Section 8 deals with the written consent required from a donor to use human reproductive material to create an embryo or to use *in vitro* embryos for any purpose. The regulations specify the type of information that the donor must receive before giving their consent, and the requirements for consent and the withdrawal of consent.

Coming to terms with terminology

Legislation: Written laws, referred to as Acts or statutes, enacted by Parliament. When legislation is first drafted and tabled in Parliament, it is called a bill. In order to become law, a bill must receive the consent of the House of Commons and the Senate and Royal assent by the Crown.

Regulations: A form of law that defines the application and enforcement of legislation. Regulations are made under the authority of an Act passed by Parliament, called an Enabling Act, which specifies the body authorized to make regulations (such as a minister or the Governor in Council, i.e., Cabinet).

Guidelines: Departmental documents used to interpret or clarify legislation and regulations. While they are derived from legislation and describe how to comply with the regulations, guidelines do not have the force of law.

Supporting the Board's contributions

The multidisciplinary membership and independence of AHRC's Board of Directors are crucial to the Agency's work of protecting the health and well-being of AHR users and children born through assisted reproductive technologies.

Since its inaugural meeting in March 2007, the Board has demonstrated its determination to apply ethical principles to all aspects of AHRC's operations. It adopted a set of Guiding Principles to govern Board members' activities. The Guiding Principles include independence, transparency, evidence-informed decision-making, inclusiveness, knowledge-sharing and accountability. These principles reinforce that the Board must place the public interest above all others in managing its programs, responsibilities and activities. At the same meeting, the Board also approved the Agency's first by-laws, budget, and the Report on Plans and Priorities for 2007–08.

At subsequent Board meetings in June and September 2007 and January 2008, Directors were briefed on key issues by representatives of the public and private sectors involved in the AHR field. In addition, Board members provided comments on Health Canada's regulatory proposals, the Agency's communications strategy, and plans for the AHRC Web site. As Directors believe it is important to listen to and learn from the

communities they serve, Board members are also meeting with groups with an interest in the AHR Act, including physicians, clinics, patients and agencies serving patients. AHRC has played a supportive role in all of these activities.

Creating and applying new knowledge

Research is vital to informed, evidence-based decision-making and a high priority for AHRC. The Agency is in the process of developing a comprehensive research agenda to support and guide its work as it moves forward and to confirm AHRC as a national centre of expertise on assisted human reproduction.

The Agency is planning the first meeting next year of a new Scientific Advisory Panel that will advise the Board of Directors on scientific matters affecting the Board's responsibilities. This will improve AHRC's ability to identify scientific innovations and assess the implications of their application.

Recognizing that research is a collaborative effort, the Agency has also entered into a Cooperative Agreement with the Canadian Institutes of Health Research (CIHR) to enable the two organizations to advance a national reproductive health research agenda. Both the Agency and CIHR are committed to achieving three related shared goals: developing a national AHR research strategy; organizing activities, such as workshops, to consult the research community and stakeholders to facilitate the development of strategic research priorities in Canadian AHR research; and, establishing a collaborative program to provide a structured, peer-reviewed funding stream for Canadian research relevant to the mandates of AHRC and CIHR.

Reaching out to Canadians

AHRC is committed to becoming a centre of expertise and a focal point for AHR information for policy makers, practitioners, researchers, patients, offspring and interested Canadians.

As well, the President and the Chair have made presentations to, or attended, numerous meetings and conferences at home and abroad to explain AHRC's mission and mandate, and to learn from others with experience in the field. An AHRC newsletter was launched in winter 2007–08 to keep stakeholders and the public apprised of the latest activities of the Agency and its Board of Directors. The newsletter will be published three times a year.

A user-friendly, interactive Web site is also under construction and will be launched in 2008. It will lead visitors to information about AHRC, the AHR Act and regulations and other issues related to the Agency's work, and will provide helpful links to other valuable resources for people interested in learning more about AHR. The site is designed to serve as a reliable source for individuals and families looking for the latest information about developments in reproductive technologies and how they affect their choices and options, and as a resource centre for providers, health professionals and children born of assisted human reproduction.

In a further effort to make it easy for Canadians to get the answers they need to their questions about AHRC or to be referred to other AHR sources, a toll-free number has been established: 1-866-467-1853. Canadians can also contact AHRC by e-mail at the following address: info.ahrc-pac@hc-sc.gc.ca.

“It is estimated that approximately one-third of cases of infertility are due to male factors, one-third to female, and the remaining third to a combination of both male and female factors. In approximately 20% of cases, the origin of the condition is unexplained.”

[Source: American Society for Reproductive Medicine, www.asrm.org]

Our plans for the future

AHR issues know no borders: today, reproductive technologies are readily available in countries around the globe. For people wanting to start a family, the option of going elsewhere for AHR services is one that many people are willing to consider. However, the risks may be great, particularly in countries that do not have a strong regulatory system. If complications arise, there is little protection for such people or the offspring they hope to create.

AHRC is working with international regulatory bodies to share knowledge and lessons learned and to establish global standards of acceptable care and treatment for people who opt for treatment overseas. The Agency is committed to ensuring that individuals seeking treatment outside Canada have the necessary information to make wise and safe choices, both prior to receiving AHR services abroad and after their return to Canada for subsequent care. It is equally determined to collaborate closely with global partners to address the challenges and opportunities presented by cross-border reproductive care.

Moving forward, the Agency will build on its collaborative arrangements with other federal departments and agencies assisting with the implementation of the regulations. It will also expand its consultations and information sessions with a variety of communities with an interest in AHR.

Financial statement

Summary financial information

In 2006–07, Assisted Human Reproduction Canada (AHRC) operated with a budget of $9,681,000 and an approved staff level of 44 employees. For 2007–08 it has a budget of $13,476,000 and an approved staff level of 44 employees.

In the fiscal year April 1, 2006 to March 31, 2007 the Agency was operating for only 90 days, and as a result spent only $134,000 of its allocated funds. Of the remaining balance, $451,000 was allocated to fiscal year 2007-08 as an operating budget carry forward, and the remaining balance was returned to the consolidated revenue fund of the Government of Canada.

In the fiscal year April 1, 2007 to March 31, 2008, the Agency undertook staffing, infrastructure and operational activities that will result in significantly higher spending.

Financial summary
($ thousands)

April 1–March 31	2006–07		2007–08	2008–09
	Approved Funding	**Actual Spending**	Approved Funding	Approved Funding
Total AHRC	$9,681	$134	$13,476	$12,418
Full Time Equivalent	44	1	44	44

Further details on the financial statements can be found at:

Departmental Performance Report

http://www.tbs-sct.gc.ca/dpr-rmr/2006-2007/inst/rap/raptb-eng.asp
and
http://www.tbs-sct.gc.ca/dpr-rmr/2006-2007/inst/rap/rap03-eng.asp#16

Departmental Report on Plans and Priorities
2007–08
http://www.tbs-sct.gc.ca/rpp/0708/AHRAC-ACCPA/AHRAC-ACCPA_e.asp

2008–09
http://www.tbs-sct.gc.ca/rpp/2008-2009/inst/rap/rap00-eng.asp

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By the numbers	
AHR technology clinics in Canada in 2005	25
Treatment cycles involving AHR	11,414
Number of *in vitro* fertilization procedures performed	8,496
AHR cycles resulting in a clinical pregnancy	3,443
AHR cycles resulting in a delivery	2,713
AHR cycles resulting in a live birth	2,687
Multiple birth sets resulting from AHR procedures	804
Total number of multiple birth infants	1,645
Number of twin births resulting from AHR procedures	767
Total number of twins	1,534
Triplet sets resulting from AHR procedures	37
Total number of triplets	111
Clinical pregnancy rate per cycle	30.2%
Live birth rate	23.8%

Source: Gunby, J., Bissonnette, F., Librach, C., Cowan, L., IVF Directors Group, Canadian Fertility and Andrology Society. "Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register," Fertility and Sterility.

Article in Press 2008, accessed April 25, 2008.