Health Canada Santé Canada

Counselling Services Under the Assisted Human Reproduction Act

Public Consultation Document

Prepared by Health Canada

Canada

Table of Contents

1. Purpose of Document 1

2. Background Information 1

2.1 Risks of AHR and Purpose of AHR Counselling 1

2.2 Consent Framework and Scope of Counselling under the *Assisted Human Reproduction Act* 3

2.3 Considerations in Making Regulations 4

2.4 AHR Counselling in Canada and Internationally. 5

2.5 Genetic Counselling 6

3. What We've Heard So Far 6

4. Policy Options for the Regulation of AHR Counselling Services 8

4. 1 When To Provide Counselling Services 9

4.1.1 Questions for Stakeholders 10

4.2 Who Provides Counselling Services 10

4.2.1 Questions for Stakeholders 11

4.3 Issues To Be Covered in a Counselling Session 12

4.3.1 Questions for Stakeholders 13

4.4 Responsibilities of Licensees 13

4.4.1 Questions for Stakeholders 14

Annex A: International Comparison of Requirements for AHR Counselling 15

Annex B: Reference List 17

Glossary of Terms 19

1. Purpose of Document

The purpose of this document is to seek input from stakeholders on options for the regulation of counselling services under the *Assisted Human Reproduction Act* (AHR Act). The AHR Act governs the area of assisted human reproduction (AHR) and related research (activities such as *in vitro* fertilization, intra-uterine insemination, embryo research, etc.). The Act prohibits unacceptable AHR practices and provides for the regulation of controlled activities and the licensing of persons authorized to undertake those activities. The Act also provides for the establishment of an agency, Assisted Human Reproduction Canada (AHRC), which will be responsible for licensing and inspecting activities controlled under the Act.

The Act requires that counselling services be made available and received prior to certain AHR activities and allows for the development of regulations pertaining to those counselling services. It is part of the mandate of Health Canada's Assisted Human Reproduction Implementation Office (AHRIO) to develop the policy for these regulations following consultations with Canadians.

This document examines the questions of when, how and by whom those counselling services should be provided. This document also provides background information on AHR, the scope of counselling under the AHR Act and the federal regulatory process. The options and recommendations in this document are based on feedback we have received to-date from stakeholders (including AHR clinics, patients, and counselling professionals), as well as on existing literature and international guidelines. Following each section on regulatory options, there are a series of questions on which we would like feedback from our stakeholders.

Based on the comments we receive on this document, Health Canada will draft proposed regulations. These proposed regulations will be published for public comment in the *Canada Gazette*, Part I and posted on the Health Canada Web site. Following that second round of consultations (including a Parliamentary review) and ministerial approval, the final regulations will be published in Part II of the *Canada Gazette* and will become law.

2. Background Information

2.1 Risks of AHR and Purpose of AHR Counselling[1]

Broadly, AHR involves the use of medical and scientific technologies to facilitate reproduction.

---

[1]Counselling in the context of AHR is commonly referred to as "infertility counselling." In this document, we use the term AHR counselling because not all users of AHR services experience infertility (e.g., same sex couples).

Counselling Services Under the AHR Act

The most commonly known procedures are artificial insemination (or intra-uterine insemination) and *in vitro* fertilization, although the fast pace of scientific developments are constantly increasing possibilities for achieving pregnancies. These AHR procedures can be done with a person or couple's own gametes, or with gametes donated by another person (also referred to as gametes donated for third party use). During the course of a particular treatment, patients may be faced with a wide range of options and decisions, such as how many *in vitro* embryos to transfer, whether to test *in vitro* embryos for certain genetic markers, whether to freeze unused gametes or *in vitro* embryos, whether to donate unused *in vitro* embryos to someone else or to research, etc.

AHR procedures can present physical risks to patients, women in particular, as well as to the children born. The medical and physical risks inherent in treatment are addressed by medical practitioners as standard protocol for obtaining informed consent to a medical procedure. However, there are psychological risks to individuals, including children, as well as psychosocial risks to families, communities and societies that require a different kind of exploration. Examples of individual psychological risks include depression, anxiety, and stress. Examples of broader social risks include work absenteeism and marital breakdown.

Indeed, the potential psychosocial challenges faced by those using AHR services are well documented. These challenges may vary and can include: feelings of guilt, anger, shame and depression regarding infertility; coping with grief and loss; learning how to manage the stress of treatment, and in some cases treatment failure; deciding whether and how to disclose AHR procedures to others, including children, family members and friends; learning how to accept a non genetically-related child; learning how to cope with the potential stigmas of using AHR procedures; and relationship distress. Many of these issues can be quite complicated and have long-term ramifications on both the physical and psychological health and well-being of individuals, including the children born from AHR procedures.

Counselling can help to lessen these risks and their potential impact and help people make informed decisions about their health and well-being. Counselling in the context of AHR involves the balancing of medical and technological issues with the social, emotional, legal and ethical impacts of the technology**.**

Although there is no single definition of AHR counselling, it broadly involves: providing psychological support; assessing attitudes, feelings and values; exploring short- and long-term ethical, social and psychological issues and consequences; improving coping mechanisms; and providing information and resources for support.

Counselling could also help to improve the success rates of AHR procedures. Many stakeholders are of the opinion that lessening symptoms of stress, anxiety and depression during AHR treatment increases the chance of pregnancy. In turn, improved success rates reduces the need for further AHR treatment and therefore, also reduces exposure to further physical and psychological risks.

2.2 Consent Framework and Scope of Counselling under the Assisted Human Reproduction Act

Discussions around informed consent for AHR services date back to the Royal Commission on New Reproductive Technologies (1989-1993). The Commission explained the difference between obtaining consent to AHR procedures and the process required in order to make an informed decision about one's health and well-being in the context of AHR:

> "...informed choice involves... the presentation of other available options, including non-medical ones, and support for patients in making choices from among those options...Informed choice means providing relevant and understandable information about the options and the possible implications of various decisions." (*Final Report of the Royal Commission on New Reproductive Technologies*, 1993)

The AHR Act is based on the guiding principle of free and informed consent. The Act also requires that the health and well-being of women should be protected. Most importantly, one of the principles set out in the Act states that the health and well-being of children born from AHR procedures should be given priority in all decisions respecting the use of AHR procedures.

Parliament felt that counselling was a necessary element to achieve fully informed consent and decided that a requirement for counselling, in addition to the other information and consent requirements in the AHR Act, was pivotal to the overall consent framework of the Act. Paragraph 14(2)(b) of the AHR Act states:

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

The Act requires that licensees ensure that the following persons receive counselling services:

- all persons donating human reproductive material (HRM);[2]
- all persons donating an *in vitro* embryo, and
- all persons providing health reporting information (which includes the above as well as

---

[2]Human reproductive material is a synonym of gametes. A "donor of human reproductive material" as defined in the Act includes individuals using their own gametes for their reproductive purposes. Similarly, it is expected that the definition of a donor, in relation to an *in vitro* embryo, will be the same as that proposed in the section 8 regulations which would include an individual or couple for whose reproductive use the *in vitro* embryo was created.

any person on whom a controlled activity will be performed, such as *in vitro* fertilization.[3])

The Act provides no additional details with respect to counselling but the regulations may establish further requirements. Therefore, questions such as who should provide the counselling and how the counselling should be provided can be addressed in regulations. This does not mean, however, that the regulations must provide these details.

It is important to note that the Act places responsibility for making counselling services available and ensuring they were received on the person licensed to undertake the AHR activity, not on the person providing the counselling. If the regulations provide details respecting how this counselling should be provided, it is the licensee who will need to ensure that the regulatory requirements were met.

Also, although the Act mandates counselling services for all the individuals listed above, this does not mean that the requirements must be the same for everyone. Indeed, the nature and severity of the potential risks may justify different requirements for different individuals or AHR activities.

2.3 Considerations in Making Regulations

While the Act provides the authority to make regulations, it is recognized that regulation is not always the best tool to achieve a desired policy goal. There are a few key points to keep in mind when developing regulations.

First, regulations have the force of law and contravention is considered a serious offence with serious penalties. Regulators must ensure that requirements are very clear, cost effective and do not impose unreasonable administrative burden.

With respect to regulations developed under the AHR Act, there needs to be a demonstrated risk to health and safety (which include risks of a psychosocial nature) that would be mitigated by regulation. If there are no health risks, or if the regulation might create significant additional burdens on those affected, other policy tools may be more suitable.

Some policies, while beneficial, are better addressed through Guidelines or Standards since these are more flexible than a regulation and can be changed and updated regularly and quickly. This is particularly important in the context of AHR where there are constant new scientific and

---

[3] Health reporting information and controlled activities are explained in the Glossary of Terms. The exact list of controlled activities under the AHR Act is still under development and will be the subject of consultations this Fall.

clinical developments. Guidelines and Standards can also be developed by stakeholders who have expertise in the area (such as AHR counselling professionals).

Finally, there are some issues that fall under provincial and territorial jurisdiction and federal regulations cannot interfere in these areas. Indeed, the federal government cannot regulate the profession of counselling.

2.4 AHR Counselling in Canada and Internationally

In Canada, there are no national guidelines for AHR counselling services. Each provider of AHR services currently sets its policies respecting the provision of counselling, including whether, when and how to recommend and/or provide counselling services.

The practice of AHR counselling is not a formally recognized profession in Canada. There are no academic or training programs currently offered in Canada that focus on counselling in the context of AHR. Most individuals who currently provide this service in Canada are mental health professionals (such as psychologists and social workers) with counselling experience and an interest in AHR issues. Most mental health professions have provincial or territorial licensing or registration requirements, however the practice of counselling *per se* is not a regulated profession[4].

In Ontario, there is a voluntary organization of infertility counsellors called the Southern Ontario Network of Infertility Counsellors (SONIC). Also, a group of Canadian counsellors has recently established a Counselling Special Interest Group of the Canadian Fertility and Andrology Society (CFAS). Membership in this group is open to professionals with academic credentials and clinical training in a counselling discipline (such as psychology, social work, psychotherapy, marital therapy and counselling). The mandate of this group includes, among other things, the development of standards of practice, the provision of professional development, and the promotion of understanding of the role of counselling in the field of AHR.

On the international front, requirements for counselling vary widely. The State of Victoria in Australia has made AHR counselling mandatory for all persons using AHR services. In other jurisdictions counselling must only be *made available* to patients. However, in many countries where there are no legal requirements for counselling, there are still accreditation requirements for clinics or professional practice guidelines that provide some direction respecting the provision of AHR counselling services. For example, both the UK and Australia provide minimum qualification requirements for professionals wanting to provide AHR counselling services. For more details respecting these international guidelines, refer to Annex A.

---

[4]With the exception of the Province of Québec which does license counselling professionals.

2.5 Genetic Counselling

In the context of AHR, a person (or couple) might also be offered genetic counselling when there is a concern respecting the transmission of a genetic disorder to the child or when a genetic condition is suspected to be the cause of infertility (or recurrent pregnancy loss).

For example, if there is a risk that an inherited disease could be transmitted to offspring, *in vitro* embryos can be tested for that particular genetic marker before they are implanted in the woman. This procedure is called pre-implantation genetic diagnosis (PGD)[5]. Or, when it is suspected that a genetic disorder might be the cause of infertility, specific AHR procedures (such as intracytoplasmic sperm injection) might be recommended.

Some stakeholders have expressed concerns that the AHR procedure itself may present a risk for genetic conditions in the child, as could the mother's age at the time of conception. In those cases, consideration may be given to providing genetic counselling before deciding on a course of AHR treatment.

It is possible for the regulations to differentiate between AHR counselling and genetic counselling. The regulations could, for example, specify for which controlled activities a person would need to receive genetic counselling, in addition to AHR counselling.

Genetic counselling is different from AHR counselling because it deals specifically with issues of genetic risk and genetic testing and because it is usually provided by a genetic counsellor who is trained to provide information about the genetic test, to help interpret the test results, and perhaps also to help make decisions respecting a course of action.

There is no legislation governing genetic counselling in Canada but the service is usually provided by trained and specialized genetic counsellors or medical geneticists. The Canadian Association of Genetic Counsellors provides certification to genetic counsellors who meet specific educational and training requirements. Medical geneticists are certified by the Canadian College of Medical Geneticists and some may also be medical doctors certified by the Royal College of Physicians and Surgeons and/or le Collège des médecins du Québec.

3. What We've Heard So Far

Health Canada has received many comments to date concerning counselling with respect to AHR

[5] For a more detailed review of issues related to PGD, please consult the public consultation document posted on the Health Canada web site at: http://hc-sc.gc.ca/ahc-asc/public-consult/col/pgd-dgp/pgd-dgp_e.html

services. In consultations on the regulations for section 8 of the Act (consent), we heard that counselling is an important element to obtain fully informed consent, particularly when gametes are donated for third party reproductive use or are used posthumously (after death).

From 2004 to 2006, Health Canada held targeted consultation activities with stakeholders who hold a particular interest in AHR counselling, including workshops with counselling professionals and with patients[6]. The purpose of these workshops was to discuss the scope of the regulations and obtain input on outstanding issues before proceeding with broader consultation on the issue of AHR counselling.

Both patients and counsellors felt that the broad objectives of counselling are to:

- enhance informed consent (provide information; make aware of options; ensure clients are informed);
- set out and discuss psychosocial ramifications and short- and long-term implications for the patients and for the children born;
- facilitate decision-making (discuss options and alternatives to treatment and family-planning, and decide when to stop treatment);
- help patients navigate and manage the process, allow patients to share painful emotions;
- help cope with the outcome of the procedure (whether positive or negative).

Health Canada also distributed questionnaires to patients to ask about their personal experiences with AHR. Patients told us that they experienced symptoms of depression, anxiety, sadness, stress, grief, fatigue and anger, to name a few. Although some patients expressed concern that mandatory counselling could further stigmatize users of AHR services, almost all respondents felt that counselling was beneficial.

Patients were mostly concerned with receiving information about AHR counselling services and having services available to them. They felt the counselling professional should be competent, qualified, and independent from the service provider; however, they stressed that they want the freedom to choose when, where, and by whom to obtain counselling.

Counselling professionals felt strongly that AHR counselling is separate from the patient care and education provided by nurses or medical staff. They hoped that standards of practice relating

---

[6]For detailed reports of these consultation activities, please visit our website at http://hc-sc.gc.ca/hl-vs/pubs/reprod/index_e.html

specifically to AHR counselling could be developed as part of the regulations. They felt that at the very least, those providing the counselling should: be mental health professionals belonging to a voluntary professional association with a code of ethics; have knowledge of issues related to AHR; and ideally, be a member of the CFAS Counselling Special Interest Group.

In addition, we heard from both counsellors and patients that although counselling for third party reproductive use of gametes is critical, the regulatory framework should provide maximum flexibility to both counselling professionals and patients.

Health Canada also undertook a telephone survey of 20 *in vitro* fertilization (IVF) clinics across Canada in June 2005 to better understand whether and how counselling is offered by clinics and to gather information to assess the possible impact of proposed policy options.

Of the 20 clinics interviewed, only one stated that it required mandatory counselling for all individuals, although all clinics made counselling available to clients, to varying degrees. Thirteen clinics made counselling mandatory for donors for third party use and/or recipients of third party donated gametes or embryos. Of the counsellors identified (either affiliated with a clinic or in private practice), 44% were psychologists, 21% were social workers, 8% were psychiatrists, and 27% were classified as "other" (including counsellors). Some clinics included the cost of counselling in their fees, while others only provided a list of referrals and clients paid for the service out-of-pocket.

Most clinic representatives interviewed agreed that counselling could be beneficial; however, many expressed concern that the Act mandated the receiving of counselling services. They felt that the decision to receive counselling should be left to the patient. Some clinic representatives also expressed the view that other AHR clinic staff, such as nurses or physicians, were qualified to provide counselling services.

4. Policy Options for the Regulation of AHR Counselling Services

Health Canada has reviewed the comments received to date concerning AHR counselling services. The department has begun to formulate options for the regulation of counselling under the AHR Act by weighing the pros and cons and examining the feasibility of all options.

Health Canada recognizes that some stakeholders are concerned with the mandatory requirement for counselling, particularly for those using their own gametes. The Act nonetheless requires that counselling services be received, to the extent required by the regulations.

We have also heard from stakeholders that the regulations should provide some parameters for counselling services, considering the absence of other tools such as professional guidelines.

Counselling Services Under the AHR Act

Those using AHR services want to know what to expect, and those providing the AHR services want to know what is expected of them.

4.1 When To Provide Counselling Services

The Act is clear that counselling must be received prior to the licensee accepting a donation or health reporting information. Stakeholders agree that counselling should be provided before obtaining consent.

Stakeholders felt that every situation is different and the regulations should not be too prescriptive with respect to the timing, amount and frequency of counselling. Counselling professionals are also concerned that regulations not limit their professional discretion.

We have heard from stakeholders that the type and amount of counselling should be directly related to the psychosocial risks of the particular course of treatment, or AHR procedure. We have also heard from stakeholders that the implications are different depending on the activity being considered and that one counselling session is not enough to discuss all of the psychosocial implications for all possible AHR services. For example, a person using their own gametes may not be interested in discussing issues related to the use of gametes donated for third party use. But if their initial course of action is not successful they may later find themselves deciding whether to examine other options, which may have more serious psychosocial implications.

As previously mentioned, the regulations can set different counselling requirements for different controlled activities. It has been suggested that activities be grouped into categories (or treatment paths), depending on the level of risk and types of psychosocial issues that can arise.

Also, because the AHR Act does not define counselling services, it is within the scope of the Act to differentiate between AHR counselling services and genetic counselling services. There appears to be consensus among stakeholders that genetic counselling is a separate service that is distinct from AHR counselling.

Regulatory Policy Options:

- For the purpose of developing the AHR counselling regulations under paragraph 14(2)(b) of the Act, AHR activities could be grouped into categories based on psychosocial implications and issues that should be addressed. The list could be as follows:

    a) IVF using own gametes;
    b) all other (non-IVF) AHR services using own gametes;
    c) IVF using gametes or embryos donated for third party use;
    d) all other (non-IVF) AHR services using gametes or embryos for third party use;
    e) donating gametes or *in vitro* embryos for third party reproductive use;

f) donating *in vitro* embryos for research;
g) removal of reproductive tissue to preserve the possibility of reproduction;
h) posthumous removal and use of gametes or *in vitro* embryos for reproductive purposes;
I) pre-implantation genetic diagnosis of *in vitro* embryos;
j) intracytoplasmic sperm injection (ICSI).

- The regulations could require that counselling be tailored to different categories of activity. If following a particular type of activity, a person wishes to undergo a new activity under a new category, additional counselling would need to be received to discuss the new/different psychosocial implications.

- The regulations could require that prior to certain controlled activities, genetic counselling should be provided and received, in addition to AHR counselling.

4.1.1 <u>Questions for Stakeholders</u>:

a) Do you think that the regulatory requirements should be different depending on the AHR activity being undertaken?

b) Do you think that AHR activities should be grouped for the purpose of developing regulations respecting counselling services? What do you think of the proposed list?

c) Do you think that the regulations should specify controlled activities for which genetic counselling should be received, separate from AHR counselling? If yes, for which activities?

4.2 Who Provides Counselling Services

This is perhaps the most complex issue for the regulation of AHR counselling. As mentioned, AHR counselling is not a formally recognized profession in any Canadian province and it is not the mandate of the federal government to regulate the counselling profession. The options for regulations are therefore limited.

The main concern is to ensure that the person providing the counselling is qualified. Health Canada is also concerned that patients receive counselling that will mitigate risks to their health and well-being, as well as to their children's health and well-being. Nevertheless, Health Canada is aware of patients' concerns with availability of services, additional costs, and freedom of choice.

<u>Regulatory Policy Options</u>:

Counselling Services Under the AHR Act

- The regulations could stay silent with respect to who can provide AHR counselling services. This would mean that anyone could provide counselling. Although this option provides maximum flexibility, there would be no way of ensuring that the person was qualified to discuss the psychosocial implications of AHR.

- Or, the regulations could require that the person providing the counselling belong to a mental health profession. The regulations could require either that:

    a) the professional be a member of a national, provincial or territorial professional association with a code of ethics, OR,

    b) the professional be licensed or registered by a provincial or territorial regulatory body.[7]

- The regulations could also have different requirements depending on the AHR activity. For example, for those activities associated with higher psychosocial risks (such as IVF and use of gametes donated for third party use) the regulations could require that the person providing counselling be a mental health professional as described above. For other activities (such as intra-uterine insemination with own gametes), the regulations could not specify who shall provide counselling (therefore, it could be any type of counsellor, or a nurse, or a doctor).

- If the regulations require genetic counselling for certain AHR activities, the regulations could specify that genetic counselling should be provided by either a genetic counsellor certified by the Canadian Association of Genetic Counsellors or a medical geneticist certified by the Canadian College of Medical Geneticists.

4.2.1 <u>Questions for Stakeholders</u>:

a) Do you think that the regulations should specify who can provide the counselling services that a licensee must make available? If yes, who do you think would be best suited to provide these counselling services?

b) Do you think the person providing the counselling must be a mental health professional? If yes, does the person need to be licensed or registered, or is membership in a voluntary professional association sufficient?

---

[7]Health Canada is studying the feasibility of grandfathering provisions for those professionals who have extensive experience providing AHR counselling services but who may not meet regulatory requirements.

c) Do you think that the requirements respecting who can provide counselling should be different depending on the type of activity being undertaken and the level of psychosocial risk for that activity?

d) Do you think that the regulations should require that the person providing genetic counselling be certified by either the Canadian Association of Genetic Counsellors or the Canadian College of Medical Geneticists?

4.3 Issues To Be Covered in a Counselling Session

As previously discussed, there are no existing national standards for AHR counselling; the range of expertise and training of those providing the service leads to variations in practice. We have heard from people using AHR services that they want to ensure that counselling meets their needs and is provided by competent, qualified persons.

The AHR Act does not provide a definition of counselling services and the regulations cannot provide a definition to outline what is meant by counselling services. There are therefore two options to provide a minimum level of national uniformity and to provide guidance to patients, clinics and professionals.

Regulatory Policy Options:

- A first regulatory option is to specify the purpose of AHR counselling. This would serve as a guide to counsellors and patients and would make it explicit that the counselling service that needs to be provided is separate and different from the medical and treatment information provided by the person performing the AHR activity. For example, the regulations could state:

  > "The purpose of the counselling service is to address psychosocial implications, that is, to help donors to understand and contemplate their options and the short- and long-term implications of the AHR activity."[8]

- Another option is to include in the regulation a minimal list of issues that should be addressed in a counselling session, regardless of who is providing the counselling. Based on literature reviewed, existing international guidelines, and feedback from stakeholders, Health Canada has developed the following list of issues that could be discussed in

[8]This was wording proposed by counselling professionals at the May 2004 Health Canada Workshop on Infertility Counselling.

counselling prior to undergoing an AHR activity. Health Canada recognizes that this is a general list and that not all of the issues listed below are applicable to each and every AHR procedure.

- Reason for and feelings about undergoing the AHR procedure.
- Psychosocial impact of undergoing the AHR procedure.
- Implications and strategies of disclosure versus non-disclosure of use of the AHR procedure to others.
- Long-term psychosocial implications unique to those children born through AHR procedures.
- Coping strategies for the management of AHR procedures and their outcome.
- Future decisions respecting the disposition (including the transfer, freezing, destruction and/or donation) of any *in vitro* embryos and/or gametes in excess of immediate reproductive needs.
- Future options and decisions respecting the use of other AHR procedures.
- Alternatives to the AHR procedure.

4.3.1 <u>Questions for Stakeholders</u>:

a) Do you think that the regulations should a) state the purpose of AHR counselling services, OR b) provide a list of issues that need to be discussed in counselling, OR c) neither is necessary?

b) If the regulations limit who can provide the counselling service, do you think there is still a need for the regulations to establish the list of issues to be discussed in counselling?

c) If you agree that the regulations should list the issues to be discussed, do you think that the list should be different for each activity or category of activities, as discussed in section 4.1?

4.4 Responsibilities of Licensees

The Act lays out two responsibilities for licensees: to make available counselling services and to ensure that they are received. The responsibility is therefore on the person licensed to undertake the controlled activity, not the person providing the counselling service. Failure to meet the

regulatory requirements respecting counselling could result in sanctions such as suspension or revocation of a license under the AHR Act or even criminal charges. The regulations will therefore need to be very clear regarding the responsibilities of licensees.

Regulatory Policy Options:

- The regulations could require that licensees provide all prospective donors of HRM, *in vitro* embryos and providers of health reporting information a list of individuals who can provide the counselling service required for the controlled activity in question. The regulations could also be more specific with respect to this list. For example, they could require that the licensee provide a minimal number of names. Also, they could require that at least one person on the list be independent from the licensee.

- Licensees will need to have evidence that counselling was received. This could be in the form a written document signed by the person who provided the counselling, or the person who received the counselling, or both.

4.4.1 Questions for Stakeholders:

a) Do you think the regulations should require the licensee to provide a list of counsellors? If yes, should the regulations provide specific requirements respecting this list, and if so, what type of requirements?

b) Are there any concerns with requiring the person who provided the counselling to sign a document stating that they provided counselling, as per the regulations, to a specific person?

c) Should there be any other requirements on the part of the licensee?

ANNEX A

INTERNATIONAL COMPARISON OF REQUIREMENTS FOR AHR COUNSELLING

United States

The United States does not have legislation pertaining to AHR and there are no statutory requirements for infertility counselling. Clinical practice varies and professional accreditation of counsellors is granted by various mental health professional bodies. However, the American Society of Reproductive Medicine (ASRM) has issued *Guidelines for Psychological Assessment and Screening for Gamete and Embryo Donation*. These Guidelines recommend that the counsellor possess a graduate degree and clinical training in either psychology, social work, marriage and family therapy, psychiatry or nursing, as well as training in the medical and psychological factors of infertility and its treatment. The ASRM also has a Mental Health Professionals Group that provides continuing education opportunities for professionals providing counselling.

Australia and New Zealand

New Zealand does have AHR legislation in place, the Human Assisted Reproductive Technology Act. Australia does not have federal AHR legislation in place.[9] However, the Reproductive Technology Accreditation Council (RTAC) that governs Australia and New Zealand issues requirements for all infertility clinics.

RTAC mandates counselling for recipients and donors in third party conception and requires that counselling be available for all AHR users. RTAC has developed *Guidelines for Counselling,* including special *Guidelines for Counselling Potential Gamete Donors*, which detail the expected outcome of the counselling session and the information and issues to be discussed in counselling.

RTAC also requires that clinic counsellors be members of the Australia and New Zealand Infertility Counsellors' Association (ANZICA). ANZICA is an association of professional counsellors and has established *Guidelines for Counselling*. To be members of ANZICA, counsellors must have a degree in either social work, psychology or psychiatry; be members of a professional association; demonstrate knowledge of infertility and its treatment; and have supervised counselling experience.

[9]However some Australian states have legislation, including the State of Victoria that mandates counselling for all persons involved in AHR procedures.

Counselling Services Under the AHR Act

United Kingdom (UK)

The UK does have AHR legislation, the *Human Fertilization and Embryology Act*. Counselling is not mandatory but it must be offered to all AHR users. Counselling is particularly encouraged for recipients of donated gametes and for embryo donors. The UK's Human Fertilization and Embryology Authority (HFEA) has developed a *Code of Practice for Counselling* which outlines the expected qualifications of counsellors, the different types of counselling that should be offered, the factors to be considered when counselling, and the issues to be discussed in a counselling session.

The HFEA also requires that counsellors possess a degree in either counselling, clinical psychology, psychotherapy or social work, or that they be accredited by either the British Fertility Society or the British Infertility Counsellors' Association (BICA). BICA is a professional association for infertility counsellors that offers training and educational services. BICA also develops Practice Guides that provide guidance on how to counsel and what issues should be discussed in particular circumstances.

Europe

The European Society for Human Reproduction and Embryology (ESHRE) has developed *Guidelines for Counselling in Infertility*. These Guidelines recommend that counselling be delivered by someone with training in a mental health profession such as psychology, social work or counselling and with training in the medical aspects of reproduction.

ANNEX B

REFERENCE LIST

The following is a list of resources that were consulted in the preparation of this document

Burns, L.H., Covington, S.N. (1999). *Infertility Counselling: A Comprehensive Handbook For Clinicians.* Parthenon Publishing, New York.

Epalan Report: The development of a risk-based classification tool to allow for the assessment of risks and classification of controlled activities for the purpose of Bill C-13, An Act Respecting Assisted Human Reproduction and Related Research (2004).

Haase, J. (2003). Infertility Counselling: A Discussion Paper on Practice Standards and Guidelines. Prepared for Health Canada.

Treatment of Infertility: Current Practices and Psychosocial Implications. *Royal Commission on New Reproductive Technologies, 10, Ontario, Canada* (1993).

Vayena, E., Rowe, P.J., Griffin, P.D. (2002). *Current Practices and Controversies in Assisted Reproduction: Report of a WHO meeting.* World Health Organization, New Delhi.

<u>Guidelines</u>:

Code of Practice for Centres Using Assisted Reproductive Technology (2002). The Fertility Society of Australia: Reproductive Technology Accreditation Committee

Code of Practice: Fourth Edition (1998). Human Fertilization & Embryology Authority.

Guidelines for Counselling in Infertility. (1999). ESHRE: Psychology & Counselling

Implications Counselling for People Considering Donor-Assisted Conception (2004). British Infertility Counselling Association.

Opening the Record: Planning the Provision of Counselling to People applying for Information from the HFEA Register (2003). Report of the HFEA Register Counselling Project Steering Group.

ANNEX B (CONT'D)

REFERENCE LIST

Journals:

The following is the list of journals that were consulted. For a detailed list of articles used, please contact Health Canada.

American Journal of Obstetrics and Gynecology
Australian Psychologist
Child Development
Developmental Psychology
Family Systems Medicine
Fertility and Sterility
Human Reproduction
Journal of Child Psychology and Psychiatry
Journal of Counseling and Development
Journal of Psychosomatic Obstetrics & Gynecology
Journal of Reproductive and Infant Psychology
Social Work in Health Care
The New England Journal of Medicine
Pediatrics

GLOSSARY OF TERMS

Assisted Human Reproduction (AHR) refers to the use of medical and/or scientific technology to facilitate human reproduction. Examples of AHR include *in vitro* fertilization, artificial insemination and intra-cytoplasmic sperm injection (ICSI).

Canadian Fertility and Andrology Society (CFAS) is an organization whose mission is to promote study and research in the field of infertility. Members include gynaecologists, urologists, reproductive endocrinologists, research scientists, and other health care professionals from across Canada as well as from other countries.

Controlled activity refers to an AHR activity that may not be undertaken except with a license and in accordance with the regulations pertaining to the AHR Act.

Donor refers to the person from whose body the human reproductive material (gametes) were obtained. Also refers to the person or couple for whom the *in vitro* embryo was created.

Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being.

Gamete means the mature male or female reproductive cell (sperm or ovum). Also referred to as human reproductive material (HRM).

Health Reporting Information (HRI) means information provided under the Act respecting (a) the identity, personal characteristics, genetic information and medical history of donors of human reproductive material and *in vitro* embryos, persons who have undergone assisted reproduction procedures and persons who were conceived by means of those procedures, and b) the custody of donated human reproductive materials and *in vitro* embryos and the uses that are made of them.

Human Reproductive Material (HRM) refers to sperm, ovum (eggs), other human cells, or human genes.

ICSI (Intracytoplasmic sperm injection) is an AHR procedure where a single sperm is injected into an egg using a microscopic needle. This procedure is used where the male partner has severely impaired or few sperm.

***In vitro* embryo** means an embryo that is maintained outside a woman's body (*in vitro* means "in a glass" and usually refers to a culture dish or other laboratory vessel).

***In vitro* fertilization (IVF)** is a common infertility treatment that involves the creation of an embryo *in vitro*. The resulting embryo is matured outside the body for a period of time and then may be transferred to the body of a woman to implant, and result in pregnancy.

Licensee refers to a person who is issued a license to undertake a controlled activity under the AHR Act.

Pre-implantation Genetic Diagnosis (PGD) is the analysis of genetic material from an *in vitro* embryo before the embryo is transferred to the body of a woman.

Psychosocial refers to both psychological and social factors. Psychosocial counselling is counselling that addresses individual psychological factors as well as the broader social factors that influence one's mental health and behaviour.