Health Canada Santé Canada

Assisted Human Reproduction Counselling Services

Workshop Report

April 28, 2006

Four Points Sheraton
Gatineau, Quebec

Canada

The following workshop report summarizes the discussions that took place at the April 28, 2006 workshop on Assisted Human Reproduction Counselling Services. The comments and opinions expressed in this document are those of the workshop participants and do not necessarily reflect the views of Health Canada.

In particular it should be noted that some of the comments in this report, made during the workshop, may be inconsistent with the policy intent and the legislative framework of the Assisted Human Reproduction Act.

Table of Contents

Executive Summary

This report summarizes the proceedings of a one-day workshop organized by the Assisted Human Reproduction Implementation Office (AHRIO) of Health Canada to gather information to develop regulations respecting counselling services for assisted human reproduction pursuant to paragraph 14(2)(b) of the *Assisted Human Reproduction Act* (the Act). The workshop was attended by a pan-Canadian group of professionals who currently provide assisted human reproduction (AHR) counselling services. In preparation for the meeting, participants were provided with background information outlining some of the considerations for the regulation of counselling services under the Act.

The workshop began with presentations on the Act and on AHR counselling services specifically, to set the context for discussions. Participants were invited to ask general questions about the Act, before proceeding with discussion on the following questions:

1. What is the purpose of AHR counselling?
2. Who should provide AHR counselling services mandated under the Act?
3. How should AHR counselling be provided?
4. How should the AHR counselling regulations be enforced?

The workshop then continued with a discussion on the purpose of AHR counselling. Participants agreed that the main goal of AHR counselling is to provide support for informed decision-making, which is not necessarily the same as what is commonly referred to as implications counselling. Although there was debate regarding the issue of counselling as assessment (gatekeeping), Health Canada explained that this is not the intent of the Act.

Participants discussed the advantages and disadvantages of the regulations listing the specific issues that should be covered in an AHR counselling session. They recognized the benefit of having some sort of list but ultimately decided that such a requirement would be best placed in a professional Code of Practice or in Guidelines, not in regulations; however, participants expressed concern that if the regulations cannot specify the education, training and knowledge of counsellors, then a list of issues to be discussed would provide some minimal assurance with respect to the quality of the counselling service.

Participants felt that the most important issue was that of who would be providing the counselling service mandated under the Act. As there are no Canadian standards or guidelines in this area, they discussed various options, including requiring that counsellors be members of professional colleges with a mental health focus, and/or requiring membership in the newly established Counselling Special Interest Group of the Canadian Fertility and Andrology Society, or even simply letting the licensee decide.

On the questions of how, when and how much counselling should be provided, participants stressed that the regulatory requirements should be practical and cost efficient for patients and

that they should allow for professional discretion and flexibility. Participants agreed that persons using AHR procedures involving third party donated gametes require more and a different type of counselling than those using their own gametes. Participants also agreed that counselling requirements should be tied to what they called treatment paths, as opposed to specific controlled activities under the AHR Act, and that counselling should be repeated once implications change and/or the person's situation changes.

Finally, participants agreed that the counsellor should be expected to provide the licensee with a form stating that counselling was provided as required by the AHR Act.

The meeting ended with an update by a workshop participant on the Canadian Infertility Counsellors' Association (now the Counselling Special Interest Group under the CFAS) and a summary of next steps by Health Canada.

1. Overview of the AHR Act and AHR Counselling Services

The meeting began with a presentation by Francine Manseau (Senior Strategic Policy Advisor, AHRIO) who provided an overview of the Act. Ms. Manseau reviewed the prohibited and controlled activities, the principles of the Act, the federal regulatory development process, and the role of the Assisted Human Reproduction Agency of Canada (the Agency).

Christine Aubry (Senior Policy Analyst, AHRIO) then made a presentation focussed on the key considerations for the development of regulations pertaining to counselling services under the Act. She explained the limitations of the Act, provided a brief overview of the Canadian and international context for AHR counselling, reviewed the outcomes of previous Health Canada consultation activities with respect to AHR counselling, and highlighted the outstanding issues that require discussion prior to the development of policy options for regulations.

Following the presentations, participants were provided with the opportunity to ask general questions, prior to examining the specific questions for discussion.

One participant noted that the Act should have been more explicit in noting that it is women's physical health that is more affected than men's, but that the emotional impact of AHR is significant for both genders.

A participant asked whether the proposed regulations would be presented to Parliament as a package. Health Canada explained that some regulations, such as the regulations respecting section 8 (consent) of the Act, could be presented in advance of others; however, the intent is to bring forward a comprehensive package of regulations.

A participant asked how Health Canada solicited participants for the April 2006 patient workshop[1]. Health Canada replied that a notice was sent to several AHR patient groups (such as the Infertility Awareness Association of Canada) and local support groups. Health Canada tried to select a cross-cultural representation of participants. The criteria that was used to choose the participants included the following: representation from individuals who had used third-party donated gametes in an AHR procedure and those who had used their own gametes in an AHR procedure as well as those who were considering AHR procedures; geographical representation by province and city including representation from both rural and urban cities; representation of both couples and single individuals, including people from the lesbian or gay community; representation from various ethnic groups; representation from individuals who were active in the development of the AHR legislation and/or who were leaders in the AHR community, as well as those with little knowledge of the AHR community.

Participants asked what is meant in the Act by ensuring that services are "made available."

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[1]Health Canada held a workshop with AHR patients in Toronto on April 7-8-9, 2006.

Health Canada replied that licensees will be required to ensure that counselling services were both available to patients and received by them, but that the Act does not require that licensees be the ones to provide the service.

A participant asked how much leeway there is for developing regulations and what is meant by the wording "to the extent required by the regulations" in the Act. Health Canada explained that receiving counselling prior to donating human reproductive material or an *in vitro* embryo or providing health reporting information (HRI) is mandatory, but that the regulations can provide further details respecting who provides the counselling, when, and how and that these are the issues to be discussed at this meeting.

2. Discussion: What is the Purpose of AHR Counselling?

Christine Aubry introduced the discussion by noting that there is no definition of AHR counselling. She presented the definition that was proposed by participants at the Infertility Counsellors Workshop in May 2004[2]. It was stressed that Health Canada does not intend for the counselling mandated under the Act to entail psychological screening for treatment suitability, but rather that it reflects what is often referred to as "implications counselling." She also explained that the regulations cannot provide a definition of AHR counselling, but that there nonetheless needs to be a common understanding of what is meant by AHR counselling services in order to develop regulations in this area.

Participants agreed that a key goal of AHR counselling is to provide support for informed decision-making. They also agreed that AHR counselling can identify patients' vulnerabilities and concerns and can provide different types of support (stress management, therapeutic support, etc.). Participants noted that AHR counselling is not always about implications counselling because in some situations there may not be any psychosocial implications (for example, in the case of a woman only using the fertility drug Clomid to achieve a pregnancy with her partner). Indeed, sometimes counselling revolves around dealing with stress and providing coping mechanisms.

There was disagreement among participants respecting the issue of counselling as assessment. Some felt that it should be the role of the counsellor to assess whether or not a patient or donor is

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[2]The definition proposed was as follows:

Infertility counselling deals primarily with the psycho social impact of infertility, in terms of intervention, treatment and aftermath of both successful and unsuccessful treatments. Infertility counselling deals with implications, that is, helping patients to understand and contemplate their treatment options and the short- and long-term implications of treatment.

suitable, based on the need to protect the health and well-being of children (much like with the adoption model). Others expressed caution at what they felt could lead to an over-pathologizing of people with fertility problems and people using AHR.

Health Canada explained that "gatekeeping" is not the intent of the Act nor of the regulations. Whether or not to assess for treatment suitability will remain the prerogative of each licensee and this issue can be explored by professionals in another forum. Participants agreed that the notion of assessment varies according to different professions and that professionals need to have degrees of freedom respecting their professional practice. Regardless, it was noted that all counsellors collect some amount of information from patients as part of a standard history-taking, and not necessarily an assessment per se.

Finally, there was general consensus that genetic counselling is a service entirely separate and distinct from AHR counselling and that receiving genetic counselling alone should not be considered sufficient to meet the counselling requirement in the Act.

2.1 Discussion: Should There Be a List of Issues Discussed in Counselling?

Participants discussed the pros and cons of the regulations listing the issues or topics that should be covered in an AHR counselling session.

They felt that one of the advantages of listing the issues is that it would ensure that all people using AHR technologies receive the same level of counselling. Similarly, if the list of issues is detailed in regulations, this would ensure that patients know what to expect from counselling. As well, tailoring such a list to the type of AHR activity could also serve to highlight the difference (in terms of psychosocial risks) between own gamete use and third party gamete use.

Although there was overall support for a suggested list of issues presented by Health Canada, participants agreed that it was not possible to develop an exhaustive list and that the field of AHR changes too rapidly for any list enshrined in regulations to remain useful. Participants also pointed out that counselling needs to be tailored to a person's needs and situation and that a list does not allow for diversity issues to be captured. Some participants expressed concern that a list can appear like a "cookbook" and that someone still needs the training to be able to provide the service. They felt that a list of this sort would be more useful as part of a training program for AHR counselling providers, as opposed to a requirement in the regulations.

Participants agreed that it is important to define a counsellor's scope of practice but that the process and tools should remain flexible. They therefore felt that a list of topics for discussion should be in Guidelines or in a Code of Practice rather than part of the regulations. Participants were not opposed to ensuring that certain issues are covered in a counselling session but they were not comfortable with it being mandated by law.

Health Canada reminded participants that the regulations target licensees and not the professionals providing the service. However, Health Canada explained that it could be a role of the Agency to develop standards or guidelines for those providing AHR counselling services.

Participants explained that in their view the issue of who will provide the counselling services is more important than how the service will be provided. Indeed, if there is a way to ensure that those providing AHR counselling are suitable, then there is less of a need (and perhaps no need at all) for a mandated list of issues for discussion. They recognized however that if the regulations cannot specify the education and training of those who may provide the service, there would be a need to outline the broad topics of discussion so that patients know what to expect, albeit without placing limits on professional practice.

3. Discussion: Who Should Provide the Mandated AHR Counselling Services?

Christine Aubry launched the discussion by explaining that the Act does not specify who must provide the counselling services (only that the licensee must make it available and ensure it is received). There are no Canadian standards or guidelines for AHR counsellors to which regulations could refer and it was explained that federal regulations cannot interfere with matters of provincial jurisdiction such as professional education and training requirements. It was proposed that in the absence of a national licensing or accreditation body for AHR counsellors, one option would be for the regulations to refer to various provincial professional bodies and/or regulations.

A discussion took place on the issue of Canadian universities offering graduate courses in AHR. It appears that only two universities offer such courses, but most psychology programs offer health psychology courses. A participant informed the group that the Southern Ontario Network of Infertility Counsellors (SONIC) is in the process of setting up a training program via the Mitchener Institute.

Participants discussed the option of only requiring that the person providing the counselling be a member of a mental health or psychosocial professional association that has a Code of Ethics; however, they expressed concern that this requirement alone would not ensure a specialized scope of practice. They noted the advantage that membership in a professional college usually requires that one has specialized knowledge in one's area of competence. This would therefore provide additional assurance that the counsellor is knowledgeable in AHR issues and the AHR Act. However, a participant expressed concern that obtaining membership in a professional college is both time consuming, costly and not desirable for all counselling professionals.

Another option presented was to possibly require counselling professionals to belong to the Counselling Special Interest Group (CSIG) of the Canadian Fertility and Andrology Society (CFAS). Requiring membership in CSIG could provide some assurance of knowledge of the issues. It was suggested that CSIG could set standards of practice; however it was not clear

whether this group should take on the role of accreditation. A participant noted that the purpose of colleges is to protect patients, whereas CSIG will not have this function.

Finally, another option was presented whereby the clinic would decide who should provide the service. Clinics could have the responsibility of referring to a counsellor and of ensuring that the counsellor has the proper training and experience.

On the issue of grandfathering, there was consensus that the regulations should allow for the grandfathering of individuals who have been providing AHR counselling services but who may not meet all of the requirements set in the regulations. However, there was disagreement with respect to whether those grandfathered should be given a specific time period within which to meet the regulatory requirements.

4. Discussion: How Should AHR Counselling Be Provided?

Christine Aubry reminded participants that the Act only specifies that counselling must be received *prior to* accepting a donation of human reproductive material or an *in vitro* embryo or HRI; there is, therefore, some flexibility respecting the exact stage at which the counselling should be provided, how often, and whether there should be a waiting period between the person receiving counselling and the licensee accepting a donation and/or HRI.

Participants were sensitive to the need to ensure that requirements are cost efficient and practical for all patients. Participants agreed that group counselling can be very beneficial and appropriate in certain circumstances, and that professionals should have the option of doing group counselling. They noted, however, that you cannot impose group counselling on someone. Participants also agreed that phone counselling should be acceptable, but again, that it should be subject to professional discretion.

Christine Aubry noted that at the patient workshop, some patients felt that attendance at a support group should be sufficient to meeting any regulatory requirement. Counsellors recognized the many benefits of support groups, but cautioned that they should not be sufficient to meet a requirement for counselling, even if the group is facilitated by a professional counsellor. They explained that the purpose of support groups is very different than the purpose of individualized counselling (for example, in individualized counselling, the counsellor is much more directive, whereas in support groups they act as facilitators).

A participant noted that there is controversy surrounding the requirement for counselling for those using their own gametes; the literature does not support the need to mandate counselling for this group. It was therefore recommended that there be general information and counselling for everyone, and a specialized session for those using third party gametes. Participants agreed that third party donors and recipients require more intensive counselling than those using their own gametes. There was also strong consensus that both persons in a couple, regardless of

whose gametes were used, should receive counselling because there is a psycho social risk to the child if the intending parent is not seen by a counsellor.

Participants noted that education is very different from counselling. There was consensus that an orientation session is not equivalent to counselling. They also noted that once the patient establishes a relationship with someone, they want to return to that person which can encourage them to seek counselling. Participants agreed that the way in which counselling is presented is critical and that clinics should normalize the counselling service to ensure that patients will not feel stigmatized.

4. 1 Discussion: When and How Often Should AHR Counselling Be Provided?

Patients asked for clarity with respect that what is meant by the wording "prior to..." in the Act. Health Canada explained that, broadly, it means the counselling should be received before treatment starts, but that there could be different time requirements for different procedures.

Participants noted that the dilemma here resides in how much intervention is needed; however, they agreed that mental health professionals are best placed to know how much counselling should be provided.

Participants discussed *how many* sessions should be provided versus the *length* of the sessions. They pointed out the need to consider practicality, especially for people travelling long distances. But in conclusion, there was consensus that the number of sessions, their length and timing should remain at the discretion of the counselling professional.

Participants discussed the option of tying counselling requirements to the provision of informed consent. That is, if someone is undertaking another treatment for which a new consent is required, it can be assumed that the implications and the risks change. Therefore, the counselling needs change as well because there are new psychosocial implications that need to be discussed. They explained that all of the implications for all AHR procedures or treatment possibilities cannot be examined in one session. Participants also noted that patients generally do not want to discuss future treatment paths.

Participants noted that because there are always new treatments, distinctions should not be made based on procedures. There was agreement that counselling should be for the overall type of treatment, not necessarily for specific consent to a controlled activity. For example, IUI (intra-uterine insemination) and IVF (*in-vitro* fertilisation) may not have the same physical risks, but they raise similar psychosocial issues (such as how to cope with the stress of infertility and how to prepare for the possible failure of the procedure). They suggested that the counselling requirement be tied to treatment pathways, based on the psychosocial/ psychological issues raised by the treatment.

Participants discussed the option of a "cooling off period" of one month before using a third party gamete or embryo donor. However, there was general discomfort with any proposal of a mandatory time period, as long as counselling is obtained before obtaining consent and beginning treatment.

Participants raised the problem of collecting sperm for oncological reasons. Diagnosis and chemotherapy can happen very fast and there may not be enough time to obtain the counselling as required.

There was also discussion about the possibility of an "expiration period" after which counselling must be repeated. Many agreed that one year would be an appropriate limit for the counselling to remain valid.

A participant raised the scenario of a person or couple returning to have the same treatment (e.g., they had a baby using a gamete donor and later return to have a second baby with the same donor). There was disagreement respecting whether in such cases the person or couple should be required to obtain counselling again. Some suggested that the requirements should mirror those of the adoption model whereby there is a requirement to touch base, without needing to repeat the entire process. Some argued that once a woman/couple has had a child, the issues can be very different and the implications could change. It was also noted that patients may not return to the same clinic for subsequent procedures, thus making it difficult for the new licensee to keep track of the counselling that was received and whether it met the regulatory requirements. Nonetheless, all agreed that any requirements should be based on the well-being of the children and the goal of obtaining informed consent prior to treatment.

5. Discussion: How Should the AHR Counselling Regulations Be Enforced?

Christine Aubry reminded participants that the onus for ensuring that counselling is made available and received is on the licensee, not the counsellor. The regulations will need to specify exactly how counselling should be both a) made available and b) received, while ensuring that patient confidentiality is protected.

Participants confirmed that current practice varies widely with respect to whether the counsellor provides the clinic with records of the counselling session. Some counsellors provide a summary of their session in the patient's chart while others do not.

Participants suggested that one option could be to mandate that the counsellor provide the clinic with a generic form that states that particular issues were discussed in a counselling session. If the patient is required to sign this form, it further ensures that the counselling met their needs.

6. Other Issue of Interest: Update on the Canadian Infertility Counsellors' Association

A participant provided an update on the voluntary counsellors' group, formerly known as Canadian Infertility Counsellors Association. The group is now a special interest group under the Canadian Fertility and Andrology Society called the Counselling Special Interest Group (CSIG).

A Terms of Reference has been developed and the next step is to elect a Board; however, the group first needs more members (and members would be required to join the CFAS).

It is hoped that the group can hold its first meeting at the next CFAS Annual Meeting scheduled for November 15-18, 2006 in Ottawa.

Conclusion and Next Steps

Participants were thanked for their comments and feedback. Health Canada explained that a draft of the meeting report would be sent to them prior to being posted on the Health Canada Web site.

Health Canada reiterated the next steps for the development of regulations (including release of a public consultation document and publication of the proposed regulations in *Canada Gazette*, Part I) and explained that all Canadians would have a chance to provide their comments on the proposed policy options for the regulation of AHR counselling services.

Health Canada explained that there may be a need for further comments and input from AHR counsellors and that various methods would be used to solicit their feedback, including e-mail and telephone calls and/or teleconferences.