Health Canada Santé Canada

Patient/Consumer Workshop

Meeting Report

April 7 - 9, 2006

Sheraton Gateway Hotel
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Prepared by Health Canada

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Canada

The following meeting report summarizes the discussion that took place at the April 7 - 9, 2006 workshop with patients/consumers of assisted human reproduction services supporting the development of regulations for the Assisted Human Reproduction Act. 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.

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Executive Summary

This report summarizes the proceedings of a two-day workshop organized by Health Canada to gather information for use in the development of regulations under the Assisted Human Reproduction Act (AHR Act) related to:

- aggregate outcomes of assisted human reproduction (AHR) procedures;
- health reporting information;
- counselling;
- and, on information to be made available to the public by the Assisted Human Reproduction Agency of Canada.

The 37 workshop participants were individuals and couples who had used or were considering the use of AHR to help them build their families. These patients/consumers[1] included:

- individuals who had used their own gametes in AHR procedures as well as individuals who had used third-party donated gametes;
- individuals who had undergone a range of AHR procedures such as artificial insemination, *in vitro* fertilization (IVF) and introcytoplasmic sperm injection (ICSI);
- single women and couples (with one or both individuals attending);
- heterosexual and homosexual individuals; and
- individuals from 7 different provinces, rural and urban regions, as well as different ethnic and cultural backgrounds.

The workshop began with a presentation on the AHR Act and an overview of issues to be discussed during the workshop. Key issues raised by participants included consideration of the needs of lesbian and bisexual women, recommendations for broader web-based consultations, and questions regarding the definition of health and the scope of health and safety risks that are being examined in the development of regulations.

Aggregate Outcomes of AHR Procedures

In the first workshop session, officials from the Canadian Institute for Health Information (CIHI) provided information on health outcomes and highlighted issues to be considered in the development of a system for the collection and dissemination of aggregate outcomes of AHR procedures. During this session, participants were led through a questionnaire designed to collect information on the information needs and preferences of AHR patients/consumers. Participants identified a significant need for information on the outcomes of AHR procedures. The group felt strongly that outcomes

[1] The terms patient/consumer and patient/client have been used in this report to refer to individuals who use AHR services to help them build their family. It should be noted that not all individuals who use AHR are affected by infertility or subfertility.

should be available in a standardized, independently verified form that could be broken down by key factors such as procedure, diagnosis, and patient/consumer age. Further, participants stated that outcome information and information on health risks should be available on at least an annual basis, aggregated at the national and clinic level in an easy to understand format. The Agency Web site, detailed patient/consumer reports or guides as well as a toll-free phone line were seen to be key methods of dissemination.

Health Reporting Information

During two breakout workshop sessions, Health Canada officials presented information on the topic of health reporting information (HRI) under the AHR Act and issues in the development of regulations pertaining to HRI. The discussion with participants centred on which HRI (e.g, identity, personal characteristics, medical and genetic information, custody and uses of sperm, eggs and *in vitro* embryos) should be kept by clinics and the Agency for health and safety purposes. Discussion also focussed on the retention and destruction of HRI.

For both the own gametes group and the third-party gametes group, participants felt it was important that the HRI collected prior to undergoing a procedure and collected during the course of procedures be retained and safeguarded by clinics for their health and safety and that of their offspring. The transfer of the HRI to the Agency generated differences of opinion, but many felt that the Agency should also retain the same HRI as the AHR clinics. Participants had various opinions as to whether the identity of patients/consumers and donors should be transferred to the Agency or shared only in non-identifiable form.

Participants' views varied as to the appropriate period of time that HRI should be retained. Overall they felt it was important that it be kept for a long period of time for health and safety reasons, suggestions spanning from 30 to 100 years to indefinitely. While participants said that some HRI could be destroyed in certain circumstances, such as when procedures do not result in the birth of an offspring or when a file is transferred to another clinic, participants noted that some HRI should nonetheless be retained.

Users of third-party donated gametes noted that they wanted clinics to collect (and the Agency to retain) wide-ranging medical histories and personal characteristics from third-party donors. Participants had a variety of views on when offspring could request to receive the identity of a donor who had consented to its disclosure, most felt there was a need to have some controls in place. Responses ranged from the age of 15 and over, to anytime that a parent or donor has given consent.

Counselling

During two breakout sessions, Health Canada officials presented information on the regulatory considerations for AHR counselling services under the AHR Act. Participants

in both groups emphasized their need for information and desire for patient/consumer empowerment. They expressed a need for four different types of information/support:

1) generic information about infertility and AHR
2) medical information about their specific treatment
3) information/counselling around psycho-social issues
4) emotional support throughout the process

Among participants, there was consensus that counselling could be beneficial and that all clinics should be mandated to provide information on the availability of counselling; however, most participants felt that decisions regarding when to seek counselling and from whom to seek counselling should be a personal decision.

Public Information to be Made Available by the Agency

Following an overview presentation on information to be made available to the public by the Agency, participants engaged in smaller roundtable discussions, each focussing on one category of information, which were then reported back to the plenary group. Participants were strongly in support of increased transparency in the area of AHR expressing a need for access to more information about almost all aspects of the AHR field. They generally agreed that the Agency could be a credible source of information for patients/consumers of AHR. They identified the Agency Web site as the primary vehicle for sharing information with the public; however, they also felt that a toll-free number was important for access. Participants repeatedly noted the need for information that was accessible to a lay audience such as plain language versions of the Act and regulations.

With respect to licences, participants noted the importance of having access to a list of licence-holders, including information on their compliance record. Participants reiterated the need for transparency of enforcement activities and availability of inspection reports. To stay informed, participants called for greater access to information about developments in the field of AHR, especially developments related to the use of fertility drugs and developments in the international arena. Finally, participants wanted access to a wide range of information on AHR procedure outcomes and risk factors.

1. Introduction and Context

Francine Manseau, Senior Advisor for Policy and Regulatory Development, Assisted Human Reproduction Implementation Office (AHRIO) of Health Canada, welcomed participants and thanked them for volunteering their time to participate in the workshop. She explained that the workshop had been organized to gather information to assist Health Canada in developing regulations for the *Assisted Human Reproduction Act* (AHR Act) related to aggregate outcomes of assisted human reproduction procedures, health reporting information, counselling, and on information to be made available to the public by the Assisted Human Reproduction Agency of Canada.

Following a presentation on the AHR Act, participants were provided with the opportunity to ask questions or comment on the information presented. Four participants raised issues for clarification and discussion.

The first participant discussed a number of issues specific to the use of AHR services by lesbians and bisexual women. The participant noted that lesbian and bisexual women are significant users of AHR, as it is often their first avenue for becoming pregnant. The participant said it is often incorrectly assumed that AHR users are heterosexual individuals with fertility problems. The participant urged Health Canada to ensure that the AHR regulations are inclusive, addressing the needs of all AHR users. The participant also expressed concern about the potential criminalization of the practice of home insemination under the AHR Act. The participant noted that individuals who had previously contacted Health Canada on this issue had received verbal assurances that it was not the intent of Health Canada to criminalize home insemination; however, the participant noted that to date, nothing to that effect had been received in writing or posted on the Health Canada Web site.

A Health Canada official responded that it is not the intent of Health Canada to criminalize the practice of home insemination. Further, as seen in the draft regulations related to consent (section 8) under the AHR Act (where consent requirements are outlined for different cases including single women, heterosexual couples and homosexual couples), the needs of all users of AHR services are being considered in the development of regulations.

A second participant identified a number of issues related to the definition of donor as well as potential uses of information collected from donors and AHR patients/consumers. In response, a Health Canada official noted that the definition of a donor of human reproductive material is provided in section 3 of the AHR Act and that the definition of a donor of an *in vitro* embryo will be outlined in regulations. The remaining questions were referred to a later workshop session on health reporting information.

A third participant noted that participants at the workshop represented a small sub-

section of AHR patients/consumers. The participant asked if Health Canada intended to conduct web-based consultations (similar to those undertaken by the Human Fertilisation and Embryology Authority in the United Kingdom) which could be completed online by a broad audience. A Health Canada official responded that the workshop was a preliminary forum to gather information that could be used to develop regulatory proposals and broader consultation documents. Further, Health Canada plans to make these consultation documents available on the Health Canada Web site.

A fourth participant noted that the phrase "health and safety" was frequently cited as a key rationale in the development of regulations for the AHR Act. The participant asked what definition of health is being used by Health Canada. A Health Canada official responded that the department is using the World Health Organization definition of health.[2] The participant noted that this definition of health encompasses aspects of health such as quality of life and emotional health which are much broader than just physical health or the absence of disease. The participant commented that much of the discussion appears to be focussed on physical health risks and asked how the broader aspects of health (beyond physical health) would be addressed. Health Canada officials noted that this would be open for discussion as issues are examined in depth in subsequent workshop sessions.

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[2] World Health Organization definition of health: *Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*.

Source: Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

2. Outcomes of AHR Procedures

2.1 Overview

Working on behalf of Health Canada, the Canadian Institute for Health Information (CIHI) was invited to run the session on outcomes of AHR procedures. Margaret Keresteci, Manager of Clinical Registries, CIHI, presented background information on health outcomes and highlighted issues to be considered in the development of a system for the collection and dissemination of aggregated outcomes of AHR procedures. She noted that the workshop session was an opportunity for participants to provide feedback regarding the type of outcome information they felt would be useful and support informed decision-making by AHR patients/consumers.

2.2 Questionnaire

Following the introductory presentation, CIHI officials led participants through a written questionnaire designed to assess participants' preferences related to issues such as the outcomes reported, the availability and dissemination of outcome information, the level of aggregation and participants' willingness to provide information for the purpose of calculating outcomes. During the session, participants spoke to a range of issues and concerns. The group also identified a number of information needs related to outcomes of AHR procedures. The key points of the discussion are summarized below.

Many participants spoke of difficulties in obtaining what they considered to be trusted and objective information on outcomes of AHR procedures, particularly information that was comparable to their situation. Participants repeatedly identified a need for the publication of independently verified outcome information that could provide patients/consumers with information about the probability of success and the probability of adverse events. Participants suggested this information should be available by type of treatment, diagnosis and other relevant patient/consumer demographics such as age. Further, participants called for the information to be provided in a standardized form to ensure that the numbers are comparable from one clinic to the next. Other information needs identified included greater information on:

- potential risks and side effects;
- long-term outcomes; and,
- emotional and psycho-social impacts and outcomes.

With respect to the availability of this information, participants noted that information should be provided in advance of treatment in written form. Participants recounted situations where they were called upon to make treatment decisions in a very short period of time such as immediately after receiving results of diagnostic tests or monitoring. It was suggested that it would be important to have information ahead of time, away from the emotions of the moment. Participants also requested that a wide range of information be provided in advance, to ensure they are prepared (as much as

possible) for the possibility of complications or failure. A number of participants explained that in their experience, doctors and clinic staff were not willing to talk about "what-if" situations. They noted that risks and the possibility of failure are often glossed over. Participants suggested that the publication of outcome information could empower patients/consumers to ask questions about their treatment and encourage doctors to provide an unbiased assessment of a patient/consumer's chance of having a successful pregnancy.

Participants recommended that the information be made available on the Agency's Web site in a printable publication. For most participants, annual or semi-annual updates of this information would be sufficient. Participant opinions regarding the level of aggregation varied; however, most participants indicated that both national and clinic-level results were important. Some recommended the use of a searchable database allowing patients/consumers to find outcomes relevant to their procedure or treatment. Additionally, some suggested the Agency should have a toll-free hotline for people to call to obtain more information, and to ask related questions.

Following the discussion, participants were asked to complete a questionnaire and submit it to CIHI officials, in person or by mail, in a sealed envelope for analysis. A total of 36 questionnaires from workshop participants were returned to CIHI. Analysis of the responses received at the workshop and in subsequent forums is ongoing. Results will inform Health Canada's regulatory development work in this area.

3. Health Reporting Information

3.1 Overview

The workshop session on Health Reporting Information was conducted in two breakout sessions dividing the participants into one group with individuals who had used or would use their own gametes (own gametes group) and a second group with individuals who had used or would use third-party gametes (third-party gametes group). France Foucault, Policy Analyst, AHRIO, began each breakout session with a presentation on health reporting information (HRI) as defined in the AHR Act and issues related to the development of regulations pertaining to HRI. Following the presentation, participants in each group were led through a discussion using a series of questions as a guide. While the initial presentation on HRI was similar for each group, the questions and discussion were tailored to the unique interests and experiences of each group.

3.2 Discussion - Own Gametes Group

3.2.1 For health and safety purposes, what HRI should be collected by AHR clinics?

The session started with a discussion about the HRI that clinics should collect for the health and safety of AHR patients/consumers. In summary, participants in the own gametes group noted that their identity, medical history, genetic information and information about the custody and uses of sperm, ova and *in vitro* embryos should be collected by clinics for health and safety reasons. Participants recognized a need for clinics to collect HRI before undergoing a procedure but also placed great importance on clinics collecting their medical history as they are undergoing procedures and having this recognized as health reporting information in the regulations.

Participants raised arguments favouring the collection of HRI by clinics. For personal health and safety reasons, they argued that clinics should have this information available in case a health problem were to arise during a procedure, and it could also be used in the future to inform clients of new or emerging health risks from AHR.

Participants also emphasized the importance of health reporting information as it relates to the custody and uses of sperm, ova and *in vitro* embryos. To them, this information is crucial in order to avoid and track any misuse of gametes, such as giving gametes to the wrong person, thawing cryopreserved gametes in error, or providing *in vitro* embryos for research when it was not intended. Participants noted that even if the reproductive material is eventually destroyed, the associated HRI on its custody and use should continue to be accessible.

Participants expect that HRI regulations will assist the Agency to administer and enforce the Act whenever required. Some participants said the regulations should impose the obligation to collect HRI on clinics as they do not trust clinics to safeguard their information. Others noted a concern that their information might not be available if a doctor leaves a clinic.

Participants in this group did not see the need to collect information on personal characteristics from people using their own gametes.

3.2.2 For health and safety purposes, what HRI should be sent to the Agency?

Discussions continued regarding the collection of HRI by clinics, and considered what information should be transferred to the Agency for health and safety purposes. A large number of the participants said they would want their HRI sent to the Agency but some were opposed. Others thought if clinics were obligated to have back-up systems, further duplication of records by the Agency would not be necessary.

Many participants wanted HRI forwarded to the Agency; however a small group of participants fetl that this should be in non-identifiable form possibly with a link to clinic-level records. There was endorsement by many that their medical history, genetic information, and information related to the custody and uses of reproductive material and *in vitro* embryos, be transferred to the Agency; however, some participants were uncomfortable sharing this HRI with the Agency. All participants agreed that the Agency would not require any personal characteristics for clients using their own gametes.

Participants highlighted a number of reasons for the Agency to have the HRI. Unlike many clinics, as a public institution the Agency is not motivated by profit. If a clinic had to close or a physician leave a clinic, the HRI would remain with the Agency. Participants also thought that with the HRI in their possession, the Agency would be in a better position to deal with complaints and to carry out enforcement activities. Other participants saw a role for the Agency as a source of information for their children.

3.2.3 How long should HRI be retained?

Participants highlighted a number of potential retention periods but none were necessarily preferred. Some of the options were to keep information long enough for children to have access, to keep it indefinitely, or to keep paper records a certain length of time and electronic records for a longer period.

3.2.4 In what instances and to what extent would you see a reason to destroy HRI?

Participants suggested cases where they could request that their HRI be destroyed, for example, when no offspring was born or if the offspring died. The case of patients/consumers changing from one clinic to another was also brought up as a possible reason to request the destruction of HRI. In this type of scenario, some participants felt that the first clinic they consulted would not require their HRI if their file was transferred to another clinic. Other suggestions were to remove the identifying information from the HRI rather than destroy the full record, or to destroy the record either at the clinic or the Agency.

3.2.5 What HRI should be disclosed to a person before they undergo a procedure?

Participants in the own gametes group did not see a need for the clinic to disclose HRI before a person in their situation undergoes a procedure. This was seen as unnecessary for individuals undergoing procedures using the gametes of their partner or spouse.

3.3 Discussion - Third-Party Gametes Group

3.3.1. For health and safety purposes, what HRI of third-party donors should be collected by AHR clinics?

The first discussion in the third-party gametes group aimed to identify HRI that should be collected from a third-party donor of sperm, ova or *in vitro* embryos. Participants agreed that for health and safety purposes, AHR clinics should collect and retain all the elements of HRI from third-party donors. Discussion of each of these elements follows.

Identity

The identity of a third-party donor was seen as essential information to be collected by clinics for many reasons, including the need to contact the donor for more information if a medical problem arises.

Personal characteristics

Participants agreed that personal characteristics of a third-party donor should be collected for the psycho-social well-being of offspring. In support of their recommendation to collect the HRI, they cited the definition of health from the World Health Organization: *Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*[3]. For the participants, a

[3] Ibid.

person's health encompasses aspects such as quality of life and emotional health which are much broader than just physical health or the absence of disease. This justifies, to them, the collection of personal characteristics about a third-party donor.

Participants outlined a number of benefits to obtaining characteristics about a third-party donor for offspring. In their view, the personal characteristics allow for the development of a child's self-identity. In general, participants felt that this information was important for the well-being and mental health of offspring.

Personal characteristics were also seen to be important in selecting a third-party donor. For example, personal characteristics would enable them to match the ethnocultural background of a third-party donor with their own.

Participants were invited to name the personal characteristics of third-party donors they would like clinics to collect. These characteristics were sometimes categorized as essential, important or optional:

Essential personal characteristics
- ethno-cultural background
- occupation of the donor - due to occupational or workplace hazards and potential long term health risks to offspring

Important personal characteristics
- height, weight, hair colour, eye colour
- education, grade point average, IQ

Optional personal characteristics
- reason the donor donated
- socio-economic background
- preference to disclose their identity or not
- hobbies, interests, skills, traits and strengths
- year of birth, country of birth
- marital status and number of children
- religion
- date the information was collected from the donor
- left- or right-handedness
- letter or message to offspring
- letter describing themselves (pen portrait/personality);
- list of favourite things such as favourite colour, food, music, sports.

Participants favoured an approach to regulations that would outline the minimum requirements for personal characteristics but that would also allow flexibility if a donor wanted to provide more information than required.

Medical and genetic information

The presenter then shared a list of medical history and genetic information that could potentially be collected from third-party donors and invited feedback from participants.

The broad types of medical history and genetic information listed for participants were:

- medical disorders of the donor (congenital disorders, asthma, cancer, diabetes etc.)
- medical disorders of the donor's biological family (congenital disorders, asthma, cancer, diabetes etc.)
- infectious diseases
- paternal and maternal ethnic origin
- donor's blood type and RH factor
- exposure to chemicals
- smoking habits
- substance abuse.

Participants added the following elements to the list:

- mental, developmental disorders and or learning disabilities – such as schizophrenia, bi-polar disorder, depression, autism;
- sexual orientation – if this presents a health concern;
- substance abuse of the donor as well as any family history of , for example, alcoholism;
- allergies
- number and characteristics of siblings and offspring
- indicator of fecundity of the donor
- genetic traits – e.g. colour blindness, hearing, vision;
- weight.

Participants also noted that the regulations should obligate the clinic to prompt the donor to provide any other medical information deemed to be relevant for health and safety.

The participants felt that if medical history of a third-party donor was updated at the clinic following the donation, recipients of the donation should be contacted and informed of the changes. The participants also want the medical information they provide to the clinic on a voluntary basis to be treated as HRI, including information about offspring.

Custody and uses of sperm, eggs and *in vitro* embryos

In closing this part of the discussion, participants flagged that the HRI related to custody and uses of sperm, ova and *in vitro* embryos from third-party donors is important for the clinic to collect and retain.

3.3.2 What HRI should AHR clinics and the Agency collect from persons who undergo AHR using third-party donated reproductive material?

Participants who use third-party donated gametes when undergoing assisted reproduction procedures recognized and agreed that AHR clinics and the Agency should have their identifying information in order to allow offspring to access information about the third-party donor.

3.3.3 What HRI about a third-party donor should be transferred to the Agency?

A majority of the participants agreed that the identity, personal characteristics, medical and genetic information, and information about custody and uses of sperm, ova, and *in vitro* embryos of a third-party donor should be transferred to the Agency. Participants recognized this could impact on donor privacy, but nonetheless recognized its importance and recommended it be transferred to the Agency.

Some participants highlighted that the same goals could be accomplished with an identifier or code given to the third-party donor rather than using their identifying information. Others were concerned that this approach would not allow the Agency to advise whether offspring are genetically related if such a request were made.

3.3.4 When a third-party donor consents to disclose their identity, should that information be given to offspring only when they reach a certain age?

While opinions were varied, there was a common view that some type of control should be put in place. Some favoured releasing the identity earlier for developmental reasons. Another suggestion was to release a donor's identity in a manner similar to what is done in adoption cases. Other participants suggested that the identity could be released at the same age that children can give medical consent, around the age of 15 or 16, or when offspring start engaging in sexual activity.

Rather than link disclosure to the age of the offspring, some participants linked it to any time there is mutual consent between the parent and the third-party donor. This could allow donors to specify at what age the offspring can receive their identifying information.

Participants noted that if the disclosure of identity is done before the age of 16, it should be done with the parents' consent. Some participants felt there would be a need to seek counselling for their offspring at the time when the donor's identity is revealed.

3.3.5 For health and safety purposes, how long should the clinic and the Agency be required to retain HRI of third-party donors?

Participants views varied on the issue. The length of time varied from anywhere

between 30 to 50 years and up to 100 years. Another participant suggested that the HRI be kept for the duration of a patient's/consumer's lifespan.

When asked how long the Agency should retain the HRI of third-party donors, some participants suggested keeping it at least as long or longer than AHR clinics, while others suggested that the Agency keep it indefinitely. Some participants expressed concern regarding the clinic's capacity to hold this information for 30 to 50 years and recommended that the Agency should become the safety net.

3.4 Additional Comments

Participants expressed other views about HRI during the course of the discussions. They noted that the Agency should create a voluntary retroactive registry for HRI of third-party donors. They also felt that some action should be taken to protect their personal and medical information currently held by clinics.

3.5 Conclusion

Participants of both groups felt is was important that the HRI collected before undergoing a procedure and during the course of procedures, should be retained and safeguarded by clinics and the Agency for their health and safety and that of their offspring.

In the own gametes discussion, participants agreed that clinics should collect their identifying information, their medical and genetic history, and information about the custody and uses of sperm, ova and *in vitro* embryos. These participants did not see a need for clinics to collect any of their personal characteristics. When asked what HRI should be transferred to the Agency, many thought that the HRI collected by clinics should be forwarded to the Agency; others either did not want their identifying information disclosed, or did not see a need for the HRI to be sent to the Agency if mechanisms were in place to secure this information with clinics. Participants' views varied on the appropriate period of time that HRI should be retained, but overall they felt is was important that it be kept for a long period of time spanning from 30 to 100 years or indefinitely. While participants said that some HRI could be destroyed in certain circumstances, such as when the procedures do not result in the birth of an offspring or when they request that their file be transferred to another clinic, they noted that other HRI should still be retained in some manner.

In the third-party gametes group, participants concluded that clinics should collect all of the HRI from third-party donors. Users of third-party donated gametes want wide-ranging medical history and personal characteristics about the third-party donors collected by AHR clinics and also saved by the Agency. Although opinions varied on whether the HRI transferred to the Agency should include the donor's identity or only be in non-identifiable form. Participants further recognized and agreed that the Agency

would require identifying information about patients/consumers who use third-party gametes for AHR in order to make the HRI accessible to their offspring. Participants had a variety of views on what is an appropriate age for offspring to learn the identity of the donor and some saw the need to control for this. Responses ranged from the age of 15 and over, to anytime that both the parent and the donor consent. Views on the length of time the HRI should be retained by clinics and the Agency ranged from 30 to 100 years, to indefinitely.

The information gathered during the discussions with patients/consumers was valuable for the development of HRI regulations, and in particular for the next stage of the process as options and recommendations are prepared.

4. Counselling

4.1 Overview

The workshop session on counselling was conducted in two breakout sessions dividing the participants into one group with individuals who had used or would use their own gametes and a second group with individuals who had used or would use third-party gametes. Christine Aubry, Policy Analyst, AHRIO, began each breakout session with a brief overview presentation of the regulatory considerations for AHR counselling services. She presented the scope of the counselling requirement under the AHR Act and provided some Canadian and international contextual information. She explained that the purpose of the session was to gather information to assist in the development of the counselling regulations. She then presented a series of questions for discussion with a summary of the responses presented below. Due to the degree of overlap between the discussion in the two breakout sessions, the responses have been presented in a combined format highlighting areas of agreement and any relevant differences between the perspectives of the two groups.

4.2 Discussion

4.2.1 What is the purpose of counselling?

Participants felt that counselling can provide patients/consumers with a forum to discuss what led them to seek AHR procedures, and that the counselling should be tailored to each person's or couple's needs. They explained that for some, the diagnosis of infertility is traumatic; patients need help grieving and need counselling before even deciding to pursue AHR. Others, such as single women and lesbian and gay couples or individuals, may have very different experiences and needs. These individuals are not infertile; they have had more time to consider using AHR procedures and may not be experiencing feelings of loss or grief.

Participants stressed that there is a difference between providing *informed consent* to a specific procedure and making an *informed choice* about using AHR procedures. They expressed concern that counselling not be based on the medical model of reviewing physical and treatment-related risks. All participants stressed the difference between receiving basic information about AHR procedures and receiving psycho-social counselling. Many expressed the view that clinics do not see the psycho-social impact of AHR procedures. They felt that AHR counselling should examine the emotional, psychological, and social risks and implications for all those concerned. Participants also felt that patients/consumers need counselling to manage expectations and to be prepared for failure and emotional distress (which they also felt is not encouraged by most clinics).

There was agreement that a main goal of counselling should be to help people develop

a treatment plan and decide where to invest their money, before making any decisions. AHR counselling should examine the long-term implications of each possible route, including all treatment options as well as treatment or family-building alternatives. As well, participants in the own gametes group stressed that counselling should help patients/consumers decide when they need to stop treatment.

Participants in the third-party gametes group stressed that the focus of AHR counselling should be on the impact on the child(ren), particularly considering the limited amount of information available on third-party gamete donors. This group felt very strongly that couples should be counselled together, as they will parent together, and that all parties involved in any third-party conception arrangement (including the partners of egg donors or surrogates) should receive counselling.

Participants in the own gametes group emphasized the need for more treatment-related information, though they also saw the need for counselling to address the psycho social aspects of infertility treatment. This group felt that the purpose of counselling is mostly educational, informative, and supportive.

4.2.2 Who should provide the counselling?

The own gametes group felt that emotional support was their greatest need, therefore they were more concerned with receiving counselling from someone who is familiar with the emotional aspect of fertility treatment. Some felt that perhaps a nurse could provide information and support and that they do not necessarily need counselling by a psychologist. A few participants felt that the counsellor should have experienced infertility, while others felt that counsellors should not bring their own biases and experiences to a counselling session.

Participants were very concerned about the quality of the counselling service, especially if it will be mandatory and they will be paying. They felt that the person providing counselling should be culturally sensitive and should have suitable credentials based on competency and some form of certification (if not specific education and training).

There was consensus that the person providing counselling should not be the same person responsible for the AHR procedure, but there was no consensus regarding whether there should be a list of acceptable professions.

Participants were concerned that a counsellor paid or employed by a for-profit clinic (or whose business depends on referrals from a clinic) could be in a position of conflict of interest (that is, they will not want to tell a patient/consumer when to stop or to look at other alternatives). They felt that there should be a way to ensure some measure of independence from the clinic.

Some noted that support groups are extremely beneficial and that attendance at a group should be enough to meet any regulatory requirement for counselling. They

stated that they would rather pay money to a support group than to a clinic for counselling (one participant suggested that governments should fund non-profit support groups). However, others felt that there was a need for individualized and private counselling in addition to any support obtained from peers.

Several participants felt strongly that clinics should be mandated to tell patients/consumers that counselling is available and where they can receive it, including a list of counselling professionals who are independent and available off-site. They noted that on-site counselling can be very effective but that there are also advantages to obtaining support outside of the clinic setting.

4.2.3 What should be the process/timing of counselling?

Participants in the own gametes group preferred a model whereby the clinic provides an information/orientation session and a guide/package of resources. They felt that clinics should be mandated to provide information about AHR to patients/consumers, including where to obtain counselling; however, patients/consumers should be allowed to choose when and where they obtain counselling.

Participants felt that counselling should be targeted to each treatment path but that the process and timing for receiving counselling should remain flexible. They recognized the benefits of reflecting on the counselling obtained before starting a procedure but unanimously rejected the notion of a mandatory waiting period between receiving counselling and beginning a procedure. One person suggested that the regulations could use language such as "within a time frame that reflects the circumstance."

4.2.4 What information do patients/consumers want?

Participants differentiated between the information they would like to receive about their treatment, which could be provided by someone on the treatment team, and information or issues that they would like covered in a counselling session. Participant suggestions for each type of information are summarized in the table below.

Treatment Information	*Psycho-social Issues*
• non-biased information about fertility and chances of success with AHR • details of their treatment & instructions (such as how to do self-injections) • information on physical risks, drugs & side effects • cost of treatment(s) (including an explanation that it is a privately provided service) • explanation of responsibilities (doctor vs. nurse) and explanation of team approach • information on regulations and clinic accountability/responsibility	• other family building options • what emotions to expect (whether successful or not) • coping strategies • where to get support • long-term implications for child, individuals, couple, families • how to deal with families, friends, public (e.g., comments; others' pregnancies) • communication issues in relationship • disclosure issues (openness vs. right to privacy)

4.2.5 What are the benefits of counselling?

Most participants saw the benefits of receiving counselling and, in particular, welcomed being provided with as much information as possible, both in writing and in person.

Some felt that the cost of counselling was not significant compared to the overall cost of treatment, and that it was a justified cost considering the potential risks involved. One participant noted that it is important to make an emotional investment in one's health.

Some felt that counselling can provide a balanced perspective and prepare for possible failure, rather than counting on success. Many noted that patients/consumers are too preoccupied with achieving a pregnancy to examine the long-term implications of their decisions. Those who had already undergone an AHR procedure noted that in retrospect they saw the need for and benefits of counselling.

4.2.6 What are the drawbacks of mandatory counselling?

Participants expressed concern that the requirement for mandatory counselling might create an additional burden for users of AHR and add more stress. For example, people in rural areas do not have the same access to health care services as those is urban areas. A requirement for multiple face-to-face counselling sessions would be problematic.

Some participants felt that cost could be a barrier and that they could not afford to pay for counselling. More importantly, most were concerned that mandatory counselling could also drive up the cost of the service because there will be more demand. Similarly, they expressed worry that clinics will charge more for treatment if they need to provide additional services.

It was noted that the way in which counselling is presented to patients/consumers can

make a significant difference in whether they will accept it. The requirement for mandatory counselling is disconcerting to many, therefore clinics should be trained in how to present the benefits of counselling services to their patients/clients. One participant suggested to use the phrase “patient preparation” rather than “counselling.”

4.2.7 Other Points Discussed

Participants felt strongly that all clinics should provide an orientation session and provide patients/clients with a comprehensive information package and list of resources, including where to obtain counselling services and information about local support groups. However participants expressed concern with each clinic developing its own package and suggested that this could be the role of the Agency.

Indeed, there was a lot of discussion in both groups with respect to the role of the Agency. Participants felt strongly that the role of the Agency should focus on education and awareness. The Agency should have a central role in information preparation and dissemination about all issues related to AHR: fertility, reproductive health, family building options, infertility, infertility treatment, AHR procedures, etc. (one participant used the phrase “centralized clearinghouse of information”).

Participants stressed that users of AHR want to have information available on a Web site so they can access it whenever they need it. They felt strongly that all Canadians seeking AHR procedures should have access to the same amount and type of information regardless of their location.

Participants were generally supportive of more, rather than less, government intervention in this area. Participants favoured a strong regulatory role for the federal government. Some felt that the federal government should have a presence in all regions, and that there should be a contact person available to answer questions and provide information in person.

For example, participants asked whether the federal government could limit what clinics charge for AHR services. Participants also asked whether the federal government could prevent the contract approach to treatment widely used in clinics (whereby a patient/client pays for a pre-determined number of cycles up-front, regardless of the outcome). They also generally do not like the team approach of clinics, and would prefer to see one person responsible for their treatment on whom they can rely for information. Health Canada explained that although the government is regulating certain aspects of AHR for health and safety reasons (such as what activities can be done, by whom and under what conditions), clinics are private businesses and the government cannot interfere with their business policies and practices.

Participants also stressed the need for a formalized complaint process. They expressed discomfort about making complaints to clinics, especially if they still need treatment. Participants also asked if the federal government could mandate that clinics evaluate

their services. It was suggested that all patients/consumers should have the opportunity to complete a post-service survey about their experiences with each clinic and that this information should be posted publicly. (They noted that individuals who have attempted to post comments about clinics on-line were either threatened with lawsuits or asked to remove their comments if they wanted to continue treatment.)

Participants expressed concern that in some clinics the counsellor's role is actually to screen patients/clients for suitability to access services. Lesbian women in particular often feel discriminated against and expressed the need for gay-sensitive counselling. Health Canada explained that the intent of the mandatory counselling in the AHR Act is certainly not to provide any sort of screening for suitability or access to services. It was noted that one of the key principles of the Act is against any form of discrimination.

4.3 Conclusion

To summarize, participants in both groups emphasized their need for information and desire for patient/consumer empowerment. They expressed a need for four different types of information/support:

1) generic information about infertility and AHR
2) medical information about their specific treatment
3) information/counselling around psycho-social issues
4) emotional support throughout the process

There was consensus that counselling could be beneficial and that all clinics should be mandated to provide information on the availability of counselling; however, most felt that decisions regarding when to seek counselling and from whom should be a personal decision.

Participants were thanked for their comments and feedback. Health Canada explained that although the regulations might not be able to capture all of their concerns, the information provided at this workshop would be captured in the report and the Agency could have a strong role in information dissemination.

Participants were asked to take some time to complete a questionnaire on their own personal experience with AHR counselling services and to leave it with a Health Canada official at the workshop or send it by mail at a later date. Analysis of the responses received at the workshop and in subsequent forums is ongoing. Results will inform Health Canada's regulatory development work in this area.

5. Information Made Available to the Public

5.1 Overview

Alexandrea Howard, Policy Analyst, AHRIO provided an overview of information to be made available to the public by the Agency as outlined in section 19 of the AHR Act and issues to be considered in the development of regulations. She noted that individuals using AHR to help them build their families are an important audience for this information and as such, one of the key objectives of the session was to determine what information participants felt was most useful or relevant to individuals who are using or considering the use of AHR.

For the purposes of the discussion, the types of information to be made available to the public were grouped into five categories:

- Information related to the operations of the Agency
- Information related to licences and licence-holders
- Information related to the enforcement of the AHR Act
- Information related to developments in the AHR field
- Information related to informed decision-making

Participants were divided into smaller working groups to discuss one of the above categories and report back to the plenary group. The results of these discussions are summarized below.

5.2 Summary of Roundtable Discussions

5.2.1 Information related to the operations of the Agency

Participants in this group noted that it will be important to have access to information that provides an overview of the Agency's operations and the governance of AHR in Canada. They reported that this information should be presented in an easy to understand format, using plain language. Participants explained that access to this kind of information serves to ensure that users of AHR services are:

- comfortable with the AHR services they are accessing;
- able to hold clinics accountable for their actions; and
- informed about the standard of care in Canada.

Participants also noted that making information available to the public would serve to "keep the Agency honest".

Participants recommended that information should be made available on the Agency's Web site, in published brochures and through a toll-free information line that would

allow users to connect to a resource person who could provide one-on-one support and information.

5.2.2 Information related to licences and licence-holders

Participants reported that currently individuals considering the use of AHR services do not have access to a great deal of information about different clinics. Individuals seeking treatment for infertility are often referred to a fertility clinic by their physician and in many cases, there is no choice of AHR provider. Individuals who had sought out information about different clinics noted that they had primarily used Internet resources.

While participants may not have had a choice of AHR provider, they noted that in order to be better informed they would like access to a range of information about specific clinics and licences including:

- clinic success-rates;
- types of research performed at the clinic;
- technologies used and quality of facilities;
- clinic's treatment philosophy;
- licence(s) held;
- accreditation information; and most importantly
- information regarding any licence sanctions such as suspensions or fines.

With respect to the Agency's licencing proceedings, participants thought it was important to have access to information about:

- the licencing process and licensing requirements;
- information about federal/provincial jurisdiction (who is responsible for what); and
- records of licencing proceedings including information on how to participate and provide input.

Participants recommended that information about licences and licence-holders should be made available on the Agency Web site.

5.2.3 Information related to the enforcement of the AHR Act

Participants reported that they currently rely on a wide range of sources for information about enforcement of the AHR Act (and other related statues such as the Semen Regulations). Health Canada, the Infertility Network and other support groups were identified as being the most useful; however, other suggestions included the AHR sector, lawyers, the media and other patients/consumers.

The group presented the following list of information about enforcement that would be important to have:

- the parameters for enforcement of clinics, individual doctors, and sperm banks;
- the range and degrees of violations;
- inspection reports, their contents, and who has access to them;
- the frequency of inspections;
- procedures for registering a complaint; and
- outlines of how issues (e.g., safety issues) are handled.

They also raised the issue of discrimination in the provision of AHR services and questioned how the AHR Act's anti-discrimination principle will be ensured and enforced.

The preferred method of accessing this information was identified as the Agency Web site.

Participants felt strongly that information about enforcement (as well as information about AHR in Canada more generally) should be broadly available. They did not foresee any issues or concerns about the release of this information. They did, however, note that there was a need for interpretation guidelines, plain language documents and general information about best practices.

5.2.4 Information related to developments in the AHR field

Participants noted that they currently rely on a wide range of information sources including medical journals, clinics, infertility associations, and the media to follow developments in the AHR field. It was noted that the Internet has increasingly made this information available to a broad audience.

The group identified information about developments in the following areas as being important for users of AHR:

- cost;
- success rates;
- treatment options (including drugs, procedures and diagnostic tests);
- coping strategies;
- access to information (e.g., medical files, donor records);
- legal aspects of third-party donation;
- government support for patients/consumers and offspring.

As well, the group noted that international developments and comparisons were also important.

With respect to information the Agency could make available to the public, the group suggested that Agency reports, fact sheets as well as Advisory Panel reports should be made broadly available to the public. Technical research reports were seen as being less important except where they were written for a lay audience. The Agency Web

site, and Agency mail outs were seen as the primary means for making this information available. Participants also suggested that it would be important for this information to be available from medical professionals, infertility counsellors and infertility associations.

Participants expressed concern that pressure from the "AHR industry" (including doctors, sperm banks, and pharmaceutical companies) could limit the information made available to public.

5.2.5 Information related to informed decision-making

Participants reported that they currently rely on a wide range of information sources including support groups, online resources, doctors, and resources from clinics to support informed AHR decision-making. Online resources, other AHR patients/consumers and infertility support groups were seen to contribute the most to their ability to make informed decisions about their use of AHR.

Participants suggested that the following information would be most useful to individuals considering the use of AHR to help them build their families:

- information about available options, procedures and risks;
- representative statistical information (outcomes), broken out by factors such as condition, fertility status, and number of treatment cycles;
- information about how AHR is regulated in Canada;
- listing of additional support resources and workshops; and
- physician accreditations or licences.

Participants recommended that this information be made available on the Agency's Web site, circulated to mailing lists, and in larger, detailed print documents (e.g., a guide to infertility). As well, the group felt a searchable electronic database would be useful for finding information such as procedure outcomes and risk information.

5.3 Additional Comments and Conclusions

Following the roundtable reports, participants were given an opportunity to ask questions and raise any additional concerns or issues. The following points were raised by participants.

A participant expressed concern that owners of clinics with poor compliance records could potentially shut-down their clinic and re-open as a new clinic to avoid being impacted by their record. It was suggested that the information to be made available by the Agency should enable the tracking of this type of activity. Records should follow the individuals involved as well as the corporate entity.

A second participant suggested that the Agency consider supporting an online discussion group for individuals considering AHR procedures mediated by a medical professional.

A third participant raised issues related to federal and provincial jurisdiction and asked whether Health Canada would consult with provinces. The participant expressed concern that aspects of AHR practice may not be addressed by regulations under the AHR Act. A Health Canada official responded that they will be consulting with provinces on the development of regulations for the AHR Act and that the Act provides tools to work with provinces in areas such as enforcement.

In conclusion, participants in this session were overwhelmingly in support of the Agency making information available to the public. Transparency was seen to be very important in all aspects of the Agency's activities and mandate, and the group had few reservations or concerns about the release of information. Participants felt that the provisions in section 19 of the AHR Act would help fill an information void in a number of important areas such as outcomes of AHR procedures, information about AHR clinics, information about standards of care and the enforcement of legal and regulatory requirements.

6. Final Discussion and Next Steps

At the conclusion of the final day, participants were provided with an opportunity to ask Health Canada officials any outstanding questions and provide final comments on the workshop or subsequent steps in the development of regulations.

A participant called on Health Canada to provide assistance setting up a voluntary, retroactive registry of health information on patients/consumers, donors and offspring similar to what has been established in Australia. In a similar vein, a second participant asked whether the Agency would accept retroactive donor and patient/consumer files if they were voluntarily provided to the Agency by a clinic. Health Canada officials noted that the department was currently focussed on creating the Agency and developing regulations; however, issues related to a retroactive registry or files could be brought to the attention of the Agency once it was operational.

A participant commented that it would be important to gather information from donors to support the development of regulations.

A participant who had experience working in a regulated sector, suggested that the Agency should fund an independent consumer association to act as a watchdog and ensure that the relationship between the AHR sector and the Agency does not become too cozy.

Other issues raised by participants included:

- the need for educational material to support the transition to an altruistic system of gamete donation;
- a call for public insurance coverage of AHR procedures; and
- several comments regarding provincial family law provisions related to parental rights and third-party donated human reproductive material and embryos.

It was noted that a meeting report would be produced summarizing the discussions at the workshop. Participants were advised that they would be provided with a copy of this report and that the full report would be published on Health Canada's Web site.

Prior to adjournment, participants were thanked for their participation and encouraged to participate in future consultation activities supporting the development of regulations for the AHR Act.