Health Canada Santé Canada

# Workshop on Licensing and Information to be Made Available by the Agency

# Meeting Report

**February 24-25, 2006**

**Four Points Sheraton Hotel**
**Gatineau, Quebec**

Prepared by Health Canada

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Canada

*The following meeting report summarizes the discussion that took place at the February 24 - 25, 2006, Workshop on Licensing and Information to be Made Available by the Agency. The comments and opinions expressed in this document are those of the workshop participants and do not necessarily reflect the views of Health Canada.*

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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 the administration of licensing under the Act (sections 40, 41 and 42) and on information to be made available by the Agency related to licensing and enforcement activities (section 19). Participants in the workshop included representatives from medical practices, fertility clinics (private and hospital-based) and laboratories providing services in assisted human reproduction from across the country.

The workshop began with a presentation on the AHR Act and an overview of the issues to be discussed during the workshop. Participants were invited to ask questions and provide comments. Discussion with participants primarily focussed on the classification of assisted human reproduction procedures and on information to be made available by the Agency.

### *Licensing*

Health Canada officials provided an overview of licensing provisions and the definition of controlled activities under the AHR Act. Key issues raised by participants included the characteristics of the licensing system and the number of licences that would be required by clinics, the licensing of satellite clinics, concerns regarding a level playing field between private clinics and hospital-based clinics, and the licensing of individual physicians performing controlled activities in their general practice.

Next, participants reviewed a list of AHR procedures prepared by Health Canada and suggested a number of modifications to the list. The revised list was used as a basis for subsequent discussions on qualification requirements and possible licensing categories.

In discussions on the qualifications of individuals who perform AHR procedures and of the individuals who supervise the conduct of those procedures, participants identified a number of common requirements.

First, due to the paucity of formal education or training programs for AHR laboratories, participants noted that on-the-job training was the most important qualification for the majority of laboratory procedures. Second, the designation of supervisor varies from clinic to clinic; however for laboratory procedures in large clinics participants noted it is most frequently a laboratory director or manager. Third, participants advised that most clinical AHR procedures are performed by physicians who are not usually supervised (unless they are a medical resident) or in some cases by a nurse supervised by a physician. Finally, participants noted the transport, import and export of human reproductive materials are subject to additional external qualification requirements related to regulations regarding the transportation of dangerous goods by land and by air.

Discussions regarding possible licensing categories revealed that with the exception of research, most controlled activities can be clearly categorized as “Clinical”, “Laboratory”, “Storage” or “Transport/Import/Export”. Participants noted that research can be a part of all AHR procedures. Participants also noted that the category “Laboratory” overlaps to some extent with the “Storage” and “Transport/Import/Export” categories in both the performance of procedures and in related administrative record-keeping.

In broader discussions on premises licensing and accreditation, participants advised there were currently a range of premises requirements in place through provincial regulation and accreditation programs and as such, it would be important to minimize overlap and ensure that any additional requirements are coordinated with these existing systems and programs.

### *Information to be Made Available by the Agency*

Following a presentation on Section 19 of the AHR Act and obligations of the Assisted Human Reproduction Agency of Canada (the Agency) to make information available to the public, participants were guided through a discussion of provisions for the availability of information related to licensing and enforcement.

With respect to what information should be made available to the public,

participants were generally hesitant to have information related to licensing and enforcement activities available. Participants noted that an up-to-date listing of individuals and entities with valid licences should be broadly available on the Agency's Web site. Participants agreed that information important for the protection of human health and safety, such as a public warning, should be broadly available on the Agency's Web site; however, some concern was expressed about how it was determined that such a warning was warranted. Other information that could be broadly available includes copies of Agency reference material such as enforcement policies or procedures, as well as documentation from licensing proceedings that was either non-identifying or that pertained to broad classes and categories of licences. In most other cases, if information was to be made available, participants suggested it should only be available upon request.

With respect to the manner of availability, participants prefered that information be made available from the Agency on an "upon request basis" or when broader availability was required, on the Agency's Web site. In terms of when information should be made available, participants suggested that information pertaining to a specific licence or licensee should only be made available at the conclusion of any proceeding or enforcement action, including the completion of any appeal procedures. Participants felt that other information such as Agency reference material, information pertaining to broad classes or categories of licences, and non-identifying materials from licensing proceedings could be made available more quickly and frequently.

# 1. Introduction and Context

Francine Manseau, Manager - 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 the administration of licensing under the Act (sections 40, 41 and 42) and on information to be made available from the Agency related to licensing and enforcement activities (section 19). The primary objectives of the workshop were:

- to develop a classification system for controlled activities that could be used for licensing administration and other regulations; and
- to identify the nature of information that should be made available to the public and the manner and frequency of its availability.

Information gathered over the course of the workshop would aid in the development of regulatory options and assist AHRIO in the preparation of broader consultation documents on these subjects.

Following the opening presentation, participants were provided with the opportunity to ask questions and provide comments on the information presented. A number of participants commented that regulations should be developed to ensure that there is a level playing field between providers, regardless of size, region, or ownership. Further, some participants noted that it would be important for Health Canada to keep regulations simple, and not unduly burden or complicate AHR clinics. One member of the group recommended that Health Canada work with the Canadian Fertility and Andrology Society (CFAS) to develop regulations based on currently recommended standards and guidelines. Finally, while outside the scope of the day's discussion, several participants raised issues related to the regulations being developed for the reimbursement of expenditures related to the donation of gametes or *in vitro* embryos.

# 2. Licensing

## 2.1 Overview

Greg Whalen, Senior Policy Analyst, AHRIO, presented information related to licensing and controlled activities under the AHR Act. He outlined the objectives of the day as follows:

- classify AHR procedures into appropriate groups for licensing purposes;
- describe the minimum qualifications that should be met for each group;
- describe the nature and scope of regulations governing premises licences; and
- identify the role of accreditation, standards and guidelines.

A number of issues were raised by participants throughout the presentation and in the subsequent open forum discussion. The following is a brief summary of these discussions.

Participants sought clarification on the definition of “to undertake” as it relates to the licensing of controlled activities and discussed what this would mean with respect to the number of licences that would be required by a clinic. Health Canada noted that two kinds of licences were required by the Act, a licence to undertake a controlled activity and a premises licence for the site in which that controlled activity is performed. Some participants expressed a preference for a single licence system, while others noted that the possibility of multiple licences, may provide greater flexibility and stability with respect to staffing and operations.

A number of participants raised questions regarding the licensing of satellite clinics. It was noted that some clinics operate or have a relationship with satellite clinics that provide a range of services to patients outside of larger centres. The group noted that the licensing system would have to consider how best to license these clinics.

Several members of the group asked about requirements for licensing of hospital-based versus private AHR services. They noted that many

accreditation schemes and provincial licensing requirements differentiate between the two types of facilities, and expressed a desire to see both treated equally under the AHR Act.

Finally, participants questioned how licensing would apply to physicians who provide AHR services to patients in general practice. Participants advised that some family physicians perform AHR procedures such as inseminations in their office.

## 2.2 Classification of Controlled Activities

Participants were presented with a list (see Box 1) of assisted human reproduction procedures and asked to review the list elements and groupings for accuracy and completeness and to suggest changes, additions or deletions to the list.

**BOX 1: Initial List of Assisted Human Reproduction Procedures**

**Semen/Sperm**
- semen/sperm collection, preparation and testing
- surgical sperm retrieval, preparation and testing (includes immature sperm)
- sperm preservation, storage and thawing
- sperm transport, import and export
- sperm destruction/disposal

**Testicular Tissue**
- testicular tissue retrieval, preparation and testing
- testicular tissue preservation, storage and thawing
- testicular tissue transport, import and export
- testicular tissue destruction/disposal

**Oocyte**
- oocyte retrieval, preparation and testing
- *in vitro* oocyte maturation
- oocyte preservation, storage and thawing
- oocyte transport, import and export
- oocyte destruction/disposal

**Ovarian Tissue**
- ovarian tissue retrieval, preparation and testing
- ovarian tissue preservation, storage and thawing
- ovarian tissue collection, transport, import and export
- ovarian tissue collection destruction/disposal

**Pre-fertilization Treatment of Gametes**
- sperm stimulation
- zona drilling or partial zonal dissection (PZD) (chemical, mechanical, laser)

**Fertilization Procedures**
- conventional IVF
- subzonal insemination (SUZI)
- intracytoplasmic sperm injection (ICSI) (using mature or immature sperm)

***In vitro* Embryo Preparation Procedures**
- *in vitro* embryo preparation and testing
- *in vitro* embryo (all stages) cryopreservation, storage and thawing
- blastocyst culture (extended embryo culture)
- preimplantation genetic diagnosis (PGD)
- assisted hatching (chemical/mechanical/laser)

**Gamete/Embryo Transfer Procedures**
- 3rd party donor insemination (DI)
- spousal/partner insemination (IUI)
- direct oocyte sperm transfer (DOST)
- gamete intrafallopian transfer (GIFT)
- *in vitro* embryo transfer
- zygote intrafallopian transfer (ZIFT)/tubal embryo transfer (TET)

***In vitro* Embryo Other**
- *in vitro* embryo transport, import, export, storage
- *in vitro* embryo destruction/disposal

Participants were guided through a discussion of the contents of the list and real-time changes were made to an onscreen version to reflect the discussion and emerging consensus. Additional changes to the list were made throughout the day, as participants considered new issues. The comments raised with respect to the list of assisted human reproduction procedures are summarized below by list category.

### 2.2.1 Semen

Participants noted that semen includes both sperm and seminal fluid and that sperm/semen is processed, not prepared. Collection, processing and testing were seen to be distinct activities which were often the responsibility of different parts of a clinic. Excluding surgical sperm retrieval, a number of participants commented that *semen collection* is done by the male donor (on- or off-site) while clinic staff *receive or obtain* the collected semen. With respect to sperm/semen testing, a number of participants questioned what testing would be included under this heading and felt that testing needed to be further defined. Finally, it was suggested that "surgical sperm retrieval, preparation, and testing (including immature sperm)" be placed under the "Testicular Tissue" category.

### 2.2.2 Testicular Tissue

Participants recommended separating testicular tissue retrieval from testicular tissue preparation and testing. Additionally, it was recommended that "surgical sperm retrieval, preparation and testing (including immature sperm)" be divided with "retrieval" and "preparation and testing" as separate entries on the list.

### 2.2.3 Oocyte

Participants recommended that "oocyte retrieval, preparation and testing" be divided into distinct activities. Additionally, it was suggested that "preparation" be changed to "identification, handling and manipulation".

### 2.2.4 Ovarian Tissue

Participants recommended that "ovarian tissue retrieval, preparation and

testing" be divided into distinct activities. Additionally, it was noted that collection should be removed from the final two list entries in this category.

### 2.2.5 Pre-fertilization Treatment of Gametes

Participants noted that sperm stimulation was a part of sperm processing and that zona drilling and partial zonal dissection were largely abandoned procedures which were no longer carried out in Canada. As such, it was recommended that the whole category be deleted from the list.

### 2.2.6 Fertilization Procedures

Participants questioned the meaning of "conventional IVF" and proposed alternative wording. It was recommended that "conventional IVF" be replaced with "IVF, with insemination" and that "intracytoplasmic sperm injection (ICSI) (using mature or immature sperm)" be replaced with "IVF, with intracytoplasmic sperm injection (ICSI)". Participants recommended that "subzonal insemination (SUZI)" be removed from the list, as IVF with ICSI had superceded SUZI as a procedure in Canada.

### 2.2.7 *In vitro* Embryo Preparation Procedures

Participants recommended replacing "preparation" with "culture" in both the category heading and the first list entry. Further they recommended amending the first list entry to "*in vitro* embryo culture, incubation" and creating a separate category for testing called "*in vitro* embryo culture and assessment". "Blastocyst culture (extended embryo culture)" was removed from the list as the group felt it was captured in the amended first two entries. With respect to "preimplantation genetic diagnosis (PGD)", participants questioned what was meant by this entry. They noted that there were two separate activities involved in PGD: embryo biopsy where the cell is isolated and prepared for analysis; and the genetic analysis of the DNA extracted from the biopsied cell which is performed by an individual with special training. Finally, under "assisted hatching", participants added "other" to the list of methods (chemical, mechanical, laser).

### 2.2.8 Gamete/Embryo Transfer Procedures

Participants engaged in significant discussion with respect to the list entries for "3rd party donor insemination (DI)" and "spousal/partner insemination (IUI)". It was noted that the distinction between using reproductive material from a sexual partner and a third party donor had not been made with respect to the use of oocytes. Further, it was noted that the procedure performed is the same, regardless of the source of the sperm. As such, participants recommended replacing the two list entries with "insemination (IUI/IC)". Participants also suggested that "direct oocyte sperm transfer (DOST)" should be removed from the list as it is not used by Canadian clinics. Finally, participants noted that "ovarian/testicular tissue transplantation" should be added to the list and that "Gonadal Tissue" should be added to the category heading to reflect this addition.

### 2.2.9 *In vitro* Embryo Other

Participants suggested that storage be removed from this category as it was captured in the previous entry for "*in vitro* embryo (all stages) cryopreservation, storage and thawing".

### 2.2.10 Additional Comments

A number of additional comments and issues were raised during the review of the AHR procedure list. First, some members of the group expressed concern regarding the specificity of the regulations as AHR is a rapidly changing field. It was felt that the regulations should be as flexible as possible to accommodate changes and to allow improvements. Second, members of the group raised issues with respect to the provision of satellite monitoring services for an IVF clinic. It was noted that different facilities provide different types of services ranging from only medical monitoring to some analysis of collected semen and possible insemination. Questions were raised about how these services would be licensed and whether satellite monitoring would be a controlled activity. Third, participants questioned whether artificial insemination would be a controlled activity requiring a licence. Participants noted that a wide range of physicians, including obstetricians, gynaecologists and family physicians, perform artificial insemination procedures in their offices. It

was suggested that this is frequently the case in remote areas. Some participants voiced reservations about the provision of these services by family physicians and suggested that the activity should be licensed. Further it was recommended that Health Canada determine the number of artificial insemination procedures performed in Canada each year as well as the number of medical practitioners performing those procedures.

The final list of AHR procedures, as revised by participants, is presented in Box 2 on the following page. This revised list was carried forward to serve as a basis for subsequent discussions on qualifications and possible licensing categories.

**BOX 2: Revised List of Assisted Human Reproduction Procedures**

**Semen (Sperm and Seminal Fluid)**
- sperm/semen receiving/obtaining
- sperm/semen processing
- sperm/semen testing
- sperm preservation, storage and thawing
- sperm transport, import and export
- sperm destruction/disposal

**Testicular Tissue**
- testicular tissue retrieval
- testicular tissue processing and testing
- testicular tissue preservation, storage and thawing
- testicular tissue transport, import and export
- testicular tissue destruction/disposal
- surgical sperm retrieval
- surgical sperm preparation and testing (includes immature sperm)

**Oocyte**
- oocyte retrieval
- oocyte identification, handling and manipulation
- oocyte testing
- *in vitro* oocyte maturation
- oocyte preservation, storage and thawing
- oocyte transport, import and export
- oocyte destruction/disposal

**Ovarian Tissue**
- ovarian tissue retrieval
- ovarian tissue preparation
- ovarian tissue testing
- ovarian tissue preservation, storage and thawing
- ovarian tissue transport, import and export
- ovarian tissue destruction/disposal

**Fertilization Procedures**
- IVF, with insemination
- IVF, with intracytoplasmic sperm injection (ICSI)

***In vitro* Embryo Culture Procedures**
- *in vitro* embryo culture and incubation
- *in vitro* embryo culture and assessment
- *in vitro* embryo (all stages) cryopreservation, storage and thawing
- embryo biopsy/preimplantation genetic diagnosis (PGD)
- DNA analysis/preimplantation genetic diagnosis (PGD)
- assisted hatching (chemical/mechanical/laser/other)

**Gonadal Tissue/Gamete/Embryo Transfer Procedures**
- insemination (IUI/IC)
- gamete intrafallopian transfer (GIFT)
- *in vitro* embryo transfer
- embryo zygote intrafallopian transfer (ZIFT)/tubal embryo transfer (TET)
- ovarian/testicular tissue transplantation

***In vitro* Embryo Other**
- *in vitro* embryo transport, import, export
- *in vitro* embryo destruction/disposal

## 2.3 Qualification Requirements

Using the revised list of AHR procedures, participants were guided through a discussion focussed on the qualifications that are required for individuals to conduct and to supervise these procedures. The group was asked to identify: 1) who performs each procedure; 2) who supervises each procedure; 3) the qualifications of each of those individuals; and 4) where the procedure is done. This information was captured in real-time in an onscreen table; however, due to technical difficulties, the column capturing where the procedure is done was not discussed.

The table, as completed by participants[1], and a summary of participant comments is presented below. The following abbreviations have been used throughout:

- IATA: International Air Transport Association (IATA) Dangerous Goods Regulations
- TDG: Transportation of Dangerous Goods Certificate
- MD: Medical Doctor
- RN: Registered Nurse
- RNA: Registered Nurses Assistant
- RPN: Registered Practical Nurse
- LPN: Licensed Practical Nurse
- BSc: Bachelor of Science
- MSc: Master of Science

There was extensive discussion by the group of the importance of on-the-job training as a required qualification for the performance of most AHR procedures. In particular, participants noted that laboratory technicians and other laboratory staff possess a wide range of credentials, but there is a paucity of formal AHR-laboratory training programs. Some participants noted that an ad-hoc group of interested laboratory directors has been created to develop standard job descriptions and qualifications for laboratory staff; however, the group had not yet presented recommendations.

[1] The final column, "Where is it done" has not been reprinted here as participants did not complete this column at the workshop.

As controlled activity licences would be issued to qualified individuals to undertake particular controlled activities, several participants noted their hesitancy to be in a position of responsibility for the conduct of fellow physicians. It was noted that physicians generally operate autonomously without direct supervision.

A number of participants commented that in general clinic operations, the person who supervises a particular activity is dependent on a number of factors including the range of procedures offered, the size of the clinic, and the organization of the clinic's staff. Participants' questioned if the intent of the exercise was to capture the qualifications of those individuals currently supervising these AHR procedures, or the minimum qualifications of the person supervising to undertake the activity. For instance, the minimum qualification to receive a semen sample may be the ability to read labels and keep simple records; however, supervision is usually performed by someone with more extensive qualifications. Whether that supervisor is a clinic administrator, nurse coordinator, physician, medical director or laboratory director may not be significant. In addition, participants noted that procedures performed by physicians are not generally supervised (physicians self-supervise) except when the procedure is performed by a medical resident under the supervision of an attending physician.

| AHR Procedure | Who does it? | Qualifications | Who Supervises? | Qualifications |
|---|---|---|---|---|
| **Semen (Sperm and Seminal Fluid)** | | | | |
| sperm/semen receiving/obtaining | nurse, technician, clerk | on-the-job-training | lab director/manager, nurse coordinator, physician, medical director | various |
| sperm/semen processing | nurse, technician, physician | on-the-job-training | lab director/manager, nurse coordinator, physician, medical director | various |
| sperm/semen testing | nurse, technician, physician | on-the-job-training | lab director/ manager, nurse coordinator, physician, medical director | various |

| AHR Procedure | Who does it? | Qualifications | Who Supervises? | Qualifications |
|---|---|---|---|---|
| sperm preservation, storage and thawing | nurse, technician, physician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| sperm transport, import and export | patient, clinic, technician | on-the-job-training, TDG, IATA | lab director/manager, nurse coordinator | various |
| sperm destruction/disposal | nurse, technician, physician | on-the-job-training | lab director/ manager, nurse coordinator, physician | various |
| **Testicular Tissue** | | | | |
| testicular tissue retrieval | physician | MD | physician (self or attending) | MD |
| testicular tissue processing and testing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| testicular tissue preservation, storage and thawing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| testicular tissue transport, import and export | patient, clinic, technician | on-the-job-training, TDG, IATA | lab director/manager, nurse coordinator | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| testicular tissue destruction/disposal | technician, physician | on-the-job-training | lab director/manager, physician | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| surgical sperm retrieval | physician | MD | physician (self or attending) | MD |
| surgical sperm preparation and testing (includes immature sperm) | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| **Oocyte** | | | | |
| oocyte retrieval | physician | MD | physician (self or attending) | MD |

| AHR Procedure | Who does it? | Qualifications | Who Supervises? | Qualifications |
|---|---|---|---|---|
| oocyte identification, handling and manipulation | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| oocyte testing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| *in vitro* oocyte maturation | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| oocyte preservation, storage and thawing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| oocyte transport, import and export | patient, clinic, technician | on-the-job-training, TDG, IATA | lab director/manager, nurse coordinator | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| oocyte destruction/disposal | technician, with witness if frozen | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| **Ovarian Tissue** | | | | |
| ovarian tissue retrieval | physician | MD | physician (self or attending) | MD |
| ovarian tissue preparation | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| ovarian tissue testing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |

| AHR Procedure | Who does it? | Qualifications | Who Supervises? | Qualifications |
|---|---|---|---|---|
| ovarian tissue preservation, storage and thawing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| ovarian tissue transport, import and export | patient, clinic, technician | on-the-job-training, TDG, IATA | lab director/manager, nurse coordinator | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| ovarian tissue destruction/disposal | technician, with witness if frozen | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| **Fertilization Procedures** | | | | |
| IVF, with insemination | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| IVF, with intracytoplasmic sperm injection (ICSI) | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| ***In vitro* Embryo Culture Procedures** | | | | |
| *in vitro* embryo culture, incubation | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| *in vitro* embryo culture and assessment | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| *in vitro* embryo (all stages) cryopreservation, storage and thawing | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |

| AHR Procedure | Who does it? | Qualifications | Who Supervises? | Qualifications |
|---|---|---|---|---|
| embryo biopsy / preimplantation genetic diagnosis (PGD) | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| preimplantation genetic diagnosis (PGD) | PGD geneticist | education and experience | PGD lab director | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations (specialization in genetics) |
| assisted hatching (chemical/mechanical/laser/ other) | technician | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| **Gonadal Tissue/Gamete/Embryo Transfer Procedures** | | | | |
| insemination (IUI/IC) | nurse, physician | provincial licence (MD, RN, RNA, LPN) | medical director or physician (self or attending) | MD |
| gamete intrafallopian transfer (GIFT) | physician | MD | physician (self or attending) | MD |
| *in vitro* embryo transfer | physician | MD | physician (self or attending) | MD |
| embryo zygote intrafallopian transfer (ZIFT)/tubal embryo transfer (TET) | physician | MD | physician (self or attending) | MD |
| ovarian/testicular tissue transplantation | physician | MD | physician (self or attending) | MD |
| ***In vitro* Embryo Other** | | | | |
| *in vitro* embryo transport, import, export | patient, clinic, technician | on-the-job-training, TDG, IATA | lab director/manager, nurse coordinator | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |
| *in vitro* embryo destruction/disposal | technician, with witness if frozen | on-the-job-training | lab director/manager | B.Sc. (M.Sc. preferable) + experience and training relevant to type of lab operations |

## 2.4 Possible Licensing Categories

Participants were presented with a possible licensing schema (see Box 3) with different categories of licences for controlled activities, outlined below, and asked to identify which categories would be relevant for each procedure in the revised AHR procedure list. The feedback from the group was captured in real-time in an on-screen table. The final table and a summary of participant comments are provided below.

**BOX 3: Licensing Schema**

- Treatment
  - Clinical
  - Laboratory
- Storage
- Transport, Import, Export
- Research

Participants noted research could be a part of all AHR procedures as clinics, physicians, or researchers look for ways to improve the practice of AHR. The group also noted that in some cases, such as for import or export activities, laboratory staff would have administrative responsibilities to ensure that human reproductive materials are properly packaged and labelled. Participants identified these cases with the notation "X-ADMIN". Finally, a number of participants questioned what was meant by laboratory, particularly with respect to smaller clinics or physicians' offices. It was noted that in some cases, there is no physical separation between clinical and laboratory spaces, nor are procedures performed by different staff. For instance, in a doctor's office a laboratory space may only consist of a small wet lab space and a microscope. One distinction suggested by a participant, was that clinical treatments, unlike laboratory treatments, directly involve a patient.

| AHR Procedure | Treatment | | Storage | Transport, Import, Export | Research |
|---|---|---|---|---|---|
| | Clinical | Laboratory | | | |
| **Semen (Sperm and Seminal Fluid)** | | | | | |
| sperm/semen receiving/obtaining | X | X | | | X |
| sperm/semen processing | | X | | | X |
| sperm/semen testing | | X | | | X |
| sperm preservation, storage and thawing | | X | X | | X |

| AHR Procedure | Treatment | | Storage | Transport, Import, Export | Research |
|---|---|---|---|---|---|
| | Clinical | Laboratory | | | |
| sperm transport, import and export | | X - ADMIN | | X | X |
| sperm destruction/disposal | | X | | | X |
| **Testicular Tissue** | | | | | |
| testicular tissue retrieval | X | X | | | X |
| testicular tissue processing and testing | | X | | | X |
| testicular tissue preservation, storage and thawing | | X | X | | X |
| testicular tissue transport, import and export | | X-ADMIN | | X | X |
| testicular tissue destruction/disposal | | X | | | X |
| surgical sperm retrieval | X | | | | X |
| surgical sperm preparation and testing (includes immature sperm) | | X | | | X |
| **Oocyte** | | | | | |
| oocyte retrieval | X | | | | X |
| oocyte identification, handling and manipulation | | X | | | X |
| oocyte testing | | X | | | X |
| *in vitro* oocyte maturation | | X | | | X |
| oocyte preservation, storage and thawing | | X | X | | X |
| oocyte transport, import and export | | X-ADMIN | | X | X |
| oocyte destruction/disposal | | X-ADMIN | | | X |
| **Ovarian Tissue** | | | | | |
| ovarian tissue retrieval | X | | | | X |
| ovarian tissue preparation | | X | | | X |
| ovarian tissue testing | | X | | | X |
| ovarian tissue preservation, storage and thawing | | X | X | | X |
| ovarian tissue transport, import and export | | X-ADMIN | | X | X |
| ovarian tissue destruction/disposal | | X-ADMIN | | | X |

| AHR Procedure | Treatment | | Storage | Transport, Import, Export | Research |
|---|---|---|---|---|---|
| | Clinical | Laboratory | | | |
| **Fertilization Procedures** | | | | | |
| IVF, with insemination | | X | | | X |
| IVF, with intracytoplasmic sperm injection (ICSI) | | X | | | X |
| ***In vitro* Embryo Culture Procedures** | | | | | |
| *in vitro* embryo culture, incubation | | X | | | X |
| *in vitro* embryo culture and assessment | | X | | | X |
| *in vitro* embryo (all stages) cryopreservation, storage and thawing | | X | X | | X |
| embryo biopsy / preimplantation genetic diagnosis (PGD) | | X | | | X |
| preimplantation genetic diagnosis (PGD) | | X | | | X |
| assisted hatching (chemical/mechanical/laser/ other) | | X | | | X |
| **Gonadal Tissue/Gamete/Embryo Transfer Procedures** | | | | | |
| insemination (IUI/IC) | X | | | | X |
| gamete intrafallopian transfer (GIFT) | X | | | | X |
| *in vitro* embryo transfer | X | | | | X |
| embryo zygote intrafallopian transfer (ZIFT)/tubal embryo transfer (TET) | X | | | | X |
| ovarian/testicular tissue transplantation | X | | | | X |
| ***In vitro* Embryo Other** | | | | | |
| *in vitro* embryo transport, import, export | | X-ADMIN | | X | X |
| *in vitro* embryo destruction/disposal | | X-ADMIN | | | X |

## 2.5 Premises Licensing and Accreditation

Following a brief overview of premises licensing under the AHR Act, participants were led through a short discussion of key issues and considerations in the development of regulations related to the administration of a premises licensing system.

Participants expressed reservations about any system of premises licensing that was overly complex and bureaucratic. Health Canada officials were encouraged to develop a system that was simple and practical. Additionally, members of the group noted that it would be important to avoid conflicts with provincial regulations, guidelines and accreditation programs. It was noted that clinics in the province of Quebec are required to conform with the ISO 15189 Medical Laboratories standard.

A number of participants noted that they are currently accredited by the Canadian Council on Health Services Accreditation (CCHSA). The group was generally in favour of accreditation; however, participants identified a number of issues of concern regarding accreditation. First, some participants felt that under current accreditation programs hospital-based clinics had an unfair advantage over private clinics because areas of responsibility for some accreditation requirements were shared with other parts of the hospitals. It was the perception of some group members that hospital-based clinics received exemptions or escape scrutiny in areas that private clinics were required to address. Second, a number of participants flagged the issue of cost for accreditation programs and noted that this may be a barrier for smaller clinics, which are often located in more remote areas. Finally, participants advised that it would be important to consider accreditation survey methods and regulatory inspection methods with respect to issues of non-conformity or non-compliance, as an accreditation model often has a different focus than a regulatory model.

# 3. Information to be Made Available by the Agency

## 3.1 Overview

Alexandrea Howard, Policy Analyst, AHRIO, presented information related to Section 19 of the AHR Act, which requires the Assisted Human Reproduction Agency of Canada (the Agency) to make a broad range of information related to the Agency's activities, and AHR in Canada, available for inspection by the public. She noted that the purpose of the day was to gather information to support the development of regulations related to the information to be made available pertaining to the Agency's licensing and enforcement activities.

A number of questions and concerns were raised by participants throughout the presentation and in the subsequent open forum discussion. The following is a brief summary of these discussions.

Some participants raised concerns about the extent to which information about their clinics and their practices would be publicly available. Questions were raised about the intent and purpose of the provisions for public availability. Reservations were expressed about how the information may be used by the media as the sector is frequently subject to media scrutiny. Participants noted that currently most fertility clinics make a wide variety of information available to patients through their clinic Web sites and other promotional and informational materials.

Participants raised several questions which linked the release of information related to licensing with issues in the licensing provisions discussed on Day 1 of the workshop. Concern was expressed about the potential impact of making information on licensing available to the public. It was felt that consumer/patient preference for treatment from a licensee, as opposed to an equally qualified individual under the supervision of a licensee, could lead to a demand for clinics to ensure that a higher number of their staff are licenced to perform controlled activities. Some participants felt that the public may distinguish between practitioners and clinics on the basis of the number of licences held rather than the

qualifications and experience of the staff. While some participants had serious concerns about this, others suggested that it would be up to individual clinics to determine who should be licensed, especially as there was no charge for licences. Similar to comments related to licensing expressed on Day 1 of the workshop, several participants also noted that regulations made for the purpose of Section 19 should apply equally to all types of clinics and practices, both private and hospital-based.

A small group of participants expressed reservations about the Agency's powers under section 44 to take or order measures to address threats to human health and safety. Participants were concerned about who would determine if something was a threat to human health and safety and who would have responsibility for the costs incurred as outlined in section 44(3); however, comments were not made related to the availability of information on measures taken under section 44.

Finally, while outside the scope of the day's discussion, a number of participants raised issues and concerns related to the publication of outcomes of assisted human reproduction procedures by the Agency. It was suggested that Health Canada work closely with the Canadian Fertility and Andrology Society and build on the existing voluntary outcome reporting organized by the IVF Director's Group. Additionally, participants noted concerns about the impact of publishing clinic-level outcomes. They strongly recommended that Health Canada speak with representatives of American fertility clinics about the US experience. It was felt that there are a number of lessons that could be learned from international efforts.

## 3.2 Information To Be Made Available

Participants were guided through a discussion pertaining to the availability to the public of Agency information related to licensing and enforcement activities. For different categories of information or records as listed in Section 19, participants were asked to consider:

- what information should be made available for inspection by the public;
- how the information should be made available; and
- when or with what frequency the information should be made available.

For each category of information, participants were asked to consider a number of different cases in which the information could be made available to the public to determine if the circumstances of each case impacted their responses to the above three questions. A summary of the discussion is presented below, grouped by category of information or record.

### 3.2.1 Applications for licence, licence renewals and licence amendments

Participants questioned the value and purpose of releasing information related to applications for licences, licence renewals and licence amendments. Concerns were raised about how the public would use this information and what purpose would be served by making the information available. It was noted that application forms could require a range of information and it would be difficult to comment on specifics without seeing what would be required; however, participants indicated it would be important for the Agency to have a process to verify information submitted in application forms prior to making it available.

Participants advised that a great deal of information that may be included in application forms is currently available on most clinic Web sites.

It was noted that some clinic employees, particularly those who work in laboratories with *in vitro* embryos, may have safety concerns about releasing information that would identify them, the nature of their work and

their place of work. While in some cases, this information is already published on clinic Web sites, it was suggested that some laboratory staff still have reservations and concerns.

A participant suggested that releasing information about an application for licence could have a detrimental impact on job mobility. It was noted that making application information broadly available could "tip-off" a clinic that one of their employees or partners could be planning to leave and set-up their own clinic or join another clinic. Other participants noted that making application information available could provide a level of protection for clinics if valuable staff (who may hold licences to undertake a controlled activity at that clinic) were considering changing clinics. Further, potential employers may wish to be able to verify that an individual has applied for a particular licence.

Participants recommended that no application information should be made available prior to a licence being issued. Once a licence has been issued, it was felt that the name of the applicant and the activity for which they were licensed could be made broadly available. Any other information that may be released should only be made available upon request. A number of participants commented that if a licence is not issued (if an application is denied), no information from that application should be released regardless of whether the application was for an initial licence or a licence renewal. Rather, participants commented that the Agency should keep an up-to-date list of licensed individuals and facilities on their Web site.

### 3.2.2 Licences Issued and Names and Addresses of Licensees

Participants felt that a minimal amount of information on licences issued should be made available to patients. Most participants agreed that the name of licensed individuals or entities, their business address, and the type of licence they hold, could be published on the Agency Web Site; however, some group members were reluctant to make this information broadly available. Some participants suggested that the information should only be available upon request, while others recommended making the information available on a per clinic basis. Some members of the group noted that some licensees and other clinic employees, particularly those who work in laboratories with *in vitro* embryos, have safety concerns

about revealing information about their work, their names and addresses. A number of participants commented that they were concerned that patients would prefer to be treated by individuals holding a licence over others in a clinic who undertake a procedure under the supervision of the individual with the licence regardless of their comparable qualifications. It was felt that any information that is made broadly available should only be released with clear explanatory notes.

With respect to qualifications of licensees, some participants had reservations concerning the public's ability to differentiate between qualifications. It was felt that prospective patients may express a preference for individuals based on their degrees (e.g., PhD vs. M.Sc.) while not recognizing the value of other qualifications such as years of experience. It was noted that information on the qualifications of medical doctors is already largely publicly available through provincial Colleges of Physicians and Surgeons; however, in most cases laboratory staff are not members of a regulated profession with similar levels of publicly available information. One participant suggested that some individuals who would be licensed to perform controlled activities, particularly those with PhDs and MDs, may want information on their qualifications to be available to the public.

When asked about changes in licence standing, such as when a licence is suspended, participants suggested that unless there was a significant health and safety reason for notifying the public, this information should only be available upon request. As previously noted, participants thought the Agency should maintain a publicly available up-to-date list of clinics and practitioners with licences in good-standing which could be changed to reflect suspensions.

### 3.2.3 Notice of Proceedings

It was explained to participants that a Notice of Proceedings could be a document released by the Agency prior to a licensing proceeding to inform individuals of the upcoming event. Alternatively, it could be a document released following a licensing proceeding that would provide a record of that proceeding.

In both cases, participants expressed concern regarding the release of information that would identify a particular licensee. If information in the notice was generic or non-identifying, participants noted that it could be released on the Agency Web site in the same way that an agenda or minutes of a meeting are posted at other regulatory agencies. Where the Agency is convening a proceeding to consider something that may broadly impact the AHR sector (e.g., changes to the terms and conditions of all licences) participants commented that this information should be broadly available so that clinics and other affected parties could stay informed. Also, in cases where the release of identifying information is necessary for the protection of human health or safety, participants noted that this information could be published on the Agency's Web site.

If notices of proceedings contain records of decisions, participants felt that they should only be made available once decisions are finalized or official. Where appeal mechanisms are available to the impacted parties, several participants commented that the information should not be available until these avenues of appeal had been exhausted by the impacted parties.

### 3.2.4 Information and Observations

Participants noted that under most circumstances, and when related to a specific licensee, information and observations submitted to the Agency should only be made available upon request, as outlined in section 43 of the AHR Act. When information or observations related to more general licensing decisions (e.g., expert recommendations on new AHR laboratory standards), participants felt that the information should be broadly available. Participants also commented that reports of Advisory Committees requested by the Agency should be broadly available except in cases where a committee had been convened to provide advice on a specific licence application.

### 3.2.5 Decisions of the Agency

The group discussed a number of issues regarding the availability of information related to decisions of the Agency respecting licensing proceedings. Some participants questioned the value and purpose of making Agency licensing decisions available to individuals who were not a

party to the decision. They expressed concerns about the potential for this information to be misunderstood or to contribute to media sensationalism. Other participants noted that, at the very least, records of decisions should be available upon request. It was suggested that the AHR sector, as well as the public at large, would have an interest in monitoring the Agency's decisions. Additionally, some group members suggested that making information available would contribute to Agency transparency and accountability.

Participants agreed that Agency decisions respecting a particular licensee or group of licensees could be made available, so long as the identity of the impacted parties was not released (either directly or indirectly). Further, the group recommended that Agency decisions pertaining to broad classes of licences or, for instance, changes to the terms and conditions of licences should be made broadly available on the Agency's Web site.

Participants expressed reservations regarding the release of Agency decisions when an affected party (e.g., an applicant or a licensee) may have an opportunity to appeal the decision. It was felt that unless there is an immediate health and safety impact, Agency decisions should not be made available to the public prior to the conclusion of any appeal proceedings.

Some participants expressed concerns about the length of time that information relating to decisions of the Agency would be available to the public. Similar to provisions at provincial Colleges of Physicians, participants noted that suspensions should only remain on an individual or clinic's record for a limited period of time.

In the case that a licence is revoked, a number of participants commented that the Agency should make this information broadly available. Other group members suggested that the licensee's information should be removed from the list of licensed individuals or entities on the Agency's Web site and further information should only be available upon request.

### 3.2.6 Enforcement

Participants were asked to consider three different categories of information related to enforcement activities:

- generic enforcement information (e.g, policies, procedures, information related to day-to-day enforcement activities);
- enforcement information when human health and safety may be impacted or at risk; and
- enforcement information that may have a licensing impact (e.g., a suspension).

The group strongly supported making generic enforcement information outlining how enforcement activities were carried out (e.g., policies, procedures, guidelines, inspection manuals, schedules, etc.) broadly available on the Agency's Web site. The group felt this information would be extremely useful to clinics and licensees. In cases where inspection, compliance or enforcement activities were carried out by a third party on the Agency's behalf, participants indicated that the terms of the enforcement agreement between the Agency and the third party would be of interest to the AHR sector and should also be broadly available. Further, participants advised that enforcement of the AHR Act and information made available to the public pertaining to enforcement activities should be consistent across jurisdictions and clinics, regardless of the who carries out the Agency's enforcement functions.

Participants were not generally supportive of making available to the public information related to specific enforcement actions or licensees except in cases where a significant health or safety risk was identified. Where a health and safety issue existed, the group agreed that information should be made broadly available as soon as possible; however, a number of participants expressed concerns about the determination of what constitutes a significant health and safety risk. They expressed a desire for greater clarity regarding the degree or type of health and safety risk that may require an Agency action such as a public warning or advisory.

In cases where enforcement information leads to a licence-related impact or action (e.g., licence amendment or suspension), participants identified a number of issues of concern regarding the availability of this information to

the public. First, a number of participants expressed concerns about information being released prior to the completion of a full investigation and, in the case of potential licence impacts, prior to licence-related proceedings and appeals. Second, participants raised issues related to the impact of releasing information that may not be fully understood by a lay audience. Third, a couple of participants recommended time limits on the availability of information related to minor violations and suspensions to ensure that practitioners and clinics were not unduly punished for issues which they would subsequently resolve. Finally, participants noted that the sector is often the subject of intense public and media scrutiny and as such, it was felt that making information broadly available on sanctions such as licence suspensions could have a detrimental impact on the broader AHR sector. As such, the majority of participants felt that this information should not be made available for inspection by the public, or should only be available upon request.

Participants felt that other enforcement information that relates to specific licensees but does not have direct health and safety or licence impacts, should not be broadly available. While it was noted that inspection reports are available to the public in the United Kingdom, a number of participants felt they were of little value to a lay audience.

# 4. Final Discussion and Next Steps

At the conclusion of Day 2, participants were provided with an opportunity to ask Health Canada officials any outstanding questions or provide final comments on the workshop and subsequent steps in the development of regulations.

Questions were asked regarding the appointment of the Agency's President and Board of Directors as well as the timing of the required parliamentary review of the AHR Act.

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 draft copy of the report for comment before the report is finalized and published on Health Canada's Web site.

In response to questions regarding the potential organization and timing of future workshops, participants commented that Friday and Saturday meetings were acceptable so long as they have at least 6 to 8 weeks notice of the planned dates.

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.