Health Canada Santé Canada

Workshop on the Licensing and Regulation of Controlled Activities under the AHR Act and the Obligations of Licensees Regarding Health Reporting Information

Meeting Report

November 24 - 25 in Montreal - Delta Centreville

December 1 - 2 in Toronto - Sheraton Downtown Hotel

December 8 - 9 in Vancouver - Delta Suites

Prepared by Health Canada

Final Report
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The following meeting report summarizes the discussion that took place at the November and December, 2006 workshops with medical fertility clinics and laboratories of assisted human reproduction services. The workshops were used to gather information on stakeholder opinions for 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 consultations organized by Health Canada's Assisted Human Reproduction Implementation Office (AHRIO). Participants in the meetings included representatives from medical fertility clinics and laboratories, both private and hospital-based, providing services in assisted human reproduction from across the country.

The objective of the consultations was to seek input from selected stakeholders to advance the development of regulations under the *Assisted Human Reproduction Act* (AHR Act). Specifically, these consultations focussed on the following sections of the AHR Act:

- the conduct of controlled activities (section 10)
- licensing of controlled activities, licensing of premises, and licensing administration (sections 40 to 43)
- health reporting information (sections 14, 15, 16 & 18)
- health reporting information registry (section 17)

For each topic of discussion, Health Canada presented preliminary policy proposals for regulatory requirements and asked participants to provide their comments and share their expertise on the issues. It is important to note that most of the discussions were focussed on the basic IVF process for persons using their own gametes for their own reproductive use.

With respect to the conduct of controlled activities, Health Canada guided participants through a discussion of the contributing risk factors and the ensuing control measures, including record-keeping, required to mitigate the risks associated with 10 specific controlled activities. Participants provided comments on the proposals generally, as well as detailed comments on the proposed wording for some requirements. Participants also provided valuable information relating to how these activities take place in their respective environments (laboratory and clinical). There was general support for the control measures proposed for laboratory activities, but with respect to the control measures for clinical controlled activities, participants were concerned that the regulatory requirements proposed may be too prescriptive and interfere with their professional practice.

The discussion on licensing was divided into the proposed qualification requirements to obtain a licence for the conduct of controlled activities as well as the proposed requirements to obtain a premises licence. There were also discussions related to the administrative processes for these licences. Again, participants expressed general support for most of the proposals presented but were concerned that prescriptive requirements would be too burdensome and could negatively impact both the AHR sector and patients. Participants also questioned the capacity of the Agency to both process and enforce the licensing requirements and expressed concern regarding the lack of formal appeal mechanisms.

In the discussion on health reporting information (HRI), participants provided valuable

information about their current practices related to the gathering and storing of HRI. Participants also expressed a wide range of views on the proposed requirements for the collection, retention and disclosure of HRI. Again, participants were mostly concerned with the role and capacity of the Agency, as well as the impact of the regulatory requirements on their operations.

1. Introduction and Context

In November and December of 2006, Health Canada held consultation workshops with a targeted group of stakeholders (clinical and laboratory staff of major clinics offering *in vitro* fertilization) in three Canadian cities (Montreal, Toronto and Vancouver) to obtain feedback on preliminary policy proposals for the following sections of the *Assisted Human Reproduction Act* (AHR Act):

- the conduct of controlled activities (section 10)
- licensing administration, licensing of premises and licensing of controlled activities - qualifications (sections 40 to 43)
- health reporting information (sections 14, 15, 16 & 18)
- health reporting information registry (section 17)

The workshops also presented the opportunity to learn from the expertise of the participants and for Health Canada to provide clarification on the scope and intent of the AHR Act and its regulatory framework.

These workshops were part of Health Canada's wider consultation strategy for the development of AHR regulations and built upon other previously held meetings and workshops. In particular, the licensing framework of the AHR Act had been the subject of a consultation in February of 2006[1]. The topic of health reporting information had also been discussed with patient groups in April of 2006.[2]

Health Canada began the meetings by emphasizing the importance of participants' feedback during this crucial stage of the regulatory development process. Representatives from Health Canada's Assisted Human Reproduction Implementation Office (AHRIO) provided a short overview of the process for the development of the AHR regulations. There was also a brief presentation on the Government of Canada's regulatory process and an overview of the challenges faced by the department in the development of the regulations.

Each session began with a presentation by an AHRIO analyst who provided the scope of their

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[1] Health Canada (2006) *Meeting Report: Workshop on Licensing and on Information Available from the Agency*. Available at: http://hc-sc.gc.ca/hl-vs/pubs/reprod/2006_meet-reunion/index_e.html

[2] Health Canada (2006) *Meeting Report: Workshop with Patients/Clients* Available at: http://hc-sc.gc.ca/hl-vs/pubs/reprod/2006-patient-meeting-reunion/index_e.html

regulatory project and presented proposed policy options for discussion. Participants were then asked to provide their feedback on the options presented.

In preparation for the meetings, participants had been provided background information on the topics to be discussed. These documents are available on the Health Canada web at: http://hc-sc.gc.ca/hl-vs/reprod/index_e.html

2. Conduct of Controlled Activities

To begin the discussion on the conduct requirements for controlled activities under the AHR Act, Health Canada reviewed the AHR Act's definition of an assisted reproduction procedure, that being a controlled activity performed for the purpose of creating a human being and which may not be undertaken except in accordance with sections 10 to12 of the AHR Act. Section 10 controlled activities are to be performed only in accordance with the regulations and a licence.

The consultation addressed only the development of a regulatory framework for controlled activities involved in the basic *in vitro* fertilization (IVF) process for persons using their own gametes for their own reproductive purposes. Health Canada reviewed the proposed classification of the controlled activities (both laboratory and clinical AHR procedures) that are necessary for the basic IVF process. Specifically, the discussions focussed on the control measures required to mitigate the risks associated with the following controlled activities:

1) semen/sperm obtaining;
2) clinically retrieving sperm;
3) semen/sperm processing;
4) controlled ovarian hyperstimulation;
5) oocyte retrieval;
6) oocyte processing;
7) IVF with insemination (conventional IVF);
8) IVF with intracytoplasmic sperm injection (ICSI);
9) *in vitro* embryo culture and assessment; and
10) *in vitro* embryo transfer.

Based on the background documents provided, the facilitators guided the participants in a discussion of the following considerations for each of these proposed controlled activities:

- the contributing factors giving rise to negative outcomes associated with the controlled activity;
- the proposed control measures for safeguarding against the identified contributing factors; and
- the proposed criteria for record keeping related to the activity.

For these discussions, participants were divided into two groups based on their expertise:

laboratory procedures and clinical procedures. However both ICSI and *in vitro* embryo transfer were discussed with the entire group due to some of the overarching issues related to developing regulatory policy for those two procedures.

2.1 Laboratory Controlled Activities

For the discussion of controlled activities taking place in a laboratory, the contributing factors to negative outcomes were first broadly discussed for all possible laboratory activities; these were:

- inappropriate use of equipment and materials;
- misidentification of samples;
- improper records.

The discussion on the laboratory controlled activities began with an overview of the risks and proposed control measures for general laboratory conduct common to all laboratory controlled activities, followed by a discussion on specific conduct requirements for each controlled activity.

Inappropriate use of equipment and materials

For this contributing factor, participants suggested that there are no specific control measures for any one individual activity and agreed that control measures were appropriate to mitigate the risk of inappropriate use of equipment and materials common to all laboratory activities.

More specifically, participants suggested that the proposed control measure to have media or protein supplements tested either in-house by the AHR clinic in cases where the manufacturer does not conduct any testing, may be too burdensome. Regarding the proposed control measure that media prepared in house be assessed for quality control, participants indicated that in most cases media is not made in-house and is purchased from a manufacturer who tests media in batches; as such, participants explained that usually media and protein supplements are tested by the manufacturer and are handled under aseptic conditions. A key concern was the testing of store-bought plastics which are generally DNA/RNA free, but not necessarily tested for quality by the manufacturer or the AHR clinic. Most participants agreed with the requirements that plastic containers and tubes should be non-toxic and made of quality material.

Participants stated that the proposed control measure to use appropriate methods to maintain temperature, pH and osmolarity was inaccurately stated. They suggested that the requirement state that appropriate culture conditions should be maintained using external measures of pH, temperature and osmolarity. Similarly, some suggested rephrasing the control measure of "appropriate use of equipment and materials" to focus on the purpose intended.

Misidentification of samples

The misidentification of samples due to improper labelling was identified as a risk common to all laboratory controlled activities. With respect to this contributing factor, participants felt that any two identifying pieces of information (i.e., the name and the date of birth) would be sufficient and that identifying information need not be specified in regulatory policy. Moreover, regulatory policy stating that the identifying information should be written on labels using indelible ink should also be removed because in some clinics ink is not used. Rather, the label is created using a permanent method such as etching.

Some participants stated that the second control measure to double-check labels may be too stringent and that double-checking ought to mean confirmation of the label twice, and not necessarily by two individuals. One participant referred to a study that showed that double-checking by two individuals is not more effective at reducing errors.[3] Some participants also suggested that the requirement should state that suitable procedures be in place to verify and track the identification of gametes and *in vitro* embryos.

Improper records

With respect to the system of maintaining proper records, all of the stakeholders concurred with the proposed control measure that records should be kept indicating each and every occasion when gametes and *in vitro* embryos are handled, and by whom. A second proposed control measure stated that records should encompass any data that may enable traceability of factors having an impact on the quality and safety of gametes. Such data would include serial numbers/batch numbers of equipment and materials coming into direct contact with gametes and *in vitro* embryos, or data related to monitoring and maintaining the required conditions. However, some participants raised the concern that plastic culture containers are not tested and so their lot numbers are not recorded, and they suggested that the control measure should reflect this practice.

Semen/Sperm Obtaining: Self-collection

Control measures

Health Canada also suggested four control measures to account for environmental factors that affect sperm quality. Some participants stated that the proposed requirement that a sterile container be used is problematic because a collection condom, if designated a container, would not be sterile. Some participants also stated that details about the container (e.g., that it be made of plastic, or that it be disposable, or have a large mouth) should not be a regulatory requirement.

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[3]Brison et al. (2004). Reducing risk in the IVF laboratory: implementation of a double witnessing system. *Clinical Risk, 10,* 176-180.

All participants rejected the proposed requirement against the use of condoms, creams or lubricants because in some cases, lubricants are needed and a collection condom would be suitable for collecting semen. Similarly, all participants suggested that the control measures should require that collection be performed with methods and materials that are not toxic to sperm.

All of the participants agreed that there should be a requirement for a period of abstinence but that the requirement should be appropriate or tailored to the individual. They stated that requiring a general abstinence of 2-5 days may still not fully cover the range of time required for abstinence in some rare cases. Also, in order to maintain the temperature of the sample during transport when collected off-site, some participants suggested that the requirements should state that the temperature should be maintained at close to body temperature. Finally, all participants agreed that the proposed requirement for the prompt delivery of the sample to the clinic was satisfactory.

Records

With respect to the requirement that proper records be maintained for the controlled activity semen/sperm obtaining, participants suggested the following:

- patient identification should include the name of the partner along with the name of the semen/sperm sample donor;
- the type of container used to collect the sample should be recorded if it is different than the standard used in the clinic;
- the period of abstinence should only be recorded if it is different than what is stated in the standard operating procedure; and
- the time and place of collection should also include the date.

Semen/Sperm Processing

Control measures

All of the participants agreed with the proposed requirement that preparation methods be tailored to the individual, but they also felt that the requirement to avoid excessive centrifugation was adequately addressed in the requirement to tailor samples to the patient and thus should not be a separate regulatory requirement.

Regarding the proposed requirement that gamete processing be performed using a sterile technique, participants noted that nothing is fully sterile in a laboratory environment and suggested that the terms “aseptic” or “clean” be used or that the term sterile be clearly defined. Some participants felt that “aseptic technique” could be specified with a few additional requirements.

Records

All participants accepted the proposed requirements regarding records and they also suggested adding the following:

- name and date of birth;
- sample parameters for sperm before and after processing to include semen volume, the concentration of sperm and sperm motility;
- date and time of processing;
- time recorded for not only collection but also processing.

Oocyte Processing

Control measures

Several control measures were proposed for the controlled activity oocyte processing. Participants explained that oocyte assessment is performed on the oocyte cumulus complex and not on the oocyte itself. They explained that after oocyte retrieval, the oocyte may not be present under the mass of cumulus cells. As such, any regulatory requirement should accurately reflect such terminology.

Participants agreed with the proposed requirement that gametes be handled in a manner which protects their quality and they stated that it was not necessary to also require that oocyte processing be performed rapidly.

Records

All participants agreed to the proposed requirement related to records and again suggested naming oocyte to oocyte corona complex to more accurately reflect what is being recorded.

***In vitro* Fertilization**

Control measures

For the controlled activity of IVF, all participants agreed that requirements should address the concentration of *motile* sperm, instead of simply sperm. Some participants felt that the requirement to avoid reinsemination of unfertilized oocytes should be addressed in ICSI, but others felt that this requirement should be addressed in IVF because someone might try to use donor sperm to reinseminate the unfertilized oocyte. Some participants felt that the theoretical risk of polyspermy is too low to be able to prevent reinsemination and that this requirement should be removed.

Records

With respect to the records required for IVF, participants explained that recording the relative time for insemination (incubation time) would require an individual to make a calculation susceptible to human error. As such, if dates and times for when oocyte cumulus mass were collected and when fertilization was observed are recorded, the incubation time can be calculated when required but should not be performed as a standard method for record maintenance.

Participants also suggested adding the following requirements:

- records should contain the names of both the sperm and egg donors;
- date and time of the beginning of insemination (incubation start time) could be recorded;
- instead of the number of oocytes inseminated, it should read the number of oocyte corona complexes inseminated.

In vitro embryo Culture and Assessment

Control measures

Perhaps the greatest amount of discussion of the controlled activity *in vitro* embryo culture and assessment was on the proposed requirement to observe the presence of two pronuclei to denote normal fertilization. There was disagreement amongst participants as to what should be permitted. Some participants stated that observing the presence of two pronuclei is the safest way to mitigate the risk of abnormal ploidy and that even in rare instances, transfer of an embryo with zero or one pronuclei should not be permitted. However, many participants stated that in rare instances, they should be permitted to transfer embryos with zero pronuclei upon having informed consent from patients. All participants stated that they never transfer anything with three pronuclei and all agreed that embryos with three pronuclei should not be selected for transfer. Some stated that criteria for fertilization should be based on the different numbers of polar bodies and pronuclei and should be defined by the clinics and not stated specifically in regulatory policy.

Although some participants stated that a broad range from 14-21 hours could be a reasonable regulatory requirement, to assess embryos for fertilization, all participants agreed that the proposed control measure should not specify a time window but that it should be defined by the clinics in standard operating procedures.

Records

There were a few concerns expressed by stakeholders on maintaining records. As stated previously, some participants felt that recording the relative time for fertilization is a calculation susceptible to human error. Therefore, in order to prevent miscalculations, both the time for when the incubation for insemination begins (if using conventional IVF for insemination), or the time when ICSI was performed, should be recorded along with the date and time for when

fertilization was observed. From those records, a relative time for fertilization can be calculated when required. Similarly, the record of the stage of *in vitro* embryo development prior to transfer should be written so that the grade of embryo should be recorded at the stage that the individual decides to assess and transfer. That does not obligate the individual to assess and record the score at each stage of embryonic development.

The misidentification of samples due to improper labeling was identified as a risk common to all laboratory controlled activities. With respect to this contributing factor, participants felt that any two identifying pieces of information would be sufficient and that specifying the identifying information should not be stated in regulatory policy (i.e., name and date of birth). It did not have to be the two proposed (proper labeling of the container which should contain the name and the date of birth using indelible ink and having suitable procedures in place to double-check the identification of gametes and *in vitro* embryos). Furthermore, all participants stated that there should be some sort of permanent labelling method since clinics use different methods, from using permanent ink to etching.

Some participants felt that the second control measure to double-check labels may be too stringent and that double-checking ought to mean confirmation of the label twice, and not necessarily by two individuals. One participant referred to a study that shows that double-checking by two individuals is not effective at reducing errors.[4] Some also suggested that the requirement should state that suitable procedures are in place to verify and track the identification of gametes and *in vitro* embryos.

2.2 Clinical Controlled Activities

In general, participants were concerned that regulations pertaining to clinical activities would be too prescriptive. They felt that prescriptive regulations would not necessarily serve the ultimate goal of safeguarding the health and safety of persons undergoing assisted reproductive procedures, particularly given the need of individual treatment approaches. They also felt that prescriptive regulations may not anticipate and address the rapid development in the field. As well, highly prescriptive requirements may not allow for ongoing practice improvements. Many felt that clinical practices are more effective than regulations and that regulations should not address all of the details that are better suited to clinical guidelines. Participants stated that regulations should not focus on the intent of the process, but on the quality of practice and the safety of the procedure.

Participants also emphasized the need for a monitoring or accreditation body flexible enough to adapt, quickly to the changing field. Many endorsed the existing voluntary accreditation process for assisted reproductive technology (clinical and laboratory services) governed by the Canadian Council on Health Services Accreditation (CCHSA).

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[4]Brison et al. (2004). Reducing risk in the IVF laboratory: implementation of a double witnessing system. *Clinical Risk, 10,* 176-180.

With respect to records, participants emphasized that the regulations should address the safety of records. Participants noted that there is already a process regarding requirements for medical records, as well as provincial and territorial licensing authorities (Colleges of Physicians and Surgeons) that govern this area and expressed concern with potential regulatory overlap. Many participants were also very concerned about how the inspection of records would be conducted, and particularly how the inspectors would interpret a requirement for recording adverse events (e.g., whether the adverse events should be documented in a summary way to facilitate inspection).

With respect to the issue of complications and adverse events, participants noted that it is important to define complications and adverse events and to record only when, not whether, an adverse event occurs. Participants emphasized that a major adverse event was usually a procedure failure.

There was general agreement that there should be Standard Operating Procedures (SOPs) for all clinical activities (i.e., written procedures or protocols). Participants also stated that SOPs should specify the way clinics communicate with their patients.

In addition to these general comments, the following sections summarize participants' suggestions and comments specific to each proposed clinical controlled activity.

Clinically Retrieving Sperm

Contributing factors to negative outcomes

In addition to those presented in the workbook prepared for the consultation, participants identified other elements that could give rise to negative outcomes associated with clinically retrieving sperm, including:

- improper clinical evaluation;
- incomplete genetic evaluation;
- inappropriate selection of sperm retrieval technique;
- poor quality of the sample retrieved;
- inappropriate timing of sperm retrieval and oocyte retrieval.

Control measures

In regards to mitigating potential negative outcomes, participants emphasized the importance of the following:

- surgical expertise (qualifications);
- relevant experience;
- proper clinical and genetic evaluation (clinical decisions should be reached through a

team approach, i.e., in consultation with a genetic counsellor or geneticist);
- proper post-procedure care and follow-up of patients to avoid complications.

Records

With respect to the criteria for records for clinically retrieving sperm, participants highlighted the following:

- records should include the operative report;
- a distinction should be drawn between a surgical procedure record and a specimen record (the latter comes out of the laboratory processing the retrieved sample);
- there should be documentation on the time of collection, the time of delivery and the transport medium used;
- there should be documentation on eventual sample destination and use (e.g., cryopreservation);
- sample labelling is the surgeon's responsibility until the sample is handed out to the laboratory, but the clinical director has overall responsibility. Once the sample reaches the laboratory, it is the laboratory director's responsibility.

Additional comments

In the discussion on clinically retrieving sperm, participants expressed that it is important to accommodate the existing physicians in the field, as well as to 'set the bar' for new practitioners. Participants also worried that imposing specific training requirements could present an obstacle because it is already difficult to access specialists.

Controlled Ovarian Hyperstimulation

Participants agreed that this controlled activity should be renamed *Ovarian Stimulation prior to Oocyte Retrieval* because this most adequately refers to ovarian stimulation performed in the context of *in vitro* fertilization (IVF, either with conventional insemination or IVF with ICSI) as well as IVF alternatives such as gamete intrafallopian transfer (GIFT).

Contributing factors to negative outcomes

In addition to those identified by Health Canada, participants identified additional elements that could give rise to negative outcomes associated with ovarian stimulation prior to oocyte retrieval, including:

- improper clinical evaluation;
- improper informed consent;
- lack of adequate patient education and communication (verbal and written) and lack of a treatment plan for the patient - clinic communication if problems arise;
- improper management of OHSS.

Control measures

Participants proposed many changes to the proposed wording for the control measures, such as:

- In line with the above-mentioned title change, participants felt that the following proposed requirement should be removed from the proposed control measures: "women undergoing treatment with clomifene citrate should be offered ultrasound monitoring during at least the first treatment cycle;"

- As well, the following proposal was regarded by many participants as highly prescriptive: "Ultrasound follicular tracking as an integral part of monitoring". Participants argued that, over time, the technological means of monitoring might change. These participants preferred more general referring to "adequate frequency of monitoring;"

- With respect to the proposal that "the use of ovarian stimulation agents should be confined to the lowest effective dose and duration of use", some participants endorsed adding "in relation to individual clinical case or patient;"

- In addition, some participants suggested using the wording "safest effective dose and duration of use" instead of "lowest effective dose and duration of use;"

- However, many participants strongly opposed the requirement that "the use of ovarian stimulation agents should be confined to the lowest effective dose and duration of use", regardless of any proposed wording adjustment. They argued that ovarian stimulation agents dosing is a clinical judgement issue and endorsed the wording "judicious use of ovarian stimulation drugs".

Records

With respect to the criteria for records regarding ovarian stimulation prior to oocyte retrieval, participants highlighted that there should be documentation on all the following:

- sperm source (partner's name);
- whether or not third party donor gametes are used;
- plan for IVF or ICSI;
- number of previous ovarian stimulation cycles;
- monitoring results (such as ultrasound data: number of developed follicles); and
- reason(s) for cancellation of cycle.

Additional comments

In the discussion on controlled ovarian hyperstimulation, participants also expressed the following views and concerns:

- Regulations should not limit the number of ovarian stimulation cycles per patient;
- It is crucial to make sure patients are informed about medications and dosage since patients self-medicate;
- Some participants stated that ovarian stimulation performed for non-IVF needs to be controlled. To achieve this, requirements for qualifications should be clear and specific; and
- Participants stated that the choice of stimulation protocol relies on medical judgement and should be tailored as per the individual patient's clinical characteristics. Nevertheless, they did not discount the possibility that some physicians performed ovarian stimulation improperly (i.e., used aggressive stimulation protocols).

Oocyte retrieval

Control measures

Participants were concerned that some of the proposed control measures were too prescriptive, in particular the following proposals:

- "Women undergoing transvaginal retrieval of oocytes should be offered conscious sedation" - some suggested instead that "Women undergoing transvaginal retrieval of oocytes should be offered adequate analgesia";
- "Women who have developed at least three follicles before oocyte retrieval should not be offered follicular flushing" - all participants felt that a decision regarding follicular flushing was a subject of professional judgement rather than a matter of regulatory oversight;
- Participants were also of the opinion that oocyte retrieval protocol should address post-operative recovery and specify optimal period for follow-up.

Records

With respect to the criteria for records in relation to oocyte retrieval, participants highlighted the following:

- instead of proposed documenting of "number of follicles aspirated", most participants preferred recording "number of oocytes retrieved";

- records should include information on: identification of sperm source (partner's name); previous oocyte retrievals; eventual use of oocytes; operative report (i.e., oocyte retrieval procedure report);

- a distinction should be drawn between clinical records and oocyte retrieval procedure records.

Additional comments

When asked by Health Canada, participants confirmed that infectious disease testing was routinely carried out for assisted reproductive procedure performed for a patient's own reproductive use.

IVF with ICSI

Health Canada launched this discussion by presenting statistics on the use of ICSI in other countries and the documented tendency of worldwide "over-application" of ICSI. Health Canada explained that analysis of that data, coupled with an ongoing unresolved scientific debate with respect to potential long-term risks of ICSI, had prompted the department to consider "unjustified use" (i.e., unnecessary) of ICSI as one of the contributing factors to negative outcomes.

Some participants disagreed very strongly with the premises of "unjustified" use of ICSI. They argued that the reported increase in relative risk for birth defects in AHR procedures produced offspring could not be conclusively attributed to ICSI.

Control measures

The proposed control measures for preventing unjustified use of ICSI elicited strong objections from the majority of participants. Although participants concurred with a requirement for a written procedure (SOP) for ICSI, they strongly disagreed with stipulating even broadly defined circumstances under which ICSI should be applied.

Namely, the following proposed requirements were regarded as both highly prescriptive and limiting to a physician's professional judgement: ...in the presence of severe male infertility; ...where prior fertilization failure or low fertilization rate by conventional IVF has occurred; ...when sperm was cryopreserved prior to cancer treatment; ...prior to preimplantation genetic diagnosis for single gene defects performed by polymerase chain reaction" Instead, participants suggested more general wording such as "ICSI should be used for appropriate clinical indications".

- In addition, many participants stated that regulations should be silent in regards to rescue ICSI. However, they agreed that it was inappropriate to wait until the IVF cycle had begun before asking patients to make a decision on rescue ICSI.

- Participants also objected to a requirement that would address "avoidance of use of spermatids." They argued that even though use of spermatids was currently considered an experimental procedure, future technological developments might prove otherwise.

- The importance of genetic testing of males/couples prior to ICSI, depending on the diagnosis, was generally undisputed. However, participants emphasized that genetic testing could only be offered and not imposed to patients.

- Participants noted that genetic counselling for patients contemplating ICSI is important for informed decision making.

Records

With respect to criteria for records in relation to ICSI, participants highlighted that records should also include:

- number of oocytes fertilized normally and abnormally;
- number of degenerated oocytes (i.e., oocyte damage rate).

IVF Embryo Transfer

Control measures

Proposed requirements that a written procedure for *in vitro* embryo transfer should address: "the type of catheter used, the use of ultrasound guidance; the number of *in vitro* embryos to be transferred (e.g., number transferred relative to the age of the woman)..." were considered limiting to a physician's professional judgement.

The main discussion was focussed on recently published "Guidelines for the number of embryos to transfer following *in vitro* fertilization" (Journal of Obstetricians and Gynaecologists of Canada, No. 182, September 2006: 799-813) which was "intended to minimize the occurrence of multifetal gestation, particularly high-order multiples, while maintaining acceptable overall pregnancy and live birth following IVF". Despite the fact that these guidelines have been jointly developed by the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the Canadian Fertility and Andrology Society (CFAS), participants were almost unanimously opposed to incorporating these into regulations.

Participants fully acknowledged the seriousness of multiple pregnancies risks. They concurred that Canada has one of the highest multiple pregnancy rates following IVF treatment. They argued, however, that a crucial obstacle to limiting the number of embryos transferred following IVF was a lack of public funding for IVF[5].

Records

With respect to criteria for records in relation to *in vitro* embryo transfer, participants highlighted that regulations should define what exactly 'justification' refers to in the proposed criterion for documenting "number of embryos transferred and justification."

3. Licensing

Health Canada opened these sessions by describing the licensing framework of the Act and explaining that the regulations are meant to ensure that controlled activities are undertaken by qualified persons in appropriate environments. Health Canada further emphasized that the ultimate goal of the licensing framework is to mitigate risks and protect the health and safety of persons undergoing AHR procedures.

Health Canada explained that two kinds of licences are required under the Act: a licence to undertake a controlled activity and a licence to permit the use of premises for a controlled activity. The discussions on licensing were divided into three different topics: A) Licensing of Controlled Activities; B) Licensing of Premises; and C) Administration of Licensing.

As with the discussion on controlled activities, participants expressed the overarching concern that the regulatory requirements not be too prescriptive. There was also some resistance to the requirement for two types of licences (for controlled activities and for premises) and to the proposal that each individual performing a controlled activity, as opposed to the laboratory or medical director, would need to obtain a licence.

Participants had many questions about section 71 of the AHR Act (the grandfathering clause) as well as when regulatory requirements would come into force. In particular, participants wanted to know how much time clinics and laboratories would have to adjust to new requirements.

Participants were also concerned about the inspection process. They questioned whether inspectors would have enough knowledge of the AHR sector to be able to perform a proper inspection.

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[5] Many stakeholders have told us that because the costs of IVF are quite high, patients often decide to transfer several embryos to increase their chances of pregnancy and avoid the need to repeat another IVF cycle. This often results in multiple pregnancy rates.

3.1 Licensing of Controlled Activities

Following a presentation on the licensing of controlled activities, Health Canada representatives reminded participants that the scope of the discussion would be limited to proposals addressing the designation and licensing of clinical and laboratory AHR procedures under section 10 of the AHR Act, and the qualifications required of individual applicants. Proposals related to the licensing of other controlled activities (such as reimbursement or research) are still being developed by Health Canada. The following summarizes participants' comments on each topic.

Designation

Participants reviewed a proposed list of clinical and laboratory AHR procedures within the scope of section 10 that could be designated as controlled activities requiring a licence.[6] Participants confirmed that the list accurately reflects what takes place within their clinics and had few suggestions for changes. While they were generally comfortable with the scope of the list, there was extensive discussion on the scope of each activity on the list. All participants noted that further work would be required to clarify what was meant by each activity on the list (such as sperm import, oocyte storage, or embryo obtaining), including what is involved in performing that activity and who would be licensed to undertake that activity. Several participants also noted their concern with the number of activities on the list and suggested that licensing this number of activities would be burdensome.

Qualifications

Participants reviewed a proposal outlining the qualifications an individual applicant would be required to demonstrate in order to be licensed to undertake each controlled activity. Many participants voiced concern regarding the licensing of every individual who performs a controlled activity (e.g., sperm processing, oocyte retrieval, etc.). They believe that only the medical and/or laboratory director should be licensed to undertake activities and that they should then take responsibility for the conduct of employees they manage and supervise.

Laboratory activities

At the outset of the discussion, participants noted that the CFAS Laboratory Special Interest Group was developing a document that would outline the competencies and qualifications of individuals in AHR laboratories. Many participants felt that Health Canada should use this document as a basis for the regulations and work with the CFAS to develop regulatory proposals.

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[6]The proposal was developed based on input received by representatives of AHR clinics at a previous consultation. Please refer to: Health Canada (2006) *Meeting Report: Workshop on Licensing and on Information Available from the Agency*. Available at: http://healthcanada.gc.ca/reproduction

Participants confirmed that an applicant should be required to have a bachelors degree in a relevant medical or scientific field or be a certified medical laboratory technologist. Several additional credentials, such as higher level degrees, medical degrees and veterinary degrees or diplomas were also recommended. For those activities which take place in smaller artificial insemination clinics (or doctor's offices), it was noted that the credentials of registered nurses should be added as an acceptable credential. Several participants commented that it would be important to recognize foreign credentials as many of their staff completed their studies in other countries. Participants also noted that an exception to the requirement for a credential may be required for individuals currently grandfathered under the AHR Act (as per section 71) who may have many years of experience, but no formal credential.

With respect to the proposed training requirements, participants felt that the topics of training were reasonable; however, they had several concerns related to how the requirements could be met. Participants raised questions about the delivery and documentation of training. It was felt that the Agency could provide clinics with standardized information and training logs to help applicants fulfill this requirement. Some participants commented that the quality of training received would depend on who was providing the training. It was noted that requirements for extensive training could be a burden on smaller clinics. Participants also noted that in some cases, there is no specific training in new techniques; rather, laboratories adopt new procedures based on scientific articles.

There was extensive discussion regarding the proposal that an applicant be required to complete many of the activities under supervision 30 times. Participants strongly argued that this requirement would be excessive and unreasonable and, in some cases, impossible to achieve. While most participants did agree that an individual should be required to complete an activity under supervision before they could be licensed to perform that activity independently, it was noted that the actual number of times it might take for that person to become competent varied widely based on: the skills and experience of the individual; the quality of the instruction and standard operating procedures; and, the complexity of the procedure. It was also noted that while experience performing the procedure was important, skill could often be developed by practising on non-human material. Participants strongly felt that an alternative requirement, such as the submission of a letter of reference from a supervisor, should be considered.

The issue of who could be a supervisor and provide attestation that an individual has completed certain requirements was raised by participants and was the source of significant debate. For some, the qualifications of this person were at least as important as the qualifications of the individual performing the procedure. A number of participants felt that supervisors should be required to have additional qualifications or competencies, such as experience mentoring employees. Other participants felt this would be excessive and noted that laboratory managers and supervisors should be able to provide this attestation without meeting additional regulatory requirements.

Many participants asked how these requirements would apply to individuals who are currently "grandfathered" under section 71 of the AHR Act; that is, whether grandfathered applicants

would be required to provide as much information as new applicants. Concerns were raised about the amount of effort required to assemble applications for licences, as well as the Agency's capacity to process those applications. Participants strongly recommended that alternative means of qualifying for a licence be considered for individuals who are currently working in the field.

Some participants questioned whether there should be a requirement for the maintenance of competency, and if there was, they questioned what the impact would be in terms of the distribution of work in clinics.

Looking at specific laboratory activities, participants provided a number of comments. With respect to import, export, and transport activities, participants noted that further clarification on the scope of the activity would be required as many parts of the shipping and receiving process are completed by administrative staff. Several participants also questioned whether a patient could transport their own material. Participants noted that many procedures related to the preservation of fertility (such as the removal of gonadal tissue in cases of cancer) may not take place in AHR clinics. It was suggested that more work is required to develop appropriate proposals related to the licensing of these activities. With respect to preimplantation genetic diagnosis, participants noted that there may be three distinct individuals involved in this process: the individual who biopsies the reproductive material or embryo; the individual who runs the actual genetic tests (i.e., PCR or FISH); and, the individual who makes the final interpretation of the results. It was noted that the qualifications of these three individuals are quite different. With respect to the qualifications of the individual who makes the final interpretation of the results, some participants felt that while the proposed requirement for certification by the Canadian College of Medical Geneticists may be desirable, they argued that it should not be a regulatory requirement.

Clinical activities

Some participants initially raised concerns with the proposed requirement that doctors must obtain a licence to undertake AHR activities. They felt that the AHR activities being licensed were medical practices and should be left to the provinces and territories to regulate.

Looking at the specific proposals, participants did not raise objections to the requirement that an applicant be a licensed medical doctor in their province or territory; however, there was significant debate regarding the other proposed qualifications. While the proposed qualifications for artificial insemination and controlled ovarian hyperstimulation (or ovarian stimulation) were not extensively discussed, it was noted that the qualifications required to undertake these activities were highly contested. Indeed, the proposal reflects current practice which many feel is too broad. Participants generally agreed that this was one area where a broader discussion would be required. Many strongly expressed reservations regarding the performance of these activities by individuals who do not have specialized training in these activities. These participants suggested that certification by the College of Family Physicians of Canada was not sufficient. Some participants suggested that individuals with specialized training or certification in endocrinology may also be qualified to perform ovarian stimulation.

Participants noted that individuals who undertake the activities of oocyte retrieval, ovarian tissue retrieval, gamete intrafallopian transfer (GIFT), *in vitro* embryo transfer, zygote intrafallopian transfer (ZIFT)/tubal embryo transfer (TET), ovarian stimulation prior to oocyte retrieval and ovarian tissue transplantation should be certified by the Royal College of Physicians and Surgeons of Canada (RCPSC) in obstetrics and gynaecology. In addition, many participants felt that new applicants should also be required to complete an RCPSC accredited fellowship in Gynecologic Reproductive Endocrinology and Infertility. However, some participants commented that smaller clinics and clinics in rural or remote areas of the country could face difficulties in securing medical staff, if such a requirement were imposed. They suggested that an alternative means of obtaining this specialized training should be considered, such as working with a fellowship-trained physician for a period of time.. Participants noted that alternative qualification requirements would be necessary for applicants currently practising in the field, as many received their formal certification prior to the advent of these programs.

Participants stated that individuals who wish to undertake the activity of clinically retrieving sperm and/or testicular tissue should be certified by the RCPSC in urology. In addition, several participants felt that additional training related to andrology and the treatment of infertility should be required. It was noted that an RCPSC accredited fellowship program was under development.

With respect to ovarian tissue retrieval and clinically retrieving sperm and/or testicular tissue, several participants noted that it would be necessary to examine the qualifications of individuals who provide treatment for cancer, as this type of procedure is often performed to preserve the fertility of patients prior to cancer treatment. Many participants questioned the necessity of licensing these activities and were concerned that this requirement could negatively impact the availability of these procedures.

3.2 Licensing of Premises

Health Canada presented participants with the proposed requirements that must be met before a premises licence can be issued as well as in order to maintain the premises. The requirements that must be met in order to be issued a premises licence will address the physical features of the premises, such as the location, design and condition of the building. Organization-related requirements would be part of the maintenance of a premises licence.

Participants generally agreed with the proposed requirements although they did express concerns with possible duplication of existing mechanisms (e.g., survey visits regarding CCHSA accreditation requirements and provincial inspection of laboratories and independent health facilities). As with the other discussions, participants were concerned with prescriptiveness of any requirements, particularly with respect to the time lines for notifying the Agency of when key events have occurred. They also raised concerns with their ability to be in compliance if proposed regulations were not clear or specific enough, with the timing of site visits in the licence issuance process and with the Agency's ability to determine compliance through its visits and inspection.

Based on the background documents provided, participants were guided through the premises-related and organization-related contributing factors to risks and the proposed control measures that would form the basis of the regulatory requirements. The following summarizes participants' key comments on the proposals presented.

Design

Participants all agreed that the location of the clinic should be close to emergency medical services. Some participants noted that clinics should not be located in a highly industrial area due to possible pollution problems. Other participants questioned how the regulations would address the decentralizing of operations and the situation of clinics outside of metropolitan areas, such as satellite clinics and physician offices.

However, they expressed concerns with including limitations on space in the regulations because all facilities are different in how they manage their activities and make use of space available.

Personnel

Participants requested consideration of alternatives to meeting proposed requirements, which was a central theme of comments received.

SOP (Standard Operating Procedures)

Participants made several wording suggestions regarding the proposed requirements for SOPs. For example, it was suggested that the term "revised if appropriate" would be more important to use than "kept up-to-date." Participants mentioned that all policies cannot be physically incorporated into the SOP manual and therefore these documents should be kept on site and be "accessible." They also informed Health Canada that reference materials such as manufacturer's instructions and certain instructions and directives for the operations of the premises are not part of SOPs.

Quality Assurance (QA)

Participants agreed with the need to have a quality management system in place in every clinic. Some participants requested clarification of some terms used (e.g., quality and health and safety) and guidance on how to meet the proposed requirements. Others noted that parameters for quality, health and safety can be determined and monitored through quality control activities and appropriate documentation. They mentioned that several QA programs existed and could be easily referenced. They also mentioned that provincial and territorial requirements for quality assurance already exists and they hope the regulations will have an equivalency clause.

Records Management

Some participants felt that a unique identification code needed to be inserted "where applicable", because records may only have the name and date of birth. Participants expressed concerns about a licensee's ability to obtain information on birth outcomes and questioned the purpose of any such requirement. Health Canada explained that proposed requirements for records management are intended to address risk issues and thus protect health and safety, which include requiring the keeping of records related to the use of gametes and embryos donated for third party use.

Permitting the tracking of health information of donors or patients and the linking of this information to children conceived from AHR is important. Participants noted that information on birth outcomes is not always available and wanted to know how far back in patients' lives would they have to go to obtain outcomes.

Adverse Event Reporting

Participants noted that existing systems for adverse event reporting already exists, such as in hospitals. Although some were concerned with liability in the reporting of adverse events, they noted that the proposed requirements only requested that a system be in place. They pointed out that an adverse event could be defined as a system-related failure or a procedural failure, such as a hemorrhage. Participants mentioned that a procedural failure would have to be reported to the College of Physicians and Surgeons.

Recall Reporting

Health Canada explained that the proposed system for recall reporting is intended to address risk situations, the highest of which involves the use of third-party gametes and embryos, where recalling of these reproductive materials may be needed, e.g., in the case of any suspected transmissible disease or disease agent. With respect to recall reporting, participants felt that for the purpose of own reproductive use, a notification system would be more appropriate and agreed that individuals should be notified as part of the system for recall reporting.

3.3 Licensing Administration

Health Canada explained that under the Act, the Agency has the power to issue a licence, as well as to attach terms and conditions to a licence at the time of issuance or at any time thereafter. In addition, the Agency may amend or renew a licence. The objective of the session on licensing administration was to seek stakeholder feedback on a broad proposal for the design of the licensing administration process, and in particular for applying, renewing or amending a controlled activity and/or a premises licence.

The focus of the presentation was on *a)* principles to guide the development of the licensing administration process; and *b)* steps for obtaining, renewing or amending a licence from the perspective of applicants and the Agency. The presentation only dealt with individual applicants for a controlled activity licence, and owners or operators for a premises licence.

Health Canada informed participants that the other steps in the licensing process (amending, suspending, revoking a licence for cause and restoring a suspended licence) would be the subject of future discussions within the broader context of compliance and enforcement.

In addition to providing general comments on the proposal, participants were asked whether the proposed process meets the needs and expectations of the AHR sector. Health Canada also asked participants whether the proposed process was clear and easy to follow and whether the proposed principles are appropriate and comprehensive. The following summarizes participants' comments on the proposal for the licensing administration framework.

Principles

Participants expressed general support for the principles presented by Health Canada to guide the development of the licensing administration framework. Participants, did however, request some clarification regarding the principle of transparency. Specifically, they wanted to know what information would be made publicly available.

Application

With respect to the process for applying for a licence, participants had many questions about the anticipated time requirements for submitting an application, as well as the information and documentation that they would be required to submit. Participants were concerned with the possible administrative burden that could be placed on applicants and expressed a desire to avoid a burdensome, repetitive or redundant process. Participants also questioned the Agency's capacity to review and assess licence, renewal and amendment applications in a timely manner. In particular, they felt that the initial issuing of licences when the regulations come into force could be problematic since everyone would be applying at the same time.

With respect to applying for a premises licence, participants asked how a new applicant would know that the premises is in compliance with the regulatory requirements before applying for and obtaining a licence? Participants also asked whether satellite clinics would be covered under a single premises licence, since some components of AHR procedures may be undertaken in other areas of the province.

Participants wanted further clarification regarding what kind of circumstances might prompt the refusal of a licence. Participants also expressed concern about not having a formal appeal process. They also asked for more clarification on how terms and conditions would be applied.

Participants requested clarification on what information would be made publicly available, and asked about possible access to the information that the Board of Directors would use for decision-making. There was general support for accessing the Board's decisions on licensing and participants asked what kind of circumstances might prompt the refusal of a licence.

Renewal

Regarding the issue of licence renewals, participants questioned the purpose of requiring a controlled activity licence to be renewed if there has been no change in the qualifications.

Participants were concerned about even notional timelines for renewal being included in regulations (the proposed requirement to send a renewal to the Agency stated "no less than 90 days prior to licence expiry date"). They felt that requirements should be more flexible given the implications for licensees as well as patients if a licence is not renewed. Participants also highlighted the need to consider the situation of clinics within hospitals where hospital administrative processes may delay meeting timelines.

Participants raised questions about renewal periods. They hoped that renewal periods would be reasonable and stated that annual renewals would place too much burden on licensees. Participants expressed concerns about the administrative burden on the Agency of having numerous licences expire at the same time and questioned the Agency's capacity to process renewal applications in a timely manner.

Finally, participants suggested that renewal periods should be coordinated with other renewal processes (e.g., medical licences expire in June in Ontario and in September in other provinces, and CCHSA requires a renewal every 3 years).

Participants therefore suggested that a standardized renewal reminder process would be optimal.

Amendment

Concerning amending a licence, participants wanted more clarification on what would constitute grounds for amendments to licences.

4. Health Reporting Information (HRI)

Health Canada officials began these sessions with a presentation highlighting the definition of HRI, the principles of the AHR Act guiding HRI regulations (such as the protection and promotion of health and safety), and the obligations of the licensee and of the Agency. Health Canada explained that the goal of these sessions was to obtain participant feedback on the collection of HRI, its retention and destruction, its disclosure to the Agency, and the financial and operational impacts of HRI regulations on licensees. These sessions also focussed only on

couples undergoing procedures using their own gametes. For discussion purposes, Health Canada officials shared feedback received during the patient consultation of April 2006[7] on these same topics.

Collection of HRI

Under the AHR Act, HRI means information regarding the identity, personal characteristics, genetic information and medical history of donors of human reproductive material (HRM) and *in vitro* embryos, persons who have undergone assisted reproduction procedures and persons who were conceived by means of those procedures. It also means information regarding the custody of donated HRM and *in vitro* embryos and the uses that are made of them. Health Canada officials outlined that a licensee will be required to collect HRI prior to accepting HRM or performing a controlled activity. A licensee will also need to inform that person in writing of the requirements of the AHR Act relating to the retention, use, disclosure and destruction of HRI and obtain the written consent of the person regarding the application of these requirements. The presenters informed participants that regulations will set out what specific information is required to be collected by licensees as HRI. It was clarified that HRI will be collected to meet the principles of the AHR Act and to allow the Agency to meet its obligations.

Participants had a number of questions and expressed some concerns regarding the obligations of a licensee to collect HRI under the Act. Although collection of HRI is based on health and safety needs, participants felt that strong evidence and justification is required to determine what information should be collected under the regulations. For example, the regulatory requirement should be linked to the risks associated with the treatment provided. Concerns were raised about the level of detail that may be required and the burden of the collection of information on clinics and patients. Participants also expressed a concern that an obligation to disclose information to the Agency may prevent some patients from seeking AHR procedures. Most participants agreed that collecting this type of information would be justified if it was used for the purpose of health and safety, or for analysis, or to understand the outcomes of AHR procedures.

Participants were also concerned with issues surrounding consent for the collection of HRI. Although consent must be obtained to collect HRI from patients under the Act, participants wondered how they would deal with situations where patients refused. Participants subsequently requested that clear guidelines and information tools be developed to help clinics deal with potential problems relating to consent.

Health Canada then asked participants about their current practice with respect to collecting information important for the patient's health and safety, prior to undertaking a procedure. Participants acknowledged that they already collect and keep a great deal of information for this purpose, and they therefore questioned the need for regulations. The participants then shared an

[7] A report of the April 2006 consultation with patients can be accessed on the Health Canada Website at http://web.hc-sc.gc.ca/hl-vs/pubs/reprod/2006-patient-meeting-reunion/index_e.html

exhaustive list of information they already gather from both partners undergoing AHR procedures, including: medical history; family history; genetic history; age; allergies; height and weight; previous infertility treatments; miscarriages; abnormal pap tests; abdominal surgeries; use medication; occupational history; lifestyle. The manner in which the information is gathered and the person responsible for the collection was also discussed. While in some clinics physicians collect the information, in others a questionnaire is given to the patients and is reviewed with the patient by a nurse or the medical doctor. Participants enquired whether the regulations will specify who is the person responsible for collecting the information and what responsibility would be placed on the licensee to ensure accuracy of the information provided by patients.

Retention and destruction of HRI

The second topic of the session focussed on the retention and destruction of HRI. The discussion revealed that the period of retention varies greatly from one clinic to another. Some retain the information indefinitely while others retain it for 10 years. Some participants mentioned that their information is stored on site for 2 years and in an external storage facility for another 7 years. Others distinguish medical records from AHR records and therefore vary their retention period, AHR records are kept longer. In some facilities, patient information is transferred to microfiche for archiving purposes.

When asked about their views on an appropriate retention period for HRI, the opinions of participants varied considerably. Some suggested keeping it long enough to allow children born of these procedures to have reached child-bearing age, or for a period of 40 years, or even that it be kept indefinitely. However, some felt that keeping the information indefinitely may not be feasible due to costs associated with archiving. Another suggestion was to retain the HRI for a period of 10 years and to supplement it with an additional period of 8 years if the AHR procedures result in a pregnancy. This would allow access to information if any complications were to arise in the health of children conceived from AHR procedures and would make it available up until their adulthood.

Participants also wondered how the retention period would vary for clinics if the Agency retained some of this information as well. For example, if the Agency were to retain HRI, there wouldn't necessarily be a need for clinics to retain it. They also highlighted a need for provisions regarding the retention of HRI if a clinic closes or loses their licence. Some believed that the Agency could assume a role for retention when a clinic closes, while others saw value in some type of central repository where a patient would pay for access. Others thought that the information could be returned to patients, but that this might prove difficult if patients relocate and do not update their address with the clinic. Transferring the information to another physician was also proposed as an option.

When asked about the destruction of HRI, participants responded that once a retention period is decided upon, that the information should be destroyed, unless it is kept for analysis purposes.

Others believed that patients should be allowed the freedom to decide if they want to have their information destroyed.

Disclosure of HRI to the Agency

The presenters opened the third topic by reminding participants of the obligations of the licensee to disclose HRI to the Agency in accordance with the regulations. The Agency may use HRI and information relating to the controlled activities for the purpose of the administration and enforcement of the AHR Act and/or for the identification of health and safety risks. The Agency cannot disclose HRI unless otherwise authorized by circumstances stipulated in the AHR Act.

Participants expressed concern about disclosing information and/or the identity of patients to the Agency. The need for a strong rationale for disclosing the information was reiterated. Some participants believed that the majority of patients wouldn't agree to give information to a government agency. Participants suggested that Health Canada seek greater input from patients on this issue, in addition to feedback received during the patient consultation.

Health Canada officials then outlined three possible approaches for disclosure to the Agency and invited participants to comment. The approaches were:

- disclosure of all the HRI collected by licensees to the Agency;
- partial disclosure of the information; and
- disclosure only when required by the Agency.

Participants had a variety of views on disclosure. Some favoured full disclosure for analysis purposes and to understand the outcomes of AHR procedures. In their opinion, a partial disclosure did not necessarily lessen the burden of storage or retrieval of information. Some participants favoured partial disclosure. Others favoured the third option, disclosing information only when required, citing it as the least expensive and requiring the least amount of time and effort to implement.

The issue of ownership of the HRI was also raised throughout the discussion. Participants felt that it should be made clear whether the ownership of HRI held by the Agency resided with the patient or the Agency.

Financial and Operational Impacts of HRI Regulations on Licensees

When asked about the potential financial and operational impacts of regulations concerning HRI participants noted that it would depend on the actual requirements of the HRI regulations. While

the group acknowledged that they currently collect a large amount of information, it would nonetheless be an operational burden to use an automated system. The costs associated with implementing such a system would also impact them.

Requirements for retention would generate a need for office space and adequate storage availability. Participants flagged that there are significant costs associated with maintaining files. Overall, participants felt that the requirements for HRI would negatively impact their operations and costs and they requested some form of funding, or alternatively that these costs be passed on to patients.

Personal Health Information Registry[8]

The Personal Health Information Registry was the final topic of the HRI session. The presenters informed participants that the registry will capture and store the HRI submitted by the licensees in accordance with the regulations. Participants shared their views regarding an information system to implement requirements for HRI.

Participants proposed and agreed that an automated data collection and transfer mechanism should be implemented to facilitate requirements for HRI. They requested that the Agency provide them with a system compatible to their own to avoid duplication and information technology instructions. Participants stated that not all clinics are automated, noting that this is a particular challenge for smaller clinics. In addition, such a system would require security protection, efficiency and accessibility. Some highlighted current difficulties with their own systems. Participants pointed out a need for appropriate coding and labelling of data, e.g., a definition of the type of information collected.

Participants suggested that Health Canada contact the Canadian Fertility Association of Canada for information on their electronic system's capability to tabulate outcomes of AHR and to seek their advice on this matter.

5. Next Steps

Health Canada closed the meetings by thanking everyone for an exciting exchange of ideas. Health Canada emphasized that the consultation process is a much needed step in the development of the regulations, and that the sharing of stakeholder expertise brings a lot of value

[8] A presentation and discussion of the Personal Health Information Registry (PHIR) was facilitated in Toronto. Due to time constraints, participants in Montreal and Vancouver received documentation on the PHIR and were encouraged to provide feedback to the information technology project manager and to become involved in a working group for the registry.

and practical knowledge to the regulatory development process. Health Canada stated that there would be ample opportunity for participants to provide more feedback as the regulations are developed.

Health Canada reminded the participants to send their workbooks and additional comments to AHRIO. There was also a reminder that Health Canada would be establishing voluntary expert stakeholder advisory panels in the near future. It was expected that an invitation letter would be sent out to all participants to seek their participation.

Finally, it was noted that a meeting report would be produced summarizing the discussions in all three cities, and it would be posted on the Health Canada Web site.