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Workshop on the Reimbursement of Expenditures for Egg and Sperm Donors

Meeting Report

November 5 – 6, 2004

**Sheraton Gateway Hotel
Toronto, Ontario**

Prepared by the Intersol Group
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The following meeting report summarizes the discussions that took place at the November 5 & 6, 2004 workshop on the Reimbursement of Expenditures for Egg and Sperm Donors. 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 meeting, may be inconsistent with the policy intent and the legislative framework of the Assisted Human Reproduction Act

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Executive Summary

This report summarizes the proceedings of a two-day workshop organized by Health Canada to gather information for use in developing regulations respecting the reimbursement of gamete donor expenditures pursuant to section 12 of the Assisted Human Reproduction Act (“AHR Act” or “the Act”). Participants in the workshop included representatives from reproduction clinics across the country, health practitioners, and representatives from non-governmental organizations.

The workshop began with a presentation on the Act, and section 12 specifically, to set the context for discussions. Participants were invited to ask questions and discuss key messages and reactions. Discussions focused mostly on the policy intent for the reimbursement of expenditures, and its implications for the supply of donor gametes in Canada.

Participants were then invited to share information on the gamete donor process as it currently operates and to provide advice on the reimbursement of expenditures. Discussions focused on sperm donation and egg donation separately.

In the discussions on sperm donation, it became apparent that most clinics in Canada rely on sperm banks for their supply. Representatives from clinics with sperm donor programs shared information with the other participants. The process is very similar in the different clinics, and involves multiple visits lasting from thirty minutes to three hours. Sperm donors would typically participate in interviews and questionnaires as well as provide blood, sperm and urine samples.

Discussions regarding the donation process and related activities for egg donors revealed that the time commitment for egg donors is much more significant than for semen donors. Estimates

ranged from about 10 to 26 days for the entire process, with significant demand placed in later stages, during stimulation and retrieval.

Participants listed similar expenditures as being reasonable for both types of donation. Travel costs were mentioned most often and were considered reasonable by all groups. A variety of other expenditures were mentioned, including time off work or lost wages, which were discussed at length.

In a broader discussion about participant concerns, many indicated that the inability to compensate donors for their time would mean that the donor is not reimbursed for the true cost of the donation. Participants challenged the policy intent that reimbursement of expenditures would be limited to amounts the donors actually pay for, out of pocket, indicating that donor recruitment would become very difficult, thus affecting the availability of donor gametes in Canada. A different perspective, which was offered, was that public education could help tap into a whole pool of potential altruistic donors that are not currently being accessed.

On the question of whether a set list of expenditures should be determined in the regulations, there appeared to be consensus that a list to be used as guidance would be useful, but that provision for exceptions would have to be made. On the question of whether or not limits should be set on expenditures, most seemed to feel that limits should not be set.

Participants made a variety of suggestions on ways to obtain the perspective of gamete donors and recipients, such as surveys, interviews or focus groups. Clinics showed a willingness to serve as intermediaries in the process, but stressed the importance of protecting anonymity.

The workshop ended with Health Canada officials summarizing the next steps in the development of the regulations, including distribution of a summary report from the workshop, analysis of the information and feedback provided, development of policy options, and publication for further consultation as part of the normal regulatory process, with an aim to having the entire regulatory framework in place by 2007 or 2008.

A. Introduction and Context

Words of Welcome and Purpose of the Workshop

Rodney Ghali, Senior Policy Advisor, Assisted Human Reproduction Implementation Office, welcomed participants and thanked them for taking the time to participate in this workshop. He explained the purpose of the workshop, which was to gather information to assist Health Canada in developing regulations for the AHR Act, specifically for section 12 of the Act pertaining to reimbursement of gamete donor expenditures. He also noted that the purpose of the workshop was not to discuss specific policy proposals related to the Act, nor to discuss section 12 of the Act as it relates to surrogacy.

The facilitator, Kathleen Connelly, then reviewed the agenda, approach, and roles for the session. She facilitated a process of introductions and identification of expectations. A list of participants is provided in appendix A. Some of the expectations raised by the group included:

- Opportunity to talk about the impact on things such as cost and availability of donor sperm;
- Clarification of whether or not the Canadian legislation is intended to ensure that US suppliers do not pay their donors;
- Clarification on the provisions for receipted and un-receipted expenditures;
- Get an idea as to timelines for the full implementation of the Act;
- Address egg sharing program;
- Direction for clinics to function in the new environment; and,
- To gauge the government's views about support for patients in the process of gamete donation in the future.

Setting the Context: Presentation on the *Assisted Human Reproduction Act*, Section 12, the Reimbursement of Gamete Donor Expenditures

Rodney Ghali then presented information on the AHR Act, its objectives and scope, and more specifically section 12, which deals with the reimbursement of receipted expenditures.

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.

Many of the participants felt that the new Act would have consequences for the supply of gametes in Canada, and that stringent requirements on receipts for expenditures would make it very difficult to recruit donors once the new regulations come into effect. Some suggested that a black market would be created as a result, and others stated that a two-tier system would be created, where people who could afford to would get services outside the country, and others would have to do without.

There was a fair amount of discussion on the importation of gametes, and the impact of the new Act. It was confirmed that clinics would be able to continue to import sperm from other countries where donors are paid, until regulations regarding importation have been developed and the regulatory / licensing framework is in place.

The lack of clarity regarding the regulatory options with respect to section 12 was a source of concern for most participants, and this highlighted the importance of ensuring that regulations under the Act are clear and easy to understand.

Concern was also expressed about the grandfathering clause and its effect on the sector. Some participants noted that it would be impossible to start up a new clinic or program between now and when the regulations take effect in 2007.

A question was raised about advertising, and it was clarified that advertising is only prohibited for activities that are prohibited under the Act. Ads recruiting altruistic donors are not prohibited.

Participants further explored the concept of commercialization and clarification was provided that commercialization, for the purposes of section 7 of this Act, refers only to the purchase of sperm, eggs, embryos or human reproductive material from a donor. Commercialization with respect to surrogacy is addressed in section 6 of the Act.

A participant asked for a clarification respecting the word “person” under the Act, and was told that a person under the Act means person in law or corporation.

It was clarified that to be grandfathered for the reimbursement of receipted expenditures; reimbursement of receipted expenditures need only be done once in the prior year.

There was interest expressed in the pilot project on recruitment strategies for altruistic donors that will be conducted on Health Canada’s behalf. Participants were told that more information will be made available in the coming weeks and months, and that a call letter will be sent out inviting interested clinics to submit proposals.

A question was raised regarding requirements for a license, and it was clarified that anyone who undertakes a controlled activity will have to obtain a license, and follow the regulations, once the regulatory and licensing regime is in place. This raised concerns by the participants that practising physicians may not bother to obtain a license, thus reducing access to services for patients.

On the question of enforcement, participants were told that no provision of the Act is retroactive, and that there is no intent to make regulations retroactive. Health Canada’s regulatory enforcement policy envisions a range of possible actions in response to non-compliance, which increase in severity from notification and education up to and including seizures & prosecution. It is expected that this policy will also be adopted by the Assisted Human Reproduction Agency of Canada, which will be created pursuant to the Act. As contravention of the Act involves criminal offences enforcement will continue to be carried out in cooperation with the police.

A participant asked what the impact of the Act would be on egg sharing*, and was told that under sub-section 7(4) of the Act, “*purchase also includes to acquire or dispose of in exchange for property or services,*” so that egg sharing would be captured under the Act as a prohibited activity.

There was also a question regarding the establishment of a national registry documenting birth outcomes for the purposes of offspring follow-up, including imported gametes. It was confirmed that under the Privacy and Access to Information section of the Act, a registry will be set up which will contain information related to third-party gametes, and that this will also be subject to consultation before it is fully defined.

* Egg sharing refers to a practice whereby a woman who is undergoing a fertility treatment will give a certain number of her eggs to another woman in exchange for a reduction in the costs of her treatment

B. The Process of Gamete Donation for Semen Donors

The Donation Process and Related Activities

There were only four people in the room who had knowledge of the donation process for semen donors, since most clinics purchase from sperm banks rather than running their own recruitment programs. It was decided that the discussion would still be useful in providing insights to all participants.

During the plenary debrief, it became apparent that processes for the donation of semen are very similar in the different clinics, with minor variations in the duration of some of the visits and timing of some of the activities. All potential donors have to visit the clinic more than once before they are accepted as donors, and visits last from thirty minutes to three hours. Requirements include interviews and questionnaires as well as blood, sperm and urine tests. There is also ongoing monitoring every three months while the donor is actively donating. Two of the clinics in Canada have experienced a reduction in the number of donors since the Act was passed.

Following the feedback from table discussions, participants again raised the question of reimbursement of expenditures, and Health Canada reiterated that under the policy intent of section 12 of the Act, a person could only be reimbursed for expenditures for which they have paid out of pocket. A number of participants reacted strongly to this response, stating that this does not capture the true cost to the donor; of particular concern was that, since clinics are open during normal business hours, donors will often have to take time off work for visits to the clinic and will not be compensated for this time.

Clinics with sperm donation programs were also invited to provide written information on the activities performed by clinic employees in the process of sperm donation and the time commitment involved.

C. The Reimbursement of Expenditures Incurred by Semen Donors

Table groups were asked to perform two tasks related to this topic:

1. Identify reasonable expenditures for semen donors; and,
2. Identify and explain administrative issues that you foresee in relation to the processing of expenditures for semen donors.

Expenditures

With respect to reasonable expenditures, groups identified the following in the plenary debrief*:

- vitamins or prescription drugs
- visual aids such as magazines, videos, newspapers
- travel – time, taxi, bus, gas, car rental, km allowance for use of personal vehicle, flights, accommodation, food allowances / meals
- child care time
- telephone long distance
- boxer shorts
- counselling – psychological and legal
- parking
- marriage or family counselling
- accompanying person's expenses – sometimes partner required
- time off work and lost wages
- risk – example 20 years later, breach of confidence, breach of anonymity: emotional expenditures

Groups did not all agree on what should be considered reasonable, and no attempt was made to build consensus.

One participant raised the question of the point at which a donation is considered complete for reimbursement purposes – this could impact on whether a reimbursement can be provided for taxi fare home after the donation, for example.

Related Issues

Administrative issues that were raised related to the processing of expenditures for semen donors included:

- taking of receipts
- legitimizing receipts within reasonable time-frames
- administrative time required by a number of different employees
- need to hire an additional individual to administer reimbursements: salary, benefits, office space, computer and telephone costs

One participant explained that this is a service to clients, and if it takes more staff to administer, then the patient will have to pay more for the service.

* some items listed may not be consistent with the policy intent or the legislative framework of the AHR Act.

D. The Process of Gamete Donation for Egg Donors

The Donation Process and Related Activities

Participants discussed the donation process and related activities for egg donors using the same process as for the discussion regarding semen donors. In plenary discussions, it was made apparent that the time commitment for egg donors is much more significant than for semen donors. Estimates ranged from about 10 to 26 days for the entire process, with significant demand placed during stimulation and retrieval.

The screening process for egg donation, similar to sperm donation, involves participating in questionnaires, interviews and preliminary medical tests such as blood and urine tests. However, unlike sperm donation, very few IVF cycles are performed with egg donors.

The egg donation process is quite lengthy and there are significant demands placed on the donor. The egg donor undergoes ultrasound and is encouraged to speak with a counsellor and perhaps even seek legal counsel. In the early stages of the process, the donor begins a treatment with fertility drugs to stimulate egg production. During this time the donor is required to call or visit the clinic frequently and may undergo further tests. Compared to sperm donation, the egg donation process is very invasive, is associated with more medical risks and involves a period of time for recovery.

E. The Reimbursement of Expenditures Incurred by Egg Donors

Expenditures

The following expenditures were identified as reasonable during plenary debrief^{*}:

- Transportation
- accommodation
- lost wages and travel time
- honorarium
- child care
- Internet
- expenditures for an accompanying person
- counselling (nutritional and psychological)
- medical and liability insurance
- medical care in the event of hospitalization
- drugs related to stimulation
- vitamins
- complementary therapies
- additional supportive care
- screening of sexually intimate partner

Related Issues

Administrative issues identified related to the reimbursement of expenditures were similar to those for semen donors – accounting processes, cost of an additional employee to track the expenditures, explaining the process to the donor. In addition, participants raised the question of how to reimburse for unexpected consequences of treatment, such as extended hospitalization due to complications, and whether this would be subject to different rules than time spent in the normal course of the donation.

^{*} some items listed may not be consistent with the policy intent or the legislative framework of the AHR Act.

F. Open Discussion of Key Concerns and Considerations

At this point in the proceedings, participants asked for a broader discussion of issues and concerns related to the new Act and Regulations. A number of different points and questions were raised during this discussion and later in the meeting; they are summarized below.

Many participants again expressed concerns with section 12 of the Act, and challenged the policy intent that reimbursement of expenditures would be limited to amounts the donors actually pay for, out of pocket.

The concern that was most strongly expressed was related to the inability, under the Act, to compensate donors for their time. It was felt by some participants that Parliamentarians did not hear their voices during debate on the Act, in particular with respect to the potential impact certain provisions may have on the sector. It was explained that Parliament had the opportunity to hear a number of viewpoints, which were conflicting at times, but ultimately had to take a policy position. In response to their concerns, Health Canada officials indicated that a copy of the meeting report would be sent to the Minister's Office.

One participant stated that gamete donation is a very lucrative business in Canada, and this elicited negative reactions from other participants, one of which was a demand for evidence. A participant suggested that the comment showed a misapprehension regarding the number of egg donations actually taking place in the country – they estimated that the clinics represented at the workshop probably do 50 retrievals collectively in one year, whereas a much larger number of patients choose to go to the US at a much higher cost.

A participant suggested that the government should leave the status quo in place, allowing direct and indirect expenses, while they attempt to set up an altruistic system, to avoid impacting the existing system with no viable alternatives.

A concern was raised regarding protection of personal information during the inspections related to the regulations; it was explained that the privacy framework within the Act, as well as other appropriate federal and provincial legislation respecting privacy would apply.

A participant asked if the Donor Semen Special Access Program established pursuant to the Processing and Distribution of Semen for Assisted Conception Regulations, which are regulations enacted pursuant to the *Food and Drugs Act*, would be allowed to continue once the regulations enacted pursuant to the AHR Act are in place, and Health Canada representatives indicated they could not respond to that question at this time.

Participants raised concerns about the ability to maintain current standards for sperm donors, such as sperm count, if donors become too scarce. This was countered by another participant who suggested that public education could help tap into a whole pool of potential donors that are not currently being accessed.

G. Other Considerations

Should there be a set list of expenditures for which donors may be reimbursed? Why? Why not?

Some tables responded yes, others responded no. In the ensuing discussion, there appeared to be consensus that a list of expenditures to be used as guidance would be useful, but that provision for exceptions would have to be made because donor circumstances vary so widely and flexibility would be required.

Should there be limits set on expenditures for semen donors? If so, why and which ones? If not, why not?

Most groups seemed to feel that limits should not be set, although a concern was raised about the risk that this might lead to expenditures spiralling out of control. Other participants seemed to feel that clinics could set their own limits.

Related issues that were raised included how to limit the number of donations, how costs would be transferred to recipients, and whether it is the clinic's place to set limits on expenditures (these could – should? – be negotiated directly with the recipient).

Should there be limits set on expenditures for egg donors? If so, why and which ones? If not, why not?

Participants raised similar points as in the discussion regarding semen donations. Most appeared to feel that limits should not be set, again because of the variety of circumstances that could come into play. One participant stated that there is a huge difference between known and anonymous donors, with limits being much harder to enforce for known donors, since there could easily be cases where the donor lives in Vancouver but the clinic is in Montreal. Another participant commented that there is an element of choice that would be supported by the recipient as well, who would bear the costs rather than the clinic. This elicited some concern from another participant, related to the patients' ability to pay.

H. Moving Forward

Obtaining the Perspective of the Gamete Donor

Participants made a variety of suggestions about ways to obtain the perspective of the gamete donor, such as surveys, interviews or focus groups. Clinics showed a willingness to serve as intermediaries in the process, but stressed the importance of protecting donor anonymity. Participants suggested that past donors and potential altruistic donors should also be consulted, not just current donors.

Health Canada invited participants to take copies of a donor workbook that they could then distribute to their donors. There was a fair amount of discomfort with this approach, linked to concerns with sample bias and how the information would be used. Health Canada acknowledged those concerns and indicated that any information obtained using this approach would be analyzed with acknowledgement of those concerns.

Obtaining the Perspective of the Recipients

Suggestions included sending an informal survey to waiting lists of egg recipients, posting a link to a survey on the Infertility Awareness Association of Canada Inc. (IAAC) website, working through psychologists and social workers, paying clinics to phone recipients, and using the Infertility Network email list. Again, the issue of confidentiality and protection of privacy was seen as significant. Ensuring that sufficient notice is provided was also seen as an important consideration.

Next Steps/Continued Involvement of Participants

Health Canada officials outlined the following next steps:

- A summary report will be sent to participants, invitees and to the Minister's office.
- Health Canada will examine and analyze the information and feedback provided at this workshop
- Health Canada will develop policy options for the regulations, and will publish them with an open invitation to all Canadians to comment
- The normal regulatory process will unfold, including publication in Gazette I and Gazette II, with the aim of having the entire regulatory framework in place by 2007 or 2008.