PAPER

Good eggs? Evaluating consent forms for egg donation

Alana Rose Cattapan

ABSTRACT

Beyond gaps in the provision of information, the informed consent process for egg donation is complicated by conflicts of interest, payment and a lack of longitudinal data about physiological and psychological risks. Recent scholarship has suggested that egg donation programmes could improve the informed consent process by revising consent documents. At a minimum, these documents should include information about eight key criteria: the nature and objectives of treatment; the benefits, risks and inconveniences of egg donation; the privacy of donors and their anonymity (where applicable); disclosure that participation is voluntary (withdrawal); the availability of counselling; financial considerations; the possibility of an unsuccessful cycle and potential uses of the eggs retrieved. This study evaluates the incorporation of these minimum criteria in consent forms for egg donation, obtained through requests to Canadian fertility clinics. Even when clinics were considered to have met criteria simply by mentioning them, among the eight consent forms assessed, none met the minimum standards. Only half of clinics addressed privacy/anonymity concerns, financial issues and the possibility of a future cycle. Improving the quality of consent documentation to meet the minimum standards established by this study may not be an onerous task. For some, this will include re-evaluating how they include one or two elements of disclosure, and for others, this will require a substantial overhaul. Using the criteria provided by this study as the minimum standard for consent could ensure that donors have the basic information they need to make informed decisions.

INTRODUCTION

Egg donation, pioneered in the early 1980s, is used as a technique to address infertility, particularly in women over 40. In Canada, the practice has been growing, with 671 cycles of in vitro fertilisation (IVF) using ‘fresh’ donor eggs (oocytes) performed in 2013 alone, nearly twice as many as a decade prior. The practice of taking one woman’s eggs, fertilising them with sperm and implanting one or more of the resulting embryos in the uterus of the intended mother is becoming a relatively well-known and accepted technology, with fertility clinics and brokers around the world searching for young women willing to give (or be paid to give) their eggs.

The process of obtaining informed consent for egg donation raises ethical concerns beyond those of regular surgical practice. Egg providers are typically young, healthy women who undergo a rigorous course of hormonal injections to stimulate the production of eggs, followed by surgical retrieval. They undergo these treatments not to improve their own health, but rather to help someone else to build their family. Egg donation thus presents circumstances not unlike those of organ donation in terms of the ethics of undertaking medical risk for someone else’s benefit, but complicated by the fact that egg donors undertake these risks not to save the life of an intended parent, but to enable them to raise a child. The matter of giving or selling one’s gametes to another person also disrupts historical understandings of biology and kinship that are ethically fraught and meaningful for many. Pervasive conflicts of interest, payment for donation, gaps in awareness of the risks of donation and a lack of data about long-term implications make obtaining informed consent for egg donation particularly challenging.

This study examines the process of informed consent for egg donation emphasising the Canadian case, focusing on disclosure via consent forms. It is important to note that consent forms are only one part of a broader process for informed consent that should ensure that the egg donor is competent to make her own decisions, that she is making them free of coercion and that she truly understands the process. At the same time, consent forms are a tangible record that can serve to represent the different approaches of different clinics, and serve as a documentary record of how the consent process may be taking place. Although informed consent can be hindered by too-lengthy, too-complicated forms, when clear and straightforward, consent forms can work to standardise, operationalise and verify the process of informed consent. If we are to accept that informed consent is possible in the absence of knowledge about long-term risks and that consent forms are purposeful, consent forms can serve as a prompt and to ensure that donors are aware of important elements of the donation process before consenting to participate. In some cases, the use of well-developed consent forms has been demonstrated to improve clinician-patient interaction in the informed consent process, by guiding clinical discussion in ways that might not otherwise occur. Therefore, this study evaluates how consent forms for anonymous egg donation from Canadian fertility clinics address relevant criteria.

The paper proceeds in two parts. First, drawing on existing literature, model consent forms and other documents, it identifies key criteria that should be included in the informed consent process.
for egg donation. While conventionally, information provided to a patient must include the risks of the intervention (including probability and gravity of those risks) to meet the legal and ethical standards of informed consent, egg donation merits a particularly high standard for disclosure given its elective nature and the overall lack of physiological benefits to the donor. Second, this paper applies these criteria to informed consent documents for egg donation provided by eight fertility clinics from across Canada, identifying the strengths and weaknesses of the consent forms as a group.

METHODS
The study identified key elements of disclosure for informed consent in egg donation, and assessed the extent to which they were employed on consent forms from Canadian fertility clinics. To do so, the study first identified key elements of disclosure through a literature search and analysis of a range of documents, including relevant scholarly literature, model consent forms (and use guidelines), law and policy documents, ethics statements and consent assessment tools. All documents that provided some information about inclusion criteria for the consent process or for consent forms were included in the study and assessed. This included 23 texts in total (see online supplementary appendix A). Particular attention was paid to documents that addressed the Canadian case, given that there are restrictions on payment for egg donation in Canada that might be reflected in concern about financial considerations, but documents considering different jurisdictions were included in the analysis. All documents were read closely with any relevant elements of disclosure catalogued. Once all documents were analysed, elements that repeated with frequency were identified as the key elements of disclosure for the assessment of consent forms.

The study then assessed consent forms for egg donation from Canadian fertility clinics. Email and telephone requests were made to 41 Canadian clinics, including those that do not advertise that they engage in egg donation. The request was part of a broader request for consent forms that also included consent forms for IVF, in addition to consent to egg freezing. For the purposes of informed consent for egg donation, the clinics were asked for consent documents pertaining to ‘consent to oocyte retrieval from donors for their party reproduction’. Where information sheets included with the consent forms, the information sheets were included in the assessment of the forms. The clinics that provided consent forms to the study vary considerably, with representation from across Canada, with both small and large clinics participating. These consent forms had a variety of different names (eg, ‘anonymous ovm donor consent and release’, ‘consent for egg donation’, ‘consent by egg donor’), but all included information explicitly intended for egg donors. As this study did not involve human participants (only assessed relevant consent documents), no research ethics approval was needed.

These documents were assessed based on the key elements of disclosure identified in the first stage of the study, with one exception. The potential uses of eggs retrieved was not included as an assessment criterion given that, due to the consent to use regulations under section 8 of the Assisted Human Reproduction Act, consent to use embryos is often met in separate documentation, and was not generally included in the consent to treatment documents that clinics provided. The text from each consent form was coded according to its adherence to the preidentified elements of consent. Forms were identified as addressing relevant elements of consent whenever they included any mention of the relevant criteria. For example, if a form included a note that risks exist (without mention of what those risks include), it was seen to fulfill the element of identifying ‘risks, benefits and inconveniences’.

RESULTS
Key elements of disclosure for egg donation
There is a general understanding in the existing research that informed consent for egg donation should meet a higher standard than conventional medical procedures due to the lack of benefits to the donor. In the process of egg donation, the donor undertakes significant medical risks without any medical benefits. The existing scholarship identifies that at the very least, disclosure for egg donation should include clear and detailed information about medical risks, how the eggs will be used (particularly if they are to be used for research purposes), the risks of multiple donation (including consanguinity among offspring), how confidentiality will be protected and the nature of compensation. Some scholarship has identified additional criteria including, for example, the qualifications of those providing care, the lack of benefits to the donor, the likelihood of success of the donation, ‘a warning about the risks of multiple donations and donating at multiple clinics’ and ‘how well established each procedure is in the field’. Taken together, these works reveal eight key criteria for disclosure related to egg donation.

First, egg donors should be informed of the nature and objectives of treatment. The donor should be informed of the purpose of the treatment, what will be involved in each stage of the egg donation process and the purposes each stage serves (ie, menstrual cycle coordination, ovarian stimulation, egg retrieval). A robust discussion of the nature and objectives of treatment could also involve informing donors about who will be providing their treatment, their qualifications5 and their experiences with egg donation, as well as where to go for additional information.

Second, donors should be informed of the benefits, risks and inconveniences of egg donation.4 7 14–21 Regarding the benefits of egg donation, clinics should disclose that there are no known physiological benefits to the donor. As to risks, given the elective nature of egg donation, clinics are legally required to disclose all known risks of egg donation, including minimal risks5 and to obtain informed consent. In addition to relatively minor risks such as swelling at the site of the hormonal injections, and important but rarely occurring risks associated with the surgical retrieval procedure, the hormonal stimulation of the ovaries can lead to ovarian hyperstimulation syndrome (OHSS). This is the most significant risk of egg donation and though it occurs relatively frequently, in most cases, the symptoms are not severe. Mild and moderate forms of OHSS involve symptoms like cramping, nausea, bloating, vomiting, diarrhoea and abdominal distension. In more severe cases, however, OHSS may involve kidney failure, stroke, respiratory distress, blood clots and haemorrhaging from the rupture of the ovaries. In some cases, severe OHSS is fatal. Risks disclosed should also include risks associated with any medications prescribed, ovarian stimulation and the retrieval process, as well as the elevated risk of pregnancy associated with intercourse during the stimulation protocol (given the number of eggs being produced).4 10 15 20 Donors should also be informed of the limited data available regarding the effects of multiple donation and egg donation more broadly. Given the important risks involved with egg donation, donors should also be informed about the potential need for and availability of follow-up care.

Regarding
Inconveniences, donors should receive information about any pain or discomfort to be expected (ie, from medications, procedures, etc), the amount of time, the expected duration of their participation and any possible restrictions on their lives (ie, restrictions on work and family life).

Third, the consent process should address concerns related to the privacy of donors and their anonymity (where applicable). Consent forms should specify how donors’ personal health information will be protected, in keeping with federal and/or provincial privacy legislation. The form should also articulate how the clinic will gather and share personal health information with donor offspring (and the clinic policy on disclosing information about the health of offspring to donors). Finally, donors should be informed that anonymity is not guaranteed; that donors have been identified even when clinics have attempted to maintain confidentiality and as a result, there is a possibility that children resulting from their donation may one day contact them regardless of how this information is protected.

Fourth, the consent process should include clear disclosure that participation is voluntary, and that refusal to participate will involve no penalty, including (but not limited to) the provision of follow-up care. It is also important that consent forms include information about the period in which it is possible (and no longer possible) for egg donors to withdraw from the donation (ie, once the eggs are fertilised, once relevant embryos have been implanted, etc). This usually appears at the end of the consent forms.

Fifth, potential donors should be informed of the availability of counselling, both prior to and following donation. Counselling can work to help donors address any psychosocial and emotional implications of donation that they may experience, and to help them think through the ways that donation will affect them and others in their lives. Clinics should also make available a list of available counselling services that are not affiliated with the clinic itself, and should ensure that the resources are in place to help donors access those services freely.

Sixth, because egg donation is a costly medical intervention, there are important financial considerations for donors. How the egg donation will be paid for, how payment for relevant medications will occur and who will cover the costs of travel, if travel is involved. A discussion of the relevant costs should also address who is responsible for any costs associated with follow-up care. Furthermore, financial issues must also include information about payment or compensation.

In the Canadian context, this should include a note that the provisions of the federal Assisted Human Reproduction Act prohibits paying donors, making clear that donors cannot, by law, be remunerated for the provision of eggs.

Seventh, the consent process should include information about the possibility of an unsuccessful cycle. Egg donation as a practice is based around the idea that one woman will provide eggs to another for the conception of a child. However, donation cycles may be cancelled for any variety of reasons, including hyperstimulation or a too-limited response to ovarian stimulation. Egg donors need to be informed of the possibility that may not in fact be providing eggs, even after initiating a cycle. Further, the eggs retrieved may not become embryos, or the embryos produced may not result in a pregnancy or live birth. Egg donors must also be informed that there is no guarantee that their donation will result in a pregnancy or live birth.

Eighth, the consent process should address the potential uses of the eggs retrieved. Donors must be informed about any potential uses of their eggs and any resulting embryos (ie, for research, for clinical training and for reproductive purposes). Under the Assisted Human Reproduction Act and its regulations (s.8), consent for the use of eggs from egg donors must be obtained prior to the use of those eggs in reproduction, clinical training or research. Donors must also be provided with information identifying that they understand and acknowledge that they will not have legal claim, responsibility or liability in regard to any offspring that result from the use of their eggs.

### Canadian consent forms

Of the eight consent forms assessed, none met all of the elements of disclosure identified (see table 1). Clinics were generally clear about the nature/objective of egg donation; the risks, benefits and inconveniences involved; the availability of counselling and the possibility of unsuccessful treatment. Most clinics identified the right to withdraw, though often in terms of the right to withdraw the donation of eggs following retrieval, rather than in terms of the right to withdraw from the process of egg donation. Financial issues were only mentioned in four of eight forms assessed, and two of those did not mention that following the Assisted Human Reproduction Act, payments for egg donation cannot be made. Only three of eight forms mentioned the protection of donors’ personal health information, and only four of eight addressed the possibility of an unsuccessful cycle.

While nearly all of the clinics, for example, included information about the nature and objectives of treatment in their consent forms, the description was not always rigorous. One clinic simply mentioned, for example, that hormones and other drugs will be administered to me to stimulate the development of the follicles which contain the ovaries, and another only stated that the consent was for the donors’ reproductive material to be used to create an embryo. Other clinics had more comprehensive forms, providing specific details about the

### Table 1 Inclusion of key elements of disclosure for egg donation on consent forms

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Nature/ objectives</th>
<th>Benefits/risks/ inconveniences</th>
<th>Privacy/ anonymity</th>
<th>Right to withdraw</th>
<th>Availability of counselling</th>
<th>Financial issues</th>
<th>Possibility of unsuccessful cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>5</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>8</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
course of the treatment. The same kind of variation was evident for other criteria. In terms of the benefits, risks and inconveniences of egg donation, for example, some clinics provided clear information about the risks of ovarian hyperstimulation, the risks of ultrasound and the possibility of pregnancy throughout the process of egg donation, while others simply stated that the donor understood that there were risks and complications, with no risks explicitly mentioned.

The assessment of consent forms also revealed a number of other interesting findings. The availability of counselling was included in six of eight consent forms, but in four of the forms the counselling was framed as already having occurred. Statements like ‘I understand that counselling is mandatory’, ‘I have received counselling’ and ‘I have met with a psychologist’ with one clinic identifying that the counselling had been independent. In this way, the availability of counselling was presented as a requirement of engaging in treatment, rather than a commitment to the donor’s psychosocial well-being. These four clinics included no mention of the availability of future counselling. The other two clinics that provided information about counselling articulated that a psychologist was available to the egg donor in an ongoing way.

Some clinics were assessed as not including information about privacy or anonymity because while they did mention privacy and anonymity, the forms only contained information about the privacy and anonymity of the recipients, not of the donor. In one case, the form stated that ‘I agree not to discover the identity of nor contact the recipients or any child or children born as a result of this procedure’. Further, only one clinic addressed both the costs incurred by donors and payment to donors in their discussion of financial issues. Two addressed only who would take care of costs incurred (ie, travel, drug expenses and/or follow-up care), while the other stated that ‘no consideration is being given to the donor or her partner’.

**DISCUSSION AND CONCLUSION**

Assuming that consent forms for egg donation are in some way reflective of the broader consent process, or at least might serve as a prompt, then at the very least they should include the elements of disclosure identified in this study. Physicians may be having discussions with patients well beyond what is included on the consent forms, but they may not be, and more comprehensive consent forms may aid in filling gaps that remain. While some of the consent forms assessed meet many of the key elements of disclosure, all could use some measure of improvement. For some, this will include re-evaluating how they include one or two elements of disclosure, and for others, this will require a substantial overhaul to include a more comprehensive discussion, for example, of the risks and inconveniences of donation. Using this framework as the minimum standard for consent could ensure that donors have the basic information they need to make informed decisions.

It is clear that more needs to be done to improve practices of informed consent than simply addressing the content of consent forms. Some evidence has suggested, for example, that even when counselling is mandated, that donors may be meeting with nurses and clinicians rather than psychologists to address psychosocial issues, which might make frank discussions about the risks, the benefits and the inconveniences of treatment more difficult.

Further, there are other important concerns about these consent forms that were not adequately captured by the assessment criteria. A number of the forms included information that was not intended to obtain donors’ consent to a medical intervention, but rather prescribed behaviours. For example, some of the forms mentioned that donors should not consume alcohol, use drugs, smoke or have sexual intercourse. And while there are important reasons to ask donors to abstain from these activities (ie, they may complicate the egg donation process), in one case there was more information about what donors should and should not do than there was about the potential risks to the donor. The emphasis on prescribing donors’ behaviours rather than disclosure may work to frame donors as signing a contract for their eggs or for their reproductive labour, rather than consenting to a medical intervention.

In this ethically contentious area of medicine, there are a number of reasons to raise concern about how informed consent occurs. There are potential conflicts of interest present in the provision of services by one physician to both donor and recipient. Or there are concerns about the provision of care in private clinics where the capacity to provide and receive financial compensation for IVF is contingent on the success of the egg donation. There are concerns as well, about egg donation with large insofar as it requires the engagement of young, healthy women in a non-essential, medical intervention. Improving informed consent through the revision of consent forms is one small, tangible reform that would work to improve the nature of egg donation. Given the framework and elements of disclosure provided by this study, it would not take much to make the consent process more clear, more open and disclosure more comprehensive.

**Twitter** Follow Alana Cattapan at @arccattapan

**Acknowledgements** The author would like to thank Tim Krahm for his hard work in compiling the consent forms for this paper. Thank you also to Vanessa Gruben for her helpful feedback on the draft manuscript, as well as Françoise Baylis, Dave Snow, Kirsten Borgeson, and other members of the Novel Tech Ethics team for their insightful comments and feedback on this paper. This paper also benefited from the feedback provided on its initial conception as a poster at the 2014 Canadian Fertility and Andrology Society annual conference in Quebec City.

**Contributors** Alana Cattapan was responsible for the conception, design, and writing of this paper. Françoise Baylis is the principal investigator on the grant which made this study possible. Timothy Krahm engaged in the collection of the consent forms, and Ashley Doyle provided research assistance.

**Funding** Canadian Institutes for Health Research (EOG111389)

**Competing interests** None declared.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**REFERENCES**


458

Reproductive ethics
Reproductive ethics

16 Senators Gray L, Pearce R; Representatives Gowan, Montenegro; Senators Allen S, Harper, Melvin, Verschoor; Representatives Antenori, Burges, Driggs, Lesko, Nichols, Stevens, Weiers J. Informed consent for egg donation; requirements; unprofessional conduct. SB 1306, 2010.