FERTILITY associates | a better understanding
TE RAUHANGA O TE WHARETANGATA

9 September 2015

Alison Douglas
Chair ACART
Ministry of Health
PO Box 5013
Wellington

Dear Alison

Thank you for inviting Fertility Associates to respond to ACART's consultation document on **Informed Consent and Assisted Reproductive Technology: Proposed advice to the Minister of Health.** This response is on behalf of Fertility Associates' staff after internal consultation and discussion.

Question 1

(a) We support patients and the public having access to regulations and guidelines about informed consent in ART. We note that the Fertility Standards NZS8181 is a copyrighted document. We would welcome the Ministry of Health making it freely available.

(b) The information in the HART Act 20014, the Code of the Health and Disability Services Consumers' Rights Regulation 1996 and the Fertility Standards should be sufficient. We would welcome the Ministry providing a plain language summary for consumers.

Question 2

(a) We agree that consent for ART shold be in writing, as is already required by the Fertility Standards workbook section 1.7.2 (a). Under New Zealand legislation, ART means the therapeutic use or storage of gametes and embryos outside the human body. Fertility Associates also requires written consent for non-ART reproductive treatments that have a reasonable risk of side effects, such as ovulation induction using gonadotrophins.

(b) Verbal consent should be allowed so that a person can withdraw from an ART procedure at short notice. Eg. A woman about to undergo insemination should be able to withdraw consent by saying 'no' at the bedside, whereas a donor with stored sperm should have to provide a written request to withdraw consent for his sperm being used.

Question 3

(a) We think patients should be required to consent to their non-viable embryos being used for training. Fertility Associates does this.

We think it is inconsistent to require gamete donors to have to give consent for embryos created using their gametes to be used in training. Discussion in paragraphs 108-119 leading to question 6 supports the concept that addition of sperm to eggs to acheive fertilisation is the 'point of no

return'. After this point, the donor does not have the right to withdraw consent, nor is the donor's permission required to use an embryo or to discard an embryo. It is inconsistent to require a donor to consent to the use of a non-viable embryo being used for training, but not for viable embryos being used or discarded

(b) No

Question 4

(a) We agree that donors should be able to set conditions on the use of their sperm, eggs or embryos, and that these conditions should be captured in their consent form.

(b) The conditions need to be feasible to action. If a donor sets conditions that are difficult to interpret or subjective (eg. if a man specifies that his sperm can only be used for couples who are 'well mannered'), then Fertility Associates would ask the person to be a personal donor and chose his or her recipient.

(c) Donors should be discouraged from changing conditions after they have donated, because often people reserve sperm to try for a subsequent pregnancy. It would be difficult emotionally for a recipient to have donor sperm withdrawn when they met the donor's original conditions but not the donor's new conditions.

Question 5

(a) Donors should be able to ask for information from the clinic at any time about the use of their donated materialin a way that preserves the confidentiality and privacy of recipients. For instance, donors can ask whether their material has been used, the number of children born, and the gender of the children.

(i, ii) We do not think a donor should have the right to require the clinic to tell them when their gamete (or embryo) is about to be used or the outcome of treatment. There are two reasons for this.

The first reason comes from our expereince of having given some egg and embryo donors this option. Recipients felt the donors were too instrusive when they wanted to know what was happening and when. Recipients may want to limit who knows and when people know if treatment was unsuccessful or if they had a miscarriage. We have had at least one formal complaint in this area which led to us defining what information we would share between donors and recipients and what we would not in donor egg treatment.

If a donor wants this level of information, we would ask the person to become a personal donor and get the information directly from the recipient.

The second reason arrises from the logistsics involved. For instance, a sperm donor may be used for up to five woman, which could mean the clinic contacting the donor up to 10 times a month to tell him about treatment cycles about to start and the outcome of completed cycles. This might go on to some extent for several years. In the past we sent sperm donors an annual letter updating them of births from their donations. We stopped doing this because of the logistical problems, including a formal complaint when a letter was opened by someone else in the family other than the donor.

In summary, we welcome and encourage donor initiated enquiries, but do not think the clinic should be pushing information to donors, apart from in the circumstances in (b) below.

(b) The clinic should proactively provide information to donors when it relates to safety. For instance, if a donor child was born with a condition that might have been inherited, the clinic should tell the donor, families with children from the same donor, and women currently using the donor to try to become pregnant. This is currently done.

Question 6

(a) We agree that a sperm or egg donor should be able to withdraw or vary consent up to the point of fertilisation, and that an embryo donor should be able to withdraw consent up to the point of embryo transfer.

(b) Not applicable.

Question 7

(a) We agree that a partner's consent should not be required for gamete donation. However, we strongly believe that the partner should have access to information and counselling about the implications and issues associated with gamete donation by their partner, and should sign a declaration that they have received this. If the partner refuses, then the clinic should undertake a risk analysis to decide whether to accept the person as a donor. There are practical risks associated with a partner not agreeing to donation or refusing to receive information, including a higher chance of the donor withdrawing later on and disharmony in the donor's relationship that can spill over to the recipient and the clinic.

(b) We agree that consent of family or whanau should not be required. However, we encourage family and whau to access information and counselling about the issues associated with donation.

Question 8

(a) We agree that there should be a cooling off period if one party disputes the future use of embryos. A period of 12 months seems reasonable, although the couple should be encouraged to come to a conclusion in a shorter time if possible.

(b) In general, we agree that if a couple cannot agree about the use of an embryo, the embryo should be disposed of. However, there is an important exception. If a couple creates an embryo using donor sperm, then the woman should be able to use that embryo even if her partner disagrees. The reasoning follows. Suppose the general pinciple applies in all cases, then this embryo would be discarded. The woman could then have a new cycle of IVF treatment using the same sperm donor to create an embryo with the same genetic composition as the embryo which was discarded. It is illogical, expensive, and wasteful of a potential human life to require an embryo to be discarded only to create a replacement embryo from the same gamete sources.

Question 9

(a) We agree that it is useful to include pinciples of informed consent in regulations, which is the current position.

(b) The three existing laws and regulations are sufficient, and their content can be adjusted if necessary.

Question 10

(a) ART is a complex area, and newer treatments or combinations of treatment (donor gametes, surrogacy, donor embryos) add to that complexity. Clinics and consumers should be encouraged to experiment, within the principles covered in regulations and guidelines, to find approaches to consenting that are easy to understand and implement.

(b) Informed consent is based on a patient's knowledge and understanding; it is likley that improvements in effective consent will largely come from finding better ways of educating patients, not from regulations about consent forms or the consenting process itself.

Best wishes

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