2007 submission attached - see Question 11

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Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

5 June 2013

John Angus
Chair
Advisory Committee on Assisted Reproductive Technology (ACART)
P O Box 5013
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WELLINGTON 6145

Attention: Betty-Ann Kelly

Dear Dr Angus

ACART Discussion Paper: Import and Export of Gametes and Embryos

Thank you for the opportunity to comment on the Advisory Committee on Assisted Reproductive Technology's (ACART) discussion paper *Import and Export of Gametes and Embryos*.

The discussion paper presents arguments on six key issues in respect of the import and export of gametes and embryos where there is "potential for a significant clash between New Zealand requirements and those elsewhere", and requests submissions on New Zealand's regulatory framework in relation to those areas. The six areas are: altruistic donation v commercial supply; right to access identifying information about donors v no right to access such information; family size requirements; use of sex selection; scope of informed consent; and the use of gametes and embryos overseas in procedures or research prohibited or precluded in New Zealand.

As Health and Disability Commissioner, I am charged with promoting and protecting the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code). One of my functions under the Health and Disability Commissioner Act 1994 is to make public statements in relation to any matter affecting the rights of health or disability services consumers.

While the discussion paper raises a number of social and ethical issues, I have decided to limit my comments in this case to the scope of informed consent, which raises direct issues under the Code. However, I reiterate this Office's previous comment to ACART in relation to the import and export of gametes and embryos[1] that the use of any imported gametes and

[1] See HDC's comments on ACART's consultation on *Advice on Aspects of Assisted Reproductive Technology: A consultation paper on policy issues* (emailed to ACART on 7 September 2007), and ACART's discussion

embryos should be required to meet the same quality and safety standards required for those originating in New Zealand, including standards relating to consent, information provision and the treatment of donors.

Consent to export gametes and embryos
You have asked whether consent should be required before gametes or embryos are exported to or from New Zealand. In other words, should export occur only where a gamete provider has given explicit consent to export?

I am surprised that this section of the discussion paper does not refer to Rights 7(9) and 7(10) of the Code. As noted in my letter to you of 7 February 2013 (in relation to the status of embryo donors as consumers), Rights 7(9) and 7(10) of the Code relate to the use, return, and disposal of body parts and bodily substances removed or obtained in the course of a health care procedure. There is no definition in either the Act or Code of "body part" or "bodily substance"; however sperm and eggs would be considered "bodily substances". As such, Rights 7(9) and 7(10) apply to the use, return, and disposal of gametes removed or obtained in the course of fertility treatment.

What this means is that, in accordance with the Code, gamete donors should receive information and make an informed decision about how their gametes will be used, stored, and what will happen to them after treatment is completed, including in relation to the export of gametes and the implications of a decision to export (as set out in paragraph 38 of the discussion document[2]). Any future use of the gametes should only be in accordance with the choice the consumer made.

Any gamete imported into New Zealand should also only be used in accordance with Rights 7(9) and 7(10) of the Code, that is, in accordance with the consent of the gamete donor. In my view, such consent should include consent for the gamete to be imported into New Zealand and for the gamete to be used for the specific purpose proposed. It should not matter that the gamete has been sourced outside of New Zealand. It would be inappropriate for different rules to apply to the use of gametes imported into New Zealand than to those sourced in New Zealand.

The exception to the above is where it is proposed that the gametes be stored, preserved or used for the purposes of research that has received the approval of an ethics committee, or for the purpose of a professionally recognised quality assurance programme, an external audit of services, or an external evaluation of services (see Rights 10(b) and (c) of the Code).

As also noted in my letter to you of 7 February 2013, the legal requirements regarding the use of embryos are less clear under the Code. This is because under the Code an embryo created in a laboratory and outside of a woman's uterus is unlikely to be regarded as a "body part" or "bodily substance" of either the genetic mother or father. Once fertilisation has taken place in

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document *Use of Gametes and Embryos in Human Reproductive Research: Determining policy for New Zealand* (emailed to ACART on 1 March 2007).

[2] Those implications include: gamete providers may not be able to withdraw or vary consent after export if gametes and embryos are exported to a country with different rules or practices concerning when a donor can withdraw consent; parties involved in import and export may have different or mistaken assumptions about when they or others may withdraw or vary their consent; conditions attached to consent given in New Zealand may not be upheld after export; and individuals who decide to withdraw consent to the use of their gametes or of embryos formed from their gametes may face difficulties in notifying the appropriate party or body that they have withdrawn consent.

the laboratory, a new entity comes into existence which may not qualify as a body part or bodily substance of a consumer for the purposes of Rights 7(9) and 7(10). Accordingly, on a strict legal reading, once an embryo is created the donors do not have the protections of Rights 7(9) and 7(10) of the Code. However, as I noted in that letter, regardless of the legal technicalities it is my view that, at the time gametes are extracted for fertility treatment, each gamete donor should be fully informed and asked about their wishes for the future use of any surplus embryos, and any future use of those surplus embryos should be in accordance with the stated wishes of the gamete donors, including the export of such embryos.

As with the import of gametes, it is my view that any embryo imported into New Zealand should only be used in accordance with the consent of the gamete donors. In my view, it would not be appropriate for embryos to be imported into New Zealand without the informed consent of the gamete donors.

In the section "Arguments in support of requiring explicit consent to gametes and embryos being exported to or from New Zealand", it is noted that in most cases, donors will not have considered the possibility that their donated gametes or embryos created from their donated gamete, might be sent to another country for use in treatment or research. In my view, this is a matter that should be discussed with gamete donors at the time of donation, if it is a real possibility.

In the section "Arguments for not requiring explicit consent to export to or from New Zealand" the discussion document states, "Once a donor has made a donation, he or she no longer has a role in decision making about gametes ..." This statement is inconsistent with Rights 7(9) and 7(10) of the Code (as outlined above) and therefore misstates the legal position in New Zealand.

I do not accept the argument that informed consent requirements will become "overly complex" if consent to the export and use of gametes and surplus embryos is required.

Conclusion

I trust that you find these comments of assistance. Please do not hesitate to contact Senior Legal Advisor Helen Davidson on (04) 494 7929 or by email at hdavidson@hdc.org.nz if you have any questions about this submission.

Yours sincerely

Anthony Hill
Health and Disability Commissioner

2007 Submission

Submission form

Name: Nicola Sladden
Chief Legal Advisor, Health and Disability Commissioner

This submission is made on behalf of: Health and Disability Commissioner

Brief description of organisation

The Health and Disability Commissioner's role is to promote and protect the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code). Under section 14(1)(d) of the Health and Disability Commissioner Act (the HDC Act) one of my functions as Commissioner is to make public statements in relation to any matter affecting the rights of health and disability services consumers.

The HDC Act and Code apply to consumers of fertility services, which within the definition of 'health services' under section 2 of the HDC Act. This means that people receiving services related to fertility, including when gametes are donated in the course of fertility treatment, have the protection of the ten rights in the Code. The Code rights also extend to those occasions when a consumer is participating in research (Right 9). Of particular relevance to research using gametes or embryos are Rights 4, 6, and 7, which state that every consumer has the right to services of an appropriate standard, to receive sufficient information, and make an informed choice and give informed consent.

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Do you wish to receive a copy of the summary of submissions?

Yes

Question 1:
Do you agree that the following procedures should remain subject to guidelines developed by ACART, and review by ECART:

- clinic-assisted surrogacy
- embryo donation for reproductive purposes
- donation of gametes between certain family members
- certain uses of PGD?

This is difficult to answer when no alternative options have been proposed. These procedures should remain subject to some form of regulation and ethical review.

Question 2:
What are your views on the proposed guidelines for clinic-assisted surrogacy?

In my view, the proposed guidelines should provide clear and comprehensive guidance to ECART about the types of procedures that should be approved and the circumstances under which the procedures should be allowed. Because of the significant psycho-social issues involved in surrogacy arrangements, access to information and counselling is particularly important. Therefore I support the proposed guidelines requiring the parties to receive independent legal advice, medical advice, and counselling sessions. However, I believe it is important to ensure that certain information and issues are considered during these sessions. For example, counselling should address things such as:

- antenatal screening (for example for spina bifida and Down's syndrome) and what should be done if the baby is found to have congenital abnormalities;
- the risk of multiple pregnancy;
- what the parents will tell the child about how he or she was conceived.

Therefore I recommend detailing in the Guidelines the information and issues that must be provided and addressed during the independent legal, medical, and counselling sessions.

Question 3:
What are your views on the proposed guidelines for embryo donation?

As above, in my view, the Guidelines should outline the specific information and issues that must be provided and addressed during the independent legal, medical, and counselling sessions.

Question 4:
What are your views on the proposed guidelines for donation of gametes between certain family members?

As above, in my view, the Guidelines should outline the specific information and issues that must be provided and addressed during the independent legal, medical, and counselling sessions.

Question 5:
What are your views on the proposed guidelines for PGD that are reviewed by ECART?

Regulation of PGD in New Zealand should accurately reflect the values of our society and cultures. Therefore the decisions of ECART about when PGD should be permitted should be guided by the values of New Zealand society, so that the uses of PGD in New Zealand are acceptable to, and supported by, the public. I note that the Bioethics Council is currently undertaking a public dialogue/deliberation process in relation to the issue of pre-birth testing, including PGD. I believe that the decision as to what forms of PGD are permitted should await the information gathered by the Bioethics Council about public opinion on this issue.

The Consultation Paper does not explain why the requirements in the current Guidelines on Preimplantation Genetic Diagnosis (March 2005) about information and counselling should be removed. These requirements are essential to ensure that those seeking PGD make an informed choice, so must be complied with before PGD is carried out.

It is essential that the Guidelines include guiding principles to assist ECART to decide whether a particular PGD procedure should be allowed. As currently proposed, the Guidelines do not identify the relevant ethical issues specific to PGD and so fall short of providing comprehensive, clear and workable guidance to ECART in this novel and controversial area. Guidance could be provided by clarification of how ECART should "review applications for preimplantation genetic diagnosis to ensure consistency with the principles of the HART Act". How the principles of the HART Act are relevant to PGD could be specified, with guidance as to the particular issues ECART should consider when reviewing an application.

For example, specific direction is needed about what information should be given to the couple seeking PGD, in accordance with principle (d) (that is, that no assisted reproductive procedure should be performed on an individual unless the individual has made an informed choice and given informed consent). Patients must be given certain information to enable them to make an informed choice.

With regard to PGD, information should include (but is not limited to):

- that PGD may not detect a given condition and that chorionic villus sampling (CVS) or amniocentesis may also be necessary;
- the fact that the child may still have some other condition or disorder that was not tested for and the possibility of termination of the pregnancy.
- the risks of the procedures (including any potential risk of long-term health effects);
- the alternatives to PGD;
- possible outcomes of the procedures and implications of those outcomes;
- genetic and clinical information about the specific condition tested for;
- the likely impact of the condition on those affected and their families (including the full range of their experiences of living with the condition;
- information about treatment and social support available for the condition.

The information provided (or to be provided) to the couple should be in writing and submitted to ECART along with the other materials during the application process.

The proposed Guidelines also do not make clear the role of genetic counselling. If the role of the genetic counsellor is simply to provide relevant information to patients, or if it is to play an active role in the use of PGD. Will genetic counsellors be expected to report their opinions to the clinics before treatment proceeds? Will they be able to advise against the use of PGD for specific patients?

The Guidelines prohibit the use of PGD to select embryos with a genetic abnormality seen in a parent. I assume that ACART is relying on principle (a) and/or principle (b) of the HART Act to justify prerequisite 1(a) of the proposed Guidelines. However, it is not clear why this prerequisite is necessary, given that ECART will be required to review applications to ensure consistency with the principles of the HART Act.

Question 6:
What are your views on the proposed guideline for PGD using HLA tissue typing?

Permitting HLA tissue typing goes a step farther than PGD, allowing selection of characteristics (i.e. tissue match) which poses no harm or benefit to a child. No medical advantage will result from this use of PGD from the perspective of the child created by it. Children born of PGD and tissue typing are not so created exclusively for their own benefit, but rather for the benefit of their families. To choose to implant an embryo on the basis of its compatibility with a sibling is to choose it based on a social reason, and the embryo owes its selection to the value others will derive from its existence. Therefore, I believe that the decision about the forms of PGD using tissue typing permitted should await the information gathered by the Bioethics Council about public opinion on this issue.

As currently proposed, the Guidelines do not provide the necessary guidance to ECART about when applications for PGD using HLA tissue typing should be

approved. I note that principle (a) in section 4 of the HART Act states that the "health and well-being of children born as a result of the performance of an assisted reproductive procedure ... should be an important consideration in all decisions about that procedure". Principle (b) states that "the human health, safety and dignity of present and future generations should be preserved and promoted". In my view, this does not provide sufficient guidance to ECART when reviewing an application for PGD using HLA tissue typing - on the one hand, the potential child's health and well-being must be "an important consideration" but, on the other hand, the health of the present child "should be preserved and promoted".

Furthermore, the Guidelines do not stipulate what constitutes "benefit" for the genetic sibling of the potential child. Will HLA tissue typing be allowed only where the existing sibling has a serious or life-threatening condition? What is the relevance of other alternative options for treating the existing sibling? How beneficial must the use of the HLA-matched tissue be for treating the particular disease the existing sibling suffers from?

There is also no restriction on what this benefit will mean for the potential child (the 'HLA-matched child). An HLA-matched child may potentially be required to be a donor of tissues and organs throughout life. Once an HLA-matched donor is created, there is potential to require further tissues after the initial cord blood donation, such as bone marrow or kidney donation. Once born, the HLA-matched child in respect of whom any health care procedure is carried out will be a "health consumer" under the HDC Act. As a health consumer, the child would have the right to be free from discrimination, coercion, harassment, and exploitation (Right 2 of the Code), and the right to dignity and independence (Right 3 of the Code). Both of these rights would prohibit the subjection of a patient below the age of consent to surgery for the benefit of another. Therefore ECART should predicate its approval upon assurance from the family and the clinic that only cord blood (and not other tissues or organs) of the new child will be used to treat the existing sibling.

As above, the information required to enable the couple to make an informed choice about PGD using HLA tissue typing should be specified in the Guidelines.

Question 7:
What are your views on whether the use of PGD should be extended to allow the testing of embryos solely for tissue typing for an existing child with a disease?

Please give reasons for your views.

In my view, the issues regarding whether the use of PGD for the testing of embryos solely for tissue typing for an existing child with a disease are very similar to those raised in Question 6. Therefore, as above, I believe that this decision should await the information gathered by the Bioethics Council about public opinion on this issue.

Question 8:
Do the guidelines proposed in chapter 3 adequately address the needs, values and beliefs of Māori?

Please give reasons for your views.

No comment.

Question 9:
What are your views on whether an embryo for reproductive purposes should be allowed to be created using a donated egg and donated sperm?

Please give reasons for your views.

No comment.

Question 10:
Do you agree that embryo splitting requires no specific recommendation to the Minister of Health (which will mean that it is unable to proceed, although it will not be prohibited)?

Please give reasons for your views.

No comment.

Question 11:
Do you agree that the import and export of donated *in vitro* embryos and gametes should be allowed, provided that the prohibitions and principles of the HART Act are met?

As outlined in the Commissioner's submission on ACART's discussion document *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand*, any imported of gametes and embryos should be required to meet the same quality and safety standards required for those originating in New Zealand, including standards relating to consent, information provision and the treatment of donors. It is possible that ECART may be able to ensure these standards, if ECART were to review applications, but this would depend on the guidelines that ECART's review was conducted under.

Given the loss of control over the use of gametes and embryos exported from New

Zealand, export of gametes and embryos should generally be prohibited. Gametes and embryos sent overseas may not receive the kind of ethical review that occurs locally, and New Zealand has no jurisdiction over processes that occur overseas. Moreover, it will not be possible in many cases to determine where gametes and embryos that are sent overseas will be stored, or to ensure that they are not provided to commercial biomedical companies or used in commercial research collaborations. However, in limited situations (such as people who have embryos or gametes stored for future reproduction purposes), export for reproductive purposes may be appropriate where certain conditions are met. It is possible that ECART may be able to ensure appropriate export, if ECART were to review applications, but ECART would need to have limited jurisdiction to approve applications and detailed guidance on when export should be approved.

Question 12:
Do you agree that requirements for the import and export of donated *in vitro* embryos or gametes should be set out in guidelines developed by ACART, rather than regulations?

Yes/ No

See above, Question 11.

Question 13:
Do you agree that it is necessary to prescribe requirements for informed consent in regulations?

Yes/ No

Please give reasons for your views.

No, I do not agree that it is necessary to prescribe requirements for informed consent in regulations at this stage. As noted in the Consultation Paper, some requirements for informed consent are detailed in the Fertility Services Standards. Therefore it would seem sensible to include any additional requirements for informed consent in this Standard, rather than create an additional source of standards for fertility service providers to comply with unless there are convincing reasons to do so. It may also be appropriate to prescribe some informed consent requirements in the guidelines ECART uses to review applications (as above).

Question 14:
What specific requirements for informed consent would you like to see?

Please give reasons for your view?

The Code requires that consumers are fully informed and make an informed choice before any health services (including fertility services) are provided (Rights 5-7 of the Code). However, as outlined above in Question 5, there is certain information that will be required to be given before informed consent can be obtained to certain procedures, and the information required may vary according to the particular procedure being considered. The consultation paper on consent to storage and use of Guthrie cards, *Newborn Blood Spot Cards: Consent Storage and Use* (March 2007), provides a good example of the information and discussions required for informed consent to screening and collection and use of tissue.

Question 15:
Do you agree that, where written consent is not given prior to death, the use of gametes from deceased persons for reproductive purposes should be prohibited?

Yes/ No

Please give reasons for your views.

Yes.

Rights 7(9) and 7(10) are of particular relevance to research using gametes or embryos, containing provisions relevant to the use, return, and disposal of body parts and bodily substances. Right 7(9) provides that "every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure". Right 7(10) provides that no body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than with the informed consent of the consumer, unless for the purposes of research that has received ethics committee approval or for quality assurance activities. In practice, this means that consumers should receive information and make a decision about how their gametes will be used, stored, and what will happen after the research is completed.

Section 2 of the Act gives a broad definition of 'health care procedure' that would encompass health research and fertility services. Although there is no definition in either the Act or the Code of 'body part' or 'bodily substance', sperm and eggs would be considered 'bodily substances'. Therefore the relevant fertility treatment consumer has the right to make a decision about the return, storage or disposal of their eggs or sperm following that treatment. The informed consent process when collecting any gametes should include consideration by the consumer of the possible future uses of his or her gametes. Any future use of the gametes should be in accordance with the choice the consumer.

Question 16:
Does the advice proposed in chapter 4 adequately address the needs, values and beliefs of Māori?
Please give reasons for your views.

Kei te tika ngā tohutohu e pā ana ki ngā tikanga Māori i te wahanga 4
Homai o whakaarō.

No comment.

Question 17:
What are your views on the Tikanga outlined in Appendix 2?
Please give reasons for your views.

He aha ōū whakaaro mo te Tikanga i roto te tāpiritanga 2?
Homai ou whakaarō.

No comment.

Question 18:
Are there any other Tikanga that ACART should take into consideration?
Please give reasons for your views.

He Tikanga ano hei whakaarohanga mā ACART?
Homai ou whakaarō.

No comment.

Question 19:
Do you have any further comments to make that have not been covered in the questions set out above?

It would have been useful for the Consultation Document to have clarified how and why existing guidelines (for example, relating to surrogacy and PGD) were being altered. Explanation and justification for ACART's proposals, and exploration of the opposing viewpoints, would also have been helpful.