

Consultation on Aspects of Assisted Reproductive Technology

Summary of Submissions:
Part Five – Responses to questions 8 -19

Citation: Advisory Committee on Assisted Reproductive Technology. 2008. *Consultation on Aspects of Assisted Reproductive Technology: Summary of Submissions: Part Five – Responses to questions 8-19*. Wellington: Advisory Committee on Assisted Reproductive Technology.

Published in July 2008 by the Advisory Committee on Assisted Reproductive Technology,
PO Box 5013, Wellington, New Zealand

ISBN: 978-0-478-31773-2 (online)
HP 4621

This document is available on the ACART website: www.acart.health.govt.nz



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Introduction

On 6 July 2007, the Advisory Committee on Assisted Reproductive Technology (ACART) released *Advice on Aspects of Assisted Reproductive Technology: A consultation paper on policy issues*.

The consultation paper included draft guidelines on:

- surrogacy arrangements involving providers of fertility services
- the donation of gametes between certain family members
- embryo donation
- pre-implantation genetic diagnosis (PGD).

The consultation paper also proposed parameters for advice on related issues, including:

- the use of donated eggs and donated sperm
- embryo splitting
- the import and export of donated gametes and embryos
- informed consent.

The consultation paper was mailed to 272 individuals and groups that had previously registered interest with ACART, including government agencies, regional Te Puni Kōkiri offices, researchers, academics, providers of fertility services, fertility consumer groups, ethics committees, bioethics organisations, and religious groups, and was emailed to other government agencies and organisations.

The consultation process was advertised in all major metropolitan newspapers on Wednesday 15 August and Saturday 18 August 2007 and in the *Sunday Star-Times* on 26 August 2007. A press release was sent to 60 news outlets, including all radio and television stations.

ACART held consultation meetings with provider staff and representatives from Fertility NZ throughout August 2007.

A hui was held on 13 August 2007 and a public oral submissions hearing was held on 5 September 2007, both in Wellington.

Submissions closed 7 September 2007. ACART received 44 written submissions and four oral submissions.

This document summarises the submissions received in response to questions 8–19 in the consultation paper.

Summary of submissions on assisted reproductive procedures

The consultation paper asked submitters to indicate if they agreed that the following procedures should remain assisted reproductive procedures,¹ that is, subject to guidelines developed by ACART and ethical review by the Ethics Committee on Assisted Reproductive Technology (ECART):

- surrogacy arrangements involving providers of fertility services
- embryo donation
- donation of gametes between certain family members
- certain uses of PGD.

The majority of submitters agreed that all four procedures should remain assisted reproductive procedures.

Several submitters disagreed in principle with assisted reproductive technology, although some of these submitters, noting that assisted reproductive technology is well established in New Zealand, agreed with having a process for the ethical review of procedures.

Reasons for supporting ethical review included:

- ethical, emotional, and psycho-social issues
- the need to protect the interests of children born as a result of the procedures
- the relative newness of the procedures
- the ramifications for families, which are unknown and potentially significant
- the lack of evidence of the long-term psycho-social and medical safety of the procedures.

Several submitters noted that part of their rationale for supporting ethical review was that ACART would monitor the application and health outcomes of assisted reproductive procedures and revisit whether the procedures would continue to require ECART review.

Feedback from providers was divided between support for the procedures to remain assisted reproductive procedures and a desire for a different kind of framework. Some providers wanted more autonomy and for ECART to function in an advisory capacity, so clinics could approach it for advice and guidance at any stage of the process. Providers envisaged being able to refer cases for established procedures to ECART where there were specific ethical concerns or a perception of enhanced risk.

¹ An assisted reproductive procedure is defined by the Human Assisted Reproductive Technology Act 2004 (HART Act) as a procedure performed for the purpose of assisting human reproduction that involves the creation of an in vitro human embryo; or the storage, manipulation, or use of an in vitro human gamete or an in vitro human embryo; or the use of cells derived from an in vitro human embryo; or the implantation into a human being of human gametes or human embryos; but does not include an established procedure under section 6 of the HART Act.

Responses to question 8: Do the guidelines proposed in chapter 3 adequately address the needs, values and beliefs of Māori? Kei te tika te takato o ngā rārangi tohutohu e pā ana i nga tikanga Māori i te wahanga 3?

Responses to question 8 about whether guidelines proposed in the consultation paper adequately addressed the needs, values and beliefs of Māori, included the following.

- As long as the guidelines are respectful of any race this should not be an issue.
- It is not possible to categorise Māori beliefs in these areas as they vary considerably. Respect should be shown for the values of all cultures.

One submitter stated that consideration of Māori issues in the consultation document was confined to listing the meaning of terms such as whakapapa and some reflections on their relevance to aspects of assisted reproductive technology. The submitter went on to say that reproduction and family are central to Māori culture and there are established tikanga about matters such as whāngai children. However, the development of tikanga about new birth technologies takes time and will require efforts to raise awareness among Māori about the causes of infertility and how their communities may be affected by infertility and genetic disorders. This submitter recommended that ACART focus on developing information, raising awareness, and developing processes more suited to Māori. They also noted the diverse range of cultures in New Zealand and that the process adopted may be inadequately inclusive for cultures other than Māori.

Most providers of fertility services indicated that they did not have the expertise to answer the question.

References included:

- Volume 6 of Keith Griffin's CD-Rom *Adoption: Māori Whangai*
- *Polynesian and Pacific Genes and Life Patents* edited by Aroha Mead and Steve Ratuva (2007, Call of the Earth Llamado de la Tierra, United Nations University – Institute of Advanced Studies).

Responses to 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?

Just over half of submitters supported the use of donated eggs and donated sperm (question 9). The remainder were opposed or undecided. Submitters who supported this were generally cautious and proposed qualifications if it were to be allowed.

Submissions supporting the use of donated eggs and donated sperm

One submitter gave unqualified support for using donated eggs with donated sperm and likened this to open adoption.

Other submitters who supported the use of donated eggs with donated sperm did so with the following provisos.

- Ongoing counselling must be available to all parties.
- Long-term follow-up studies are needed.
- Children should have knowledge of their genetic parents and potential siblings and half-siblings as soon as they are able to comprehend the situation.
- Issues of informed consent must be addressed for all parties.
- The number of families for which any single donor has helped conceive a child must be limited.
- Donors should already have their own children.
- Visitation during childhood should be provided for in the interests of the child and the donors.
- An advocate for the child should be required.
- This treatment could be accessed by “much older women” (especially if they are single).
- Assisted reproductive technology has already repeated many of the mistakes associated with adoption, and care should be taken to ensure this does not happen here as well.
- Embryo donation is a better option and should be promoted first.
- The commodification of eggs and sperm and their patenting must be strictly prohibited before this can happen.

Many submitters commented on the process of gaining information, stating that this should not be an issue if the information is made available to the recipients and the child (when they are old enough), and this would also apply to half-siblings, as the child could pursue contact with donors when old enough.

Other submissions made the following comments.

- A distinction could be made between donations by strangers and donations by people with a genetic link to the recipient/s, on the basis that the potential psycho-social issues may be less where the donors have a genetic link to the recipient/s and resulting child.
- There would be no substantial ethical difference between donated embryos and the use of donated eggs with donated sperm, compared with artificial insemination where

- the main limitation on the child’s access to information would be whether the parents had told them they had been created from donor gametes
 - there would not necessarily be an increased likelihood of half-siblings, as the number of donations could be controlled
 - a prohibition on use of donated eggs and donated sperm would not necessarily be discriminatory, as donated embryos are available, but the availability of this option would increase options for infertile recipient/s.
- This possibility represents a shift in previous thinking, as the child would not be genetically related to their parents.
 - It would be unfair and discriminatory not to allow the use of donated eggs with donated sperm, and further, it should be acknowledged that a donor may be known to the parents or prepared to act in a parenting role (eg, in the case of same-sex couples or where a family member donates gametes).
 - This should be an established procedure because not allowing it is inconsistent with the Human Rights Act 1993 (eg, because a single infertile woman could not access an egg donor), and in the situation of lesbian and gay couples intending to co-parent, the male co-parent is wrongly identified as a donor by providers, and this is inconsistent with the Human Rights Act.
 - Not to allow this would be discrimination against people with “severe infertility”.
 - The primary consideration should be whether a child has a right to be genetically related to at least one parent.
 - It would be discriminatory not to allow this, but complications occur when there is more than one donor party.
 - There will be a need to look more closely at applications if there is only one parent involved.
 - There are issues around which of the parties should be given counselling.
 - If donors are anonymous there may be a possibility that they will be related.
 - This is different from embryo donation, which provides a family for a living individual.
 - It would be inappropriate for the donors and recipients to be “total strangers”.
 - There is no reference to the information-keeping regime in Part 3 of the HART Act to ensure that people born from donated embryos or cells can find out about their genetic origins.
 - This situation, and that of donated embryos, should be available to fertile couples or people and not restricted to the treatment for infertility.

Providers of fertility services submitted that the use of donated eggs with donated sperm should be made available on the basis of demand from potential clients. It was noted that the situation of older women seeking donor sperm is becoming more common, and these women may have fertility issues due to their age or issues that have not been discovered earlier.

Providers suggested that guidelines should be developed, with the guidelines on donation of gametes as a starting point.

Submissions opposing the use of donated eggs with donated sperm

Several submitters rejected the proposition that to not allow this option was discriminatory, stating that no person has the right to another person's germinal material, and that in any case donated embryos are available.

One submitter suggested that discrimination is a lesser concern to deliberately creating a child without any genetic connection to his or her natural parents. Another considered that not allowing this option is only discriminatory if you base your argument on the premise that children are a right to which adults are entitled.

Other submissions in opposition stated the following.

- There are significant ethical and psycho-social issues as well as family issues for a child born from two donors who may never have been in any relationship together.
- Lessons learned from adoption should guide decision-making, with the interests of the potential child having the highest priority.
- Interference of this kind is treating children as objects. Human beings do not necessarily have the right to have children just because they want them.
- Embryos are human beings and should be conceived in a "truly human way".
- An embryo should be the result of sexual intercourse between a man and a woman, and putting sperm cells and ovum into test tubes will lead to "unsuitable parents (ie, lesbians and homosexuals)".

One submitter suggested that allowing the use of donated eggs and donated sperm would be contrary to principle (a) of the HART Act (in section 4), and would further complicate the relationships of marriage and parenting. This submitter preferred encouraging access to embryos already in storage.

Another submitter suggested that this would undermine principles (a) and (g) of the HART Act (in section 4) by ignoring the:

- deeper cultural and spiritual reality of our human nature
- concept of whakapapa –" the genesis ... the core, the nature, the history and origins of a people"
- Catholic teaching on the transmission of human life centring on a commitment to hold together the genetic, gestational, and social dimensions of family and parenting.

This submitter cited the importance of genetic origins and affective relations in establishing enduring human relationships and securing a healthy self-identity, and considered that one parent should be genetically related to the child.

Another submitter suggested that it should be taken into consideration that infertility could be accepted rather than all possible procedures having to be tried, and the difficulty of acceptance may be accentuated by social pressures that encourage people to feel inadequate if they do not become parents.

One submitter stated that the use of donated eggs and donated sperm would remove procreation out of the loving bounds of a committed relationship, and that if both donors “abandon[ed]” their gametes, which are then frozen and united in a laboratory to create a child, this may have psycho-social impacts on the child, affecting the relationship between birth parents and the child, and create problems if the birth parents separate and the child has not been adopted.

Suggestions for guidelines included:

- a framework for multiple donors that requires one biological investment from any one of the egg, sperm or uterus
- a requirement for a close relationship between donor(s) and recipients (taking into consideration that people may enter a relationship to get around the requirements)
- the criteria for receiving donated eggs should be medically based
- a requirement for donors to be advised how their gametes were being used
- protecting the child’s access to information.

It was noted that the oldest donor egg recipient in New Zealand is 56 (the oldest mother in New Zealand), and that in Australia, the use of donated eggs with donated sperm is permitted and donors are not required to meet.

Responses to 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)?

Responses from submitters who did not state whether they agreed or disagreed with this question were divided among those strongly opposed to embryo splitting, those who supported embryo splitting, and those who needed further information.

Submissions agreeing that embryo splitting requires no specific recommendation to the Minister

Providers of fertility services agreed with the approach ACART proposed, in one case noting that embryo splitting may decrease the viability of an embryo, so is unlikely to be contemplated in the near future.

One submitter considered that it is reasonable to defer advice until it is necessary, and another considered that it is premature to be consulting on this issue. Several other submitters considered that decision-making should be deferred until providers sought to use the procedure, with one noting that this would ensure that the procedure would be available later if it becomes an important alternative.

Submissions disagreeing that embryo splitting requires no specific recommendation to the Minister

Several submitters were uncomfortable with embryo-splitting being left “in limbo”, commenting that it would be better to be prepared by developing guidelines or at least a preliminary policy.

Several submitters stated that, even if embryo splitting is unable to proceed, it should be specifically prohibited. One found it difficult to understand how it would not be able to proceed unless it were prohibited, and another considered that it should be prohibited or it could take place covertly. Others submitted that it should be prohibited because splitting might harm the embryos and increase the risk of congenital malformation. Two submitters considered that it was already prohibited by the HART Act as it is a form of cloning.

Other comments from submitters opposed to embryo splitting included the following.

- The split embryo has the potential to be donated to a different family, so could create a situation of identical twins being unnaturally separated from each other.
- An embryo could be frozen and implanted later, creating an unnatural separation in time of identical twins or triplets.
- No procedure is justified if it exposes the subject’s life or physical and psychological integrity to disproportionate risks.

Responses to 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?

The majority of submitters indicated agreement that the import and export of donated in vitro embryos and gametes should be allowed (question 11), although most did so with specified qualifications. Some submitters supported the import but not the export of donated in vitro embryos and gametes.

Submissions supporting the import and export of donated in vitro embryos and gametes

Submissions giving unqualified support to the import and export of donated in vitro embryos and gametes stated that this should be allowed:

- so people could seek treatment overseas and import their embryos into New Zealand after treatment, for subsequent genetically related children
- because the proposed provisions seem to provide an acceptable balance between facilitating individuals' reproductive autonomy and ensuring necessary safeguards to avoid the risk of international gamete and embryo trafficking
- because to expect people to remain in one geographical place is unrealistic.

One submitter considered that the prohibition on commercial supply should be lifted because of the shortage of donors and children available for adoption.

A submitter noted that annotating birth certificates would ensure that donor offspring would be able to trace their genetic origins.

One submitter "broadly agreed" with allowing import and export, and considered it would be ethical to pay a nominal amount to donors to help cover costs.

Some submitters were more cautious about supporting the import and export of donated in vitro embryos and gametes and said it should occur:

- only by the couple who have "ownership" of the embryos
- only if it precludes embryos affected by pathogenic diseases
- only if the supply is to genetically related persons (eg, siblings or cousins of biological donors) or so that children can be genetically related to each other (eg, genetically related siblings of existing children)
- only if they are not from countries that permit the sale of gametes and embryos, even for "family reunification" scenarios
- only if donors are not exploited physically or financially
- only if commercial supply is prohibited
- only for personal use (ie, not for donations)
- with ongoing discussions with different ethnic groups, including Māori
- so embryos could have a life in the context of a family and be protected in the event of a power outage or other "disaster"

- if the parties have had treatment overseas (bearing in mind that loopholes might be created such as finding donors on the internet)
- where there is an established existing relationship between the donors and recipients
- for the purposes of having a first child where previous attempts have failed and embryos remain in storage
- for people who want to reclaim their own previously donated gametes (eg, for medical reasons)
- if source countries for imported embryos conform to New Zealand's ethical principles and prohibitions and the principles of the HART Act
- for the purposes of having children of the same ethnicity in the case of minority ethnicities
- in limited circumstances where gametes and embryos meet the same quality and safety standards as those originating in New Zealand, including standards relating to consent, information provision, and the treatment of donors (import only).

Other submitters stated that the import or export needs to fit with “what happens here” (ie, New Zealand's regulatory environment), be consistent with the HART Act, and be from or to countries with a strong regulatory framework where donors are traceable and their “consent” able to be validated.

Providers of fertility services supported the import and export of donated in vitro embryos and gametes to allow a family to have a full sibling for an existing child, even if some principles of the HART Act could not be met (eg, if there was financial consideration or the donor could not be identified).

One provider commented, “The interests of having a full sibling override the HART Act and therefore import/export should be allowed, to accommodate this situation”.

Another provider considered that a child could be disadvantaged if one sibling knew their donor and the other did not, and that it is in the children's best interests to have balance in the family.

Submissions opposing the import and export of donated in vitro embryos and gametes

Submitters opposed to the import and export of donated in vitro embryos and gametes were concerned about the:

- risks associated with demand being driven by wealthier countries
- difficulty of establishing informed consent
- risk of exploitation of donors
- difficulty establishing whether a commercial transaction has occurred
- commodification of body parts
- immoral trade in human beings.

Several submitters considered that the import and export of donated in vitro embryos and gametes should not be necessary because in vivo transport is safer, and the ability to have a full sibling for an existing child could be achieved by travelling to the country where the embryos or gametes are stored. One submitter of this view considered that it was not appropriate to change New Zealand's regulatory situation to suit this limited situation.

Other submissions in opposition stated the following.

- If the local supply is inadequate to meet demand, this reflects social, cultural, and ethical views on the inappropriateness of the practice. Demand should not subvert supply as it reflects the social norms of the community, which must be respected.
- "Desperate" parents should adopt orphaned or disabled children in other countries. More effort should be put into creating good local homes or facilitating adoption rather than pursuing some peoples' need to give birth to children "similar to themselves".
- Overseas clinics could "enhance" the embryos and this would be impossible to police. As laws are only as good as their enforcing body, New Zealand should not alter its laws for the few circumstances that this would apply to.
- In vitro fertilisation is abhorrent because it dehumanises the circumstances in which a child is conceived.
- The import and export of embryos and gametes is not in accordance with the principle of protecting human life.
- Export should be prohibited because of the loss of control that occurs once embryos or gametes are overseas. This submitter considered that ECART should be given limited jurisdiction, with detailed guidance, over very restricted situations (export for reproductive purposes where people have embryos stored).

Responses to 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?

Submissions supporting guidelines

The main reasons cited for supporting guidelines (rather than regulations) for the import and export of donated in vitro embryos or gametes were that they allow flexibility and adaptability, would be more transparent, and would allow wider or public consultation.

Other submitters who supported guidelines considered that guidelines:

- are sufficient, especially if developed by way of an open process
- would keep everything under the one organisation (ie, ECART or ACART)
- give more flexibility if they do not cause delay via the ECART process
- are appropriate so long as imported embryos conform to New Zealand ethical principles and prohibitions and the HART Act.

Submissions supporting regulations

Submitters who preferred regulations (rather than guidelines) for the import and export of donated in vitro embryos or gametes considered that:

- regulation is strong, binding, and enforceable, whereas “guidelines” are just guidelines
- regulations will have greater force than guidelines
- regulation is safer than having only guidelines
- highly risky and socially unacceptable practices are at stake
- it is difficult to regulate overseas sources and destinations
- the seriousness of the inherent risks, including biosecurity risks, means regulations are appropriate
- regulation will prohibit commercial supply
- the “family reunification” example will not be the only source of applications, especially if donor gametes and embryos are scarce in New Zealand, so regulations will be necessary
- guidelines do not have the benefit of parliamentary process, making them arguably less rigorous, and a requirement for a parliamentary process would signal the significance of these issues
- regulations are better than guidelines as people will always find ways to ignore guidelines.

One submitter did not support the import and export of donated in vitro embryos or gametes but considered that it should be regulated with penalties for breach if it was allowed.

Several submitters who responded to the question but did not express a preference for guidelines or regulations were opposed in principle to assisted reproductive technology. One of these submitters stated that the import and export should be banned and it should be a requirement that life before birth at all stages should be accorded the respect of a human person and not supplied commercially or otherwise. Another stated that separate legislation should ban such activities.

Providers of fertility services considered that this should be an established procedure, as scenarios will generally be straightforward (eg, where a family is moving and wants to take their own (presumably donated) embryos). This situation could, therefore, be allowed and provided for in regulations.

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

Submissions opposing prescribing requirements for informed consent in regulations

Submitters who disagreed with prescribing requirements for informed consent in regulations considered that:

- informed consent is a well-established principle, and the existing law together with the professional standards of health professionals are adequate
- any additional requirements (to the existing legal framework) should be included in the Fertility Services Standard and guidelines
- informed consent is already covered by the Code of Health and Disability Consumers' Rights, ECART's ethical review of applications, and a body of law in other statutes and the common law.

Providers of fertility services considered the level of detail provided in the Code of Practice for Assisted Reproductive Technology Units sufficiently covered informed consent.

Submissions supporting prescribing requirements for informed consent in regulations

Submitters who supported regulations for informed consent stated that:

- there is potential for a wide and varied interpretation of informed consent, and regulations give a clear, unambiguous course of action
- the Code of Health and Disability Consumers' Rights is not specific enough for the peculiarities of assisted human reproduction
- the practice of ensuring informed consent is obtained in the maternity and reproductive health sectors is often seriously lacking, and given the ethical and psycho-social issues involved and the risks associated with the use of this technology, it is essential that informed consent requirements are strengthened
- consumers of assisted reproductive technology are often emotionally and physically vulnerable and desperate in their desire to become parents, so it is important to ensure they are not exploited
- the processes of assisted reproductive technology are frequently long and arduous with numerous procedures, so informed consent needs to be carefully provided for
- this is an area of significant commercial gain for pharmaceutical companies and providers, and potential exists for commercial, professional, and research gains, and the blurring of interests.

Submitters identified the following areas of concern around informed consent.

- Some couples do not consider what will happen to surplus embryos once they have completed their families or what will happen if they separate. This should be covered before any procedure is undertaken.
- The practice of ensuring informed choice and informed consent is not always well applied, and “informed consent currently means subtle manipulation and indoctrination by providers”.
- Statistics on assisted reproductive technology are confusing, and the chances of taking home a live baby are not high (possibly around 17 percent). People need to be fully informed of their chances.

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

Submissions supporting the adaptation of international provisions about informed consent

Suggestions for informed consent requirements included adopting or adapting the:

- Human Fertilisation and Embryology Authority (United Kingdom) requirements for consent from people donating embryos for research
- United Kingdom draft Tissues and Embryos Bill
- World Medical Association Declaration of Helsinki principle, “It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject”.

Submissions supporting requirements to protect rights

Submissions were made that the following rights should be protected in any informed consent requirements.

- The rights of the unborn child.
- The right to withdraw consent.
- The rights to be fully informed, to make an informed choice, and to give informed consent.
- The rights of children to access information about their genetic origins.
- Two submitters considered that unborn children have the right to informed consent, and this should be undertaken by an advocate or representative.

Submissions supporting more information being available

Submissions were made that the following information should be made available to consumers as part of informed consent requirements.

- A full explanation of treatments and their physical and emotional effects.
- The statistics about the likelihood of giving birth to a live baby.
- In vitro fertilisation will involve the death of a high percentage of the embryos formed.
- The short- and long-term risks for mother and baby.
- What is involved in treatments and the treatment pathway or experience, including psycho-social, emotional, financial, physical, and time dimensions.
- Where donations are involved, the full responsibilities and expectations of the donor and parent with respect to disclosure and the interests of the child.
- What happens if a partner dies before or during procedures.
- What happens to surplus embryos once the family has been completed.
- What happens to embryos if a couple separates.
- Genetic, medical, legal, and independent counselling in an informed consent package.

- All information about all forms of treatment.
- An embryo is a human life from conception.
- Information regarding the reduced chance of a live birth following an embryo biopsy should be included in consent forms.

Submissions supporting requirements for providers of fertility services

The following requirements for providers of fertility services were proposed.

- The standardisation of consent forms across providers.
- Declarations of any research and commercial interests by providers.
- Any conflicts of interest by providers to be disclosed.
- Specific written consent to be obtained for each procedure, any research involvement, the sharing of information, and the disposal of tissues including gametes, embryos, stem cells, embryonic cells, and any stem cells that become established stem cell lines.
- A requirement that counselling be independent of the provider so women have an opportunity to explore their feelings regarding the demands of the procedures.
- Providers should be required to review literature in order to provide accurate, up-to-date information on relevant issues that may affect consumers.
- A requirement for fertility staff to read consent forms to ensure consent has been given.
- A requirement that fertility staff be accountable in terms of the 10 rights in the Code of Health and Disability Services Consumers' Rights.
- A requirement to ensure material is not heterosexist.

Other suggestions for informed consent requirements

Other provisions to be included in informed consent requirements included the following.

- A legal definition of informed consent covering what constitutes informed consent and how it is obtained.
- An acknowledgement that a consent form is only an indication that the matters it covers have been discussed, and does not constitute consent of itself.
- Informed consent requirements to be split into two areas of concern: embryos and gametes.
- Consent that has a family dimension, on the basis that consent requirements will not be met simply by obtaining consent from individuals, because families are the foundation unit within society, so consent should be culturally appropriate, given at all stages, and through a "family lens".
- Time periods should be specified for involved persons to receive and consider information.
- Gamete donors should not be able to withdraw consent after an embryo has been created.
- Consent form signing to be witnessed by a third party who has evidence that the person consenting has received counselling and been provided with all relevant information.

- Requirements to be in plain language and ‘living’ documents (ie, ongoing and reviewable).
- Consent to be required from children born as a result of PGD as “saviour siblings” or potential donors for existing siblings.
- In the case of a donor who has withdrawn consent, providing that gametes should continue to be stored for, say, 10 years unless the donor gives written consent to their destruction, to allow for changes in the donor’s circumstances.

Responses to 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?

The majority of submitters considered that there should be a process allowing for exceptions to any rule requiring written consent for the use of gametes from deceased people for reproductive purposes.

While the responses indicate that a requirement for written consent was supported, there was confusion among submitters as to what this meant. Several indicated that their answer to the question was “yes”, but then went on to state that in certain circumstances (eg, where consent was clear but not written) a case should be considered by ECART or “the prohibition waived”. Other submissions from those who answered “yes” to the question included:

- use should be allowed after “lots and lots of grief counselling and a certain period of time after death, eg, five years”
- gametes should not be used except by the married partner of the deceased (two submitters)
- consent should be “legally arranged at the time of consent to the procedures”
- use should not proceed without specific consent.

A submitter, who did not understand if the written consent referred to was for the use of the gametes or specifically the use of the gametes after death, considered that applications should be reviewed by ECART.

Some submitters were opposed to the use of gametes from deceased people at all on the basis that there would be psycho-social issues for a child born after the death of their parent, and this could not occur naturally, so the natural boundary should be left intact. Those submitters all answered “yes” to the question.

One submitter disagreed with the proposed requirement for written consent on the basis that informed consent does not need to be in writing, and in certain circumstances consent may be given by proxy. This submitter also noted that a person who unexpectedly falls ill or suffers an accident may not have made provision for that eventuality, and in that situation the family would be likely to know the wishes of the deceased, and, as long as the deceased had not indicated an objection to gametes being collected and used, the immediate family should be able to give consent using “substituted judgement” (ie, the decision that best reflects the wishes of the deceased during their life).

Another submitter disagreed strongly with ACART’s proposed approach and submitted that a range of scenarios should be considered on a case-by-case basis, and that the “whole purpose” of ACART issuing guidelines is so ECART can consider exceptions to the requirement of written informed consent.

One submitter agreed with ACART’s proposal on the basis that any future use of gametes should be in accordance with the choice of the consumer.

Points from submitters who considered that written consent should not be mandatory, and suggestions from consultation meetings, included the following.

- The strength of written consent is questionable. This could have been revoked or the person could have changed their mind and it may not have been recorded.
- There should at least be an opportunity to prove there was consent, although not in writing.
- Requiring written consent is against the oral traditions of the Māori culture.
- Provider consent forms are not watertight. For example, in response to the question covering who may use their gametes, patients may write “My partner” (which could refer to a current or a future partner) rather than the full name of the person.
- The requirement for written consent should be compared with the consents required in health care generally. Most can be revoked or given verbally, so requiring written consent in this scenario would be contrary to requirements for other health procedures.
- There may be more than one written version of the patient’s wishes (eg, in a will and in provider consent forms), so there needs to be a process to consider which is valid if they conflict.

Providers noted that if a patient dies, gametes (sperm) are generally not used unless there is already a sibling.

During consultation it was noted that in the United States written consent is not required but a one-year stand-down is mandatory if consent is established. Comments from providers on a stand-down period included:

- this is appropriate as it would allow time for the mourning process
- this is not appropriate if a couple was already going through fertility treatment when the death occurred, so they should be able to proceed
- this is not appropriate if consent is proven, because if there is consent, there should be no need to delay treatment
- a year’s stand-down may have a negative impact on the ability of a surviving female partner to conceive.

Responses to question 16: Does the advice proposed in chapter 4 adequately address the needs, values and beliefs of Māori? Kei te tika ngā tohutohu e pā ana ki ngā tikanga Māori i te wahanga 4

The response rate to question 16 was very low.

One submitter stated that:

The issues are raised and considered but you cannot say they have been addressed. The basis of being Māori is to have whakapapa and this [assisted reproductive technology] potentially destroys unbroken descent of whakapapa and does not allow whanau, hapu, or iwi the mana to decide. The basis of New Zealand society is individual rights, which is in direct opposition to Māori values, needs, and beliefs. This is almost impossible to overcome. Whakapapa is not individually “owned” and so to give people individual rights to decide opposes a collective Māori view.

Another submitter stated that the principle of individual choice is sometimes used as an excuse not to take full account of Māori concerns and as a reason for ignoring culturally different processes for obtaining consent. They went on to suggest that ACART should examine whether the application of processes and guidelines surrounding assisted reproductive technology excludes a characteristically Māori approach to obtaining consent and/or undermine key cultural values.

One submitter considered that the chapter addressed concepts important to Māori. Another considered that it was important to be “appropriate” for all cultures.

One submitter stated that a desire to maintain whakapapa has resulted in Māori patients asking for donor gametes in “intergenerational matters”.

Responses to question 17: What are your views on the tikanga outlined in Appendix 2? He aha ōū whakaaro mo te tikanga i roto te Tāpiritanga 2?

The response rate to this question was very low.

One submitter stated that the tikanga should have been set out at the start of the consultation document and underpinned all the recommendations. Another commented that the issues were raised and outlined but not addressed.

One submitter suggested that it was inappropriate for the tikanga to apply only to Māori, stating that they should be taken into consideration when determining what is appropriate and permissible for all assisted reproductive technology procedures and practices, and that this would respect both the rights of tino rangatiratanga and the fact that these values are more widely held in New Zealand culture.

Another submitter stated that Māori opinion on the tikanga is diverse.

Responses to question 18: Are there any other tikanga that ACART should take into consideration? He tikanga ano hei whakaarohanga mā ACART?

The response rate to this question was very low.

Submitters stated that:

- the issues for prime consideration had been raised but the next step of what to do and how to ensure that they are enshrined has not yet been done
- Māori as a population are no more homogenous in their views than is any other ethnic population, so there is no shared view on these issues
- non-Māori should be able to adopt a Māori perspective on human assisted reproductive technologies.

One submitter offered the following:

Wairua is deeply and personally felt, but there are differing views. The most common and traditional view is that wairua is everywhere and begins at conception.

Whakapapa. A serious concern and risk is that [assisted reproductive technologies] have the potential to impact significantly and negatively on Māori.

Whanaungatanga: this is closely and inextricably linked to whakapapa which must be consulted in any assisted reproductive technology. We are not individuals, we are part of a whānau.

Mana: this is a critical issue for Māori collectively as Māori cannot be Māori and act individually. Your whakapapa and your mana is not yours solely.

Kaitiakitanga and tino rangatiratanga. This is a very serious concern because traditional decisions could be placed in the hands of those who are neither qualified nor experienced enough to decide. The issue of collective rights of whānau versus the individual have the potential to clash. This is a significant risk.

Another submitter proposed that ACART undertake a process to expand its understanding of the tikanga principles in Appendix 2 of the consultation paper, by way of a transparent consultation process with Māori with disabilities, suggesting that further work with Māori and Māori with disabilities would provide more context to the implications of tikanga on assisted reproductive technology and allow them to be expressed more fully.

This submitter suggested that adding “all things Māori” to the definition of mauri is a limiting parameter, as the concept embraces those who do not identify as tangata whenua, and a broader view may encourage a more inclusive way of thinking about these issues. The submitter agreed with the ACART definition of whanaungatanga being “the care and support amongst relatives”, and emphasised the importance of family and whānau in not only decisions involving donations of embryos but also in the development and maintenance of natural and reciprocal supports when a child is born, and stated that in their experience, if these supports are put in place for families and whānau, whanaungatanga can make the positive difference for families who have children with impairment. They suggested that ACART uses whanaungatanga in its broadest sense, so that families and whānau can make informed choices about assisted reproductive technology and about the decisions made after the birth of children born due to this procedure.

This submitter offered the following:

Weaving the Tukutuku.

Kotahi, te kohao o te ngira e kuhuma ai te miro ma, te miro pango, te miro whero. I muri, kia mau ki te arohaki te ture, ki te whakapono.

Through the eye of the same needle pass the white threads, the black threads, and the red threads. Afterwards, looking to the past as you progress, hold firmly to your love, to the law, and to your faith.

Potatau Te Wherowhero, the first Māori King, at the birth of the Kingitanga movement spoke of the imagery representing strength and beauty through unity and diversity. He alluded to the outcome as the beauty and the strength of the woven tukutuku. Individual threads are weak, and the process of weaving multiple threads makes a strong fabric. Individual colours tell no story, but woven together they become beautiful, and can tell a story of inclusion and diversity.

[Submitter] believes that the values of inclusion and diversity need to be considered and brought to the forefront when considering the implications of and planning for Assisted Reproductive Technology. The wisdom of current disability thinking and voices of people with lived experience of impairment can only add to the rich tapestry of whānau and the endeavours to have children.

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

Further comments about the Advisory Committee on Assisted Reproductive Technology

A small number of submitters had concerns about ACART and/or the consultation process, including:

- the closed questions in the consultation document may have framed the issues too narrowly and not elicited the views and concerns of the public
- the public may not have had a reasonable opportunity to make submissions, as there were no public meetings or hui
- ACART should reconsider established and prohibited procedures because assisted reproductive technology is an area of rapid change
- ACART should undertake public engagement with regard to cultural, ethical, and spiritual issues
- the consultation period was not long enough and should have involved hui, public meetings, and fono.

One submitter was concerned at the lack of diversity of membership of ACART, with no one who identified as disabled, no mention of ACART's commitment to the New Zealand Disability Strategy, and no one to represent children or young people. (There was no Children's Commissioner representative on the committee at the time the consultation document was circulated.)

Other submissions included that:

- ACART needs to be conversant with the HART Act and identify and rectify glitches
- ACART must be careful not to let the goalposts move according to the persuasive powers of the advocates for acceptance of assisted reproductive technologies
- it should be considered whether appointees to ACART are pro-abortion
- the concept of having established procedures or procedures subject to ECART, and nothing in between, feels like bad law.

Further comments about the Ethics Committee on Assisted Reproductive Technology

Many submitters focused their comments on ECART. These included the following.

- Concern that if the guidelines are too liberal, the membership of ECART may dictate the results.
- Concern about the appointment of ECART members and how they are chosen.
- Applications should not be subjected to the ECART process and have a final decision made by faceless people who have not even met the applicants.
- Applicants should be able to appear before ECART in person, even if just for 5–10 minutes to introduce themselves.

- The guidelines should be transparent, so applicants understand the process and know their rights (eg, the ability to see their own application and to write to ECART in support of their application).
- Applicants need to be educated about how they can, and be empowered to, participate in the process.
- Fertility issues and deciding to try certain procedures often involve enormously intense personal decisions. Medical practitioners are appropriate sources of advice. The laypeople on the committee come with prejudices and lack of insight, and may not be able to imagine what it is like to be in this position. Medical practitioners are the most qualified and should dominate ECART. What qualifies other members to make life-changing decisions for people?
- Lay people are not qualified to make psycho-social decisions. ECART should just be checking that the process is followed, and not reviewing the entire application.
- ECART could have a recommendatory role, rather than giving approvals and making final decisions.
- The timeline is difficult (eg, if you just miss out on an ECART meeting you have to wait for the next one).

Further comments about providers of fertility services

Comments about providers of fertility services included the following.

- Providers need to communicate better with applicants about the ECART process. For example, counsellors should tell applicants and surrogates that they can write letters in support of their application and what these letters should include.
- Two fertility services providers have a hold on the market, meaning consumers have no choice and consumers cannot complain if they receive substandard service.
- With only two fertility services providers in New Zealand, price fixing may occur and providers may not introduce new techniques because of a lack of competition.
- Providers should not be able to have the final say on applications, because anecdotal evidence suggests that people are not getting the best advice from providers. There need to be checks and balances.
- It needs to be recognised that providers have prejudices.
- If there is an issue with a provider, where should a patient go? The Fertility Services Standard should require consumer feedback.
- Consumers have limited opportunities to make their views known, and fertility provider staff can be hostile to their views. Access to fertility treatment in New Zealand is difficult. Access to timely, high-quality treatment needs to be improved within sensible ethical boundaries that protect any resulting children.
- Fertility services providers should work together to improve access to donors.
- Fertility services providers should be required to make their success statistics available.
- Fertility services providers should not be able to impose their own time restrictions on treatment (eg, there is no need for a six-month delay before starting treatment with fresh eggs, and in the case of donor sperm it does not take six months for sexually transmitted infections to become detectable).

Further comments about egg donation

The following submissions were made about egg donation.

- Applications should be based on the age of the egg donor, not the recipient, if viability is key.
- There is inconsistency because egg donors must meet with recipients, but sperm donors can be anonymous.
- Providers having to vet donors complicates the process. Even though the patient is paying, they are not in control. Why should the provider be able to set the criteria?
- There was a case where a donor was in Wellington and recipient in Christchurch and the process “fell over” because the providers could not coordinate everything. This should not be allowed to happen.
- The current process allows people to advertise on their own account for donors, and this could be taken advantage of with people providing false information to secure a donor. It would be preferable to be able to pay and get an egg immediately, especially when time is short. There is no evidence in the United States that there is any damage to young people as a result of donating.
- The current rules for egg donation provide only a very narrow window – the donor’s family must be completed, but she must also be within the age range for fertility. Donors should not have to have completed their own family. The question needs to be asked as to whether the evidence supports the policy. The rules tend to be over-protective, whereas the evidence might suggest that more leeway is appropriate.
- ACART should recommend investigation of the pros, cons, and practicalities of payment for donors for time and inconvenience.

Further comments about sperm donation

One submitter commented in detail on sperm donation, stating that from personal experience providers should be prevented from using donors who do not already have children, unless the recipient is personally known and the donor will have visitation rights or a role with the child. This submitter had been left feeling bereft of known offspring with unrelenting feelings of grief, and considered that many donors would feel disappointed and hurt about the lack of information about and contact with donor offspring. He suggested that current practices discriminate against male donors, who are not given any information about, or the opportunity to meet, potential recipients unless the recipient so requests. The submitter considered that this was unfair as the emotional and psychological impact of donation for both genders is the same, and there is no biological difference between adoption and donation. He concluded that the priority to women afforded by the HART Act is not justified.

Further comments about surrogacy

Submissions relating to surrogacy included the following.

- Surrogates should be able to be impregnated with donated embryos.
- Consumers should be able to use international surrogates.
- Monetary compensation for pain, time, inconvenience, and expenses would not be bad.

Further comments about funding

The following comments were made about the funding of assisted reproductive procedures.

- Canterbury District Health Board has restrictions on funding that create inequity with other areas. A percentage of fertility funding (perhaps 40 percent) is allocated to other health areas.
- The stand-down period for funding and the time-frame between the start and the end of treatment can create difficulties.

Further comments about disability advocates

Disability advocates made the following points.

- CCS Disability Action uses the term 'mauri'. Mauri is used to give importance to the 'life force' that everyone has.
- As everyone has a life force, everyone has the same right to life, including people with disabilities.
- The views of people with disabilities need to be included in any work to do with PGD.
- Any information on assisted reproductive technology needs to be in plain language.
- The tikanga in Appendix 2 of the consultation paper needs further work to make it more useful for everyone.

One submitter provided a quote from Sir William Liley concluding that it would be unfeasible and economically impossible to eliminate illness through genetic testing.

Further comments about matters relating to other agencies

Matters relating to other government agencies included the following.

- The legislation and the consultation paper may be difficult to understand for a non-heterosexual layperson, and a focus group consultation with gay, lesbian, bisexual, transgender, and intersex people is recommended.
- The suitability of the adoption process for surrogacy arrangements, including Child, Youth and Family's "12-day rule".
- The rationale for parents adopting their own biological child was raised, and the status of the Law Commission's recommendation that specific mechanisms be enacted for transferring legal parenthood in surrogacy arrangements was questioned.

Further comments about education

A common thread running through many submissions was that of education for consumers of fertility services. The importance of education and information-giving was emphasised.

Further comments about research

Concerns raised in this area echoed those raised in answer to the consultation questions on PGD.

One submitter stated that there is an urgency to further understanding which currently-used HART practices may harm the human embryo. Areas of concern included pre-implantation genetic screening, where the process makes having a live birth less likely (25 percent compared with 35 percent), and PGD, where the particular cells taken could affect the embryo's development. Research was cited in support of this comment.

Further comments about surplus embryos

Several consumers advised that they had not fully understood the implications of having surplus embryos, and were now unable to decide what to do with these embryos.

Other submissions

Other submissions made the following points.

- ACART should encourage people to donate their surplus embryos.
- Fertility processes should be consistent with adoption processes.
- It is hypocritical to want "ethical" guidelines for dealing with human beings at the embryo stage when a human being up to birth has effectively no rights at all, and can be legally aborted up to 24 weeks.
- There is concern over New Zealand following the United Kingdom's approach to assisted reproductive procedures.
- The use the expression "to develop into an individual" is inappropriate, as the embryo is already an individual.

Appendix: List of submitters

Individuals

Brian Gerard Quin
Carolyn Hutton
David Fisk
Eric Blyth
Helen Davies
Hilary Stace
Hugh Moran
Jeanne Snelling
Joan Sullivan
John France
Karen Raaymakers
Lynette and Ian Mason
Maria Jones
Patricia A Hammond
Paul Clarke
Paul Elwell-Sutton
Phillipa Malpas
Robert Ludbrook
Susan Fraser
Dianne Yates MP

An additional four submitters requested that their personal details be kept confidential, and one submitter did not provide any personal details.

Organisations

Abortion Law Reform Association of New Zealand
Auckland Women's Health Council
Bioethics Council
Canterbury District Health Board
CCS Disability Action
Ethics Committee on Assisted Reproductive Technology
Families Commission
Federation of Women's Health Councils
Fertility Associates
Fertility NZ Canterbury
Fertility NZ Auckland
Health and Disability Commissioner
Health Law Committee, New Zealand Law Society
Humanist Society of New Zealand Inc
Ministry of Social Development
Right to Life NZ
The Fertility Centre
The Interchurch Bioethics Council
The Nathaniel Centre – the NZ Catholic Bioethics Centre
Voice for Life Wellington
Voice for Life
Women's Health Action Trust