Subject:	**COMMITTEE ADVICE ON PREIMPLANTATION GENETIC DIAGNOSIS**	
Date:	MAY 2008	**File Ref:** AD20-86-10
Attention:	HON STEVE CHADWICK, ASSOCIATE MINISTER OF HEALTH	
Copy to:	HON DAVID CUNLIFFE, MINISTER OF HEALTH	

Advice

Purpose

1. To provide you with information, advice and recommendations regarding preimplantation genetic diagnosis (PGD), pursuant to section 38(e) of the Human Assisted Reproductive Technology (HART) Act 2004.

2. In preparation for giving this advice to you, ACART consulted publicly on PGD from July to September 2007. A summary of submissions is attached as Appendix A.

Executive Summary

3. ACART has reviewed current policy and guidelines on PGD with Human Leukocyte Antigen (HLA) tissue typing. At present, it may only be used to benefit a sibling, where that sibling suffers from a genetic disorder or disease which the embryo/resulting child is also at risk of having (such as Fanconi anaemia, which was the first application of HLA tissue typing in 2000 in the United States). ACART recommends extending this policy to include non-genetic diseases (such as leukaemia) and close family members other than siblings. Draft guidelines to implement this recommendation, should you agree to it, have been prepared for consultation (attached as appendix B).

4. ACART considers that PGD should not be used for the express purpose of selecting an embryo with a genetic disorder. As this is the current position, no action is needed to ensure that this option is not available in New Zealand.

5. Finally, it was apparent during the consultation that the scope of the "established procedure", that is, those uses of PGD that can be undertaken routinely, without case-by-case ethical approval is not well understood. ACART intends to publish an information sheet to clarify the scope of the established procedure.

Background

6. PGD is a procedure for genetically testing embryos for specific genetic conditions or chromosomal abnormalities prior to implanting the embryos into a woman's uterus. The main purpose is to select embryos that do not have a disorder or disease present in the family.

7. PGD can also be used with HLA tissue typing to select an embryo that will result in a child whose tissue is compatible for donation to an existing individual suffering from a

disease. In this situation, stem cells are harvested from the cord blood (or bone marrow) of the resulting child to treat the existing individual.

8. The HART Act separates uses of PGD into two categories:

   - Uses of PGD provided for in the "established procedure", which are set out in the HART Order in Council 2005. This category describes those uses of PGD that can routinely proceed under the management of a fertility services provider, and
   - Other uses of PGD which are not included in the established procedure and can only be performed with the approval of ECART. ECART considers and determines applications to perform assisted reproductive procedures on a case-by-case, based on guidelines developed and issued by ACART.

Established procedure for PGD

9. The consultation highlighted some uncertainty concerning the parameters of the established procedure, particularly whether it may be used to test for low-penetrance and late-onset conditions[1], to select against carrier status[2] embryos and to select an embryo with a genetic disorder where no unaffected embryos are available.

10. ACART considers that the established procedure governing the use of PGD allows for:

    - selection against carrier status embryos,
    - use of PGD for low-penetrance and late-onset disorders, provided criteria to determine risk and severity are met, and
    - selection of embryos with a genetic disorder where no unaffected embryos are available and where the options are severely limited, provided PGD was not undertaken with the express purpose of selecting an embryo with a genetic disorder.

11. ACART intends to publish an information sheet to clarify the parameters of the established procedure.

Other uses of PGD: PGD with HLA tissue typing

Current guidelines

12. At present, the only use of PGD permitted in New Zealand and not covered by the established procedure is PGD with HLA tissue typing. The current guidelines, which were issued by the National Ethics Committee on Assisted Human Reproduction (NECAHR) in March 2005, restrict its use to situations where an existing sibling has a genetic disorder and the future sibling is at risk of that same disorder. Conditions

[1] PGD may be used to select against disorders that confer a susceptibility to develop a disease later in life. Examples include some forms of breast cancer, ovarian cancer and colorectal cancer. These have low penetrance in that having gene mutations only sometimes produce the symptoms with which the gene is associated and, therefore, only increase the susceptibility to developing the disease. By comparison, other diseases are highly penetrant or very likely to occur (for example, mutations in the gene responsible for Huntington's Disease, which also develops later in life, is essentially 100 percent penetrant).

[2] PGD may be used to identify the genetic status of embryos as carriers of disease. Carriers of disease are usually unaffected by it, but may pass the disease on to their offspring. The risk that any carrier will have an affected child depends partly on the chance that his or her mate is also a carrier of the condition.

which fall into this category, for which PGD with HLA tissue typing has been used overseas include Fanconi anaemia and beta thalassaemia.

13. The rationale for restricting the use of PGD with HLA tissue typing to a genetic disorder seen in a sibling is that it was considered that the embryo, or resulting child, would also benefit from the procedure, in that he or she would be born free of the genetic disorder.

14. ACART doubts that a child conceived in this manner can be said to benefit or be harmed by PGD and HLA procedures. The alternative for a *specific* child is not to exist at all, as the child owes its existence to the production of a tissue match for an existing individual. This is true whether or not the resulting child is at risk of a genetic disease: any purported harms or benefits accrue equally in both cases. An implication of this argument is that PGD with HLA tissue typing should not be restricted to only those situations where the future child is at risk of a genetic disorder affecting an existing sibling.

Consultation on PGD with HLA tissue typing

15. ACART has consulted on whether this restriction should be removed so that PGD with HLA tissue typing may be used where an existing individual has a non-genetic disorder, for example, leukaemia.

16. The submissions were split between opposition to and support for an extension of PGD policy to allow its use for a non-genetic disorder. Some of those opposed to the extension were also opposed to existing uses of PGD as set out in the established procedure and current guidelines. Those opposed were concerned about:

    - commodification of the embryo and resulting child
    - adverse impact on family dynamics
    - adverse psychosocial impacts on the resulting child
    - inability of the embryo/resulting child to give informed consent
    - inability of the parent/s to give informed consent, given they would likely be under considerable pressure to do anything that might save the life of their sick child.

17. A number of those supportive of the extension considered that the objections noted above were speculative and that one could similarly speculate that motivations and outcomes would be positive.

18. Specific issues raised in submissions in relation to possible future guidelines included:

    - that the interests of the resulting child must be protected. This related to both the motivations of the parent/s and to the potential for the child to be an ongoing source of tissue and organ donation.
    - that the disorder must be severe enough to warrant the risks associated with PGD and subsequent donation. Some submitters called for ACART to define severity.
    - that a restriction of PGD to benefit an existing *sibling* is unnecessarily narrow and that it may be appropriately used to benefit a cousin.

Future guidelines

19. ACART has taken the submissions into account, along with consideration of the ethical literature, current New Zealand policy and international policy developments. ACART recommends that policy and guidelines for PGD with HLA tissue typing

should be extended to include its use to select an embryo that will be a tissue match for an existing individual with a non-genetic disorder.

20. ACART has prepared draft guidelines which are attached as appendix B. The draft guidelines assume your agreement to the policy extension recommended by ACART. Should you not agree to the extension, the guidelines will be revised to reflect your decision.

21. Pursuant to section 41(1) of the HART Act, ACART intends to consult on these draft guidelines. The consultation will particularly target those who commented on the earlier discussion paper and, in particular, ECART, fertility clinics and the Ministry of Health. This is to ensure that the proposed guidelines are workable.

22. Following public consultation, ACART will consult with you on the draft guidelines, pursuant to section 41(2) of the HART Act, prior to issuing them to ECART.

23. In drafting the guidelines, ACART has taken into account submitters' concerns that the interests of the resulting child be protected: draft guideline 2(a)(iv) (appendix B) states that "medical and counselling reports satisfy ECART that the health and well-being of the resulting child is safeguarded". With respect to concerns about the ongoing use of the resulting child as a donor, ACART considers that New Zealand has an established legal and ethical framework which guards against children being used unacceptably as tissue and organ donors.

24. ACART considers that the severity of the condition is an important factor and that the clinical team and the parent/s must agree that the condition is sufficiently severe. This concern is captured in guideline 2(a)(v) (appendix B) which states that "the condition for which HLA tissue typing is undertaken is judged by the clinical team and prospective parent/s to be of sufficient severity to justify undertaking the procedure".

25. ACART also considers that the procedure may be of benefit to family members other than siblings, and that it should be allowed to be used to benefit a close relative, who would most likely be a sibling. ACART considers that, once it is medically determined that PGD with HLA tissue typing is appropriate, the key issues in determining whether it should be undertaken in a specific situation are ethical and that ECART is, therefore, in the best position to consider whether any individual proposal is acceptable. Guideline 2(b)(i) (appendix x), which states that "ECART must take into account … whether the relationship between the parties safeguards the well-being of all parties and especially any resulting child" is intended to give ECART the flexibility to consider and determine specific applications for PGD with HLA tissue typing based on the relationships between those involved.

<u>Other uses of PGD: to select an embryo with a genetic disorder</u>

26. PGD could potentially be used for the express purpose of selecting an embryo with a genetic disorder. For example, the use of PGD to select deaf embryos is being debated in the United Kingdom, as legislation currently before the House of Commons would not allow a deaf woman or couple to use PGD to ensure they have a deaf child. At present, this use of PGD could not proceed in New Zealand as it is not part of the established procedure or the current guidelines. It could only proceed if ACART developed guidelines to allow the use of PGD for the express purpose of selecting an embryo with a genetic disorder.

27. It may seem that, to be consistent with the established procedure that allows selection of an affected embryo in limited circumstances, the use of PGD should be allowed for the express purpose of selecting an embryo with a genetic disorder. ACART has considered this and determined that this is not the case as there is a morally relevant difference in purpose between a) using PGD to select a child without a genetic

disorder, but producing only affected embryos, one of which is implanted and b) the use of PGD to select a child with a genetic disorder.

28. Therefore, in its consultation document, ACART proposed that PGD must not be used for the purpose of selecting an embryo with a genetic disorder. Most submitters commenting on this point were supportive.

29. ACART considers that, as the use of PGD for the express purpose of selecting an embryo with a genetic disorder cannot proceed in the absence of guidelines, no action is required to prevent it.

Communications

30. ACART intends to publish the summary of submissions (Appendix A). In addition, it seeks your approval to publish this report to you.

31. Should you agree to recommendation d) below, there may be public interest in a policy extension to allow PGD with HLA tissue typing for non-genetic diseases. Those who are generally opposed to any manipulation of embryos are opposed to any extension of the policy, as are those who consider PGD specifically to be unsafe[3] or unethical.

32. To date there has been little public interest in these issues in New Zealand. Two of the issues in this report are, however, currently causing significant controversy in the United Kingdom. The Human Fertilisation and Embryology Bill, which is currently before the House of Commons would:

- prevent the selection of an embryo with a disorder in preference to an embryo without a disorder (a deaf couple are leading the campaign against this clause), and
- allow the use of PGD with HLA tissue typing to select an embryo who is a tissue match to an existing sick sibling (sometimes referred to as a "saviour sibling").

33. These are not new policies in the United Kingdom. However, it is the first time they will be in primary legislation rather than within the scope of the regulatory authority's decision-making powers, which has afforded an opportunity for significant public debate.

Recommendations

ACART recommends that you:

a)	**Note:** the established procedure for PGD allows for 1) selection against carrier status embryos, 2) use of PGD to test embryos for low-penetrance and late-onset disorders and 3) selection of embryos with a genetic disorder where no unaffected embryos are available and the options are severely limited, provided that PGD was not undertaken with the express purpose of selecting an embryo with a genetic disorder.	Yes / No
b)	**Note:** ACART intends to publish an information sheet clarifying the points in a) above.	Yes / No
c)	**Note:** current policy and guidelines for PGD with HLA tissue typing restrict its use to situations where the existing individual is a sibling and suffers from a genetic disease.	Yes / No

[3] There is no evidence to suggest that PGD causes harm to the resulting child. The latest European Society for Human Reproduction and Embryology PGD consortium report concludes that no pregnancy complication or malformation at birth is particularly occurring in the PGD population.

d)	**Agree:** to extend policy on PGD with HLA tissue typing to include its use to select an embryo that will be a tissue match for an existing close relative, generally a sibling, with a non-genetic disorder.	Yes / No
e)	**Note:** if you agree to d) above, individuals will be able to undertake PGD with HLA tissue typing, provided they have ECART approval, whether or not the resulting child would themselves be at risk of a genetic disorder.	Yes / No
f)	**Note:** ACART has drafted guidelines (appendix B) which would implement d) above.	Yes / No
g)	**Note:** that ACART intends to undertake limited consultation on the draft guidelines attached as appendix B.	Yes / No
h)	**Note:** that, following the consultation outlined in g) above, ACART will consult with you on the draft guidelines, before finalising and issuing them to ECART.	Yes / No
i)	**Note:** that ACART will publicly release the summary of submissions attached as appendix A.	Yes / No
j)	**Agree:** that ACART may publicly release this report to you.	Yes / No

Sylvia Rumball
Chairperson
Advisory Committee on Assisted Reproductive Technology

MINISTER'S SIGNATURE:

DATE:

Appendix A: Summary of Submissions on Preimplantation Genetic Diagnosis

Introduction

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

The document included draft guidelines on surrogacy arrangements involving providers of fertility services, donation of gametes between certain family members, embryo donation and preimplantation genetic diagnosis (PGD), as well as proposed parameters for advice on related issues, including use of donated eggs with donated sperm, embryo splitting, import and export of donated gametes and embryos and informed consent.

The discussion document was mailed to 272 individuals and groups that had previously registered an 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, and in the *Sunday Star-Times* on 26 August. A press release was sent out to 60 news outlets, including all radio and television stations.

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

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

Submissions closed on 7 September 2007. ACART received 48 submissions, including four oral submissions.

This document summarises the submissions received on PGD. A summary of submissions on surrogacy arrangements involving providers of fertility services and donation of eggs or sperm between certain family members was released in March 2008. Summaries of submissions on embryo donation and related issues will be made available at a later date.

Should certain uses of PGD remain subject to guidelines?

It was noted during consultation that guidelines were necessary only for PGD with HLA tissue typing because PGD on its own was covered by the established procedure.

Submissions indicated strong support for certain uses (that is, those not part of the established procedure) of PGD remaining an assisted reproductive procedure[4] (ARP) and, thus, subject to guidelines.

The majority of submitters wanted a more rigorous and prescriptive framework around PGD than that proposed by ACART in its consultation document.

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[4] An assisted reproductive procedure is defined by the Human Assisted Reproductive Technology (HART) Act 2004 as a procedure performed for the purpose of assisting human reproduction that involved 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 pursuant to section 6 of the HART Act.

Submitters expressed considerably more disquiet about PGD than about other reproductive procedures, for example, one submitter expressed concern that PGD has great potential for use in ways that are not acceptable to New Zealand society, for example, sex selection, and advocated for strong regulatory oversight.

Policy extension to allow testing of embryos for tissue typing for an existing child with a non-genetic condition

Those opposed to the extension of New Zealand policy to allow tissue typing for a non-genetic condition cited the following reasons:

- commodification of the embryo and resulting child
- adverse impact on family dynamics
- adverse psychosocial impacts on the resulting child
- inability of the embryo/child to give informed consent
- inability of parents to give informed consent given the stress associated with having a gravely ill child.

One submitter stated that there was "deep discomfort" in the community about "this type of reproductive relationship" and that it was "widely unacceptable". Another submitter considered that such an extension would push us further along the continuum that makes it easier to see children as commodities.

Two submitters opposed to the extension considered that ACART should, for now, monitor developments overseas for the psychosocial impacts on the resulting child, as well as for any emerging safety concerns about PGD.

Many of those who responded, but were neither supportive nor opposed, cited similar misgivings.

One submitter considered that concerns that the resulting child is an 'object' could be explored in counselling.

Two submitters pointed out that concerns about psychosocial impacts on the child and family were speculative and it could similarly be speculated that such outcomes would be positive.

Many of those supportive of an extension to the policy also cited concerns that the interests of the resulting child somehow be protected.

A few submitters suggested that the resulting child (or both children) should have an independent advocate. One submitter proposed that guidelines be developed covering the use of tissue from the resulting child until they reach maturity. Another considered that New Zealand needs a formal policy on repeat donation involving minors.

A number of submitters were concerned that use of cord blood only should be allowed, while other submitters stated that living donation is covered by health law, child law and informed consent, not by ACART.

Several submitters considered that, while this procedure was contentious, parents would love and care for the resulting child, and that this was not an easy option for parents to take. One submitter considered that it would not be 'instrumentalising'[5] in such a circumstance.

[5] Using someone as a means to an end, rather than an end in themselves.

Another submitter expressed concern about a possible future where parents with sick children, who had exhausted alternatives, felt pressured to undergo this procedure to cure the existing child.

These concerns were seen by some as issues to be explored in counselling and considered by the Ethics Committee on Assisted Reproductive Technology (ECART) in its determination of applications.

A few submitters – both supportive of and opposed to the procedure – said there was no difference between the use of PGD with HLA tissue typing for a genetic disorder compared with a non-genetic disorder, for example, the psychosocial concerns apply to both. ACART should, thus, be consistent in its policy advice.

Two submitters suggested that ACART should await the outcome of the Bioethics Council dialogue[6] before making a decision on this policy.

One submitter considered that, if the procedure is not permitted in New Zealand, parents will travel abroad for the treatment and it would be better to provide for domestic regulation and oversight of the procedure.

Proposed Guidelines

Those opposed to the guidelines were concerned that every embryo is an actual, and not just a potential, human being, and it was inappropriate to select embryos on this basis. A few submitters saw PGD as an instrument to facilitate abortion, to which they were opposed.

Selection of an embryo with a genetic condition

Several submitters commented on the prohibition in the proposed guidelines on the selection of an embryo with a genetic disease. It was apparent that there was uncertainty as to whether the guideline "PGD is not used for the purpose of selecting an embryo with a genetic disease" also meant that such an embryo may not be selected for implantation when there is no alternative for the patient/s.

Some submitters considered that parents should have the autonomy to make such a choice, while two submitters opposed the prohibition; one stating that if a couple was willing to raise a child with disabilities then this must be allowed, the other stating that it may be a couple's only chance to have a child, in which case it was a decision for the parents to make.

Two submitters supported the prohibition, although it is unclear how they interpreted the guideline.

Severity of condition

Some submitters raised concerns around the definition of a genetic disease – does it include carrier status, or a predisposition to a disease? Who decides what is serious enough?

Several submitters considered the draft guidelines too vague, expressing particular concern at the word "benefit". Alternative suggestions included:

[6] The Bioethics Council is conducting a public dialogue on pre-birth testing which includes preimplantation genetic diagnosis.

- demonstrate other sources of tissue and treatment have been explored but HLA tissue typing is the optimal procedure
- require that the condition is serious and no other treatment is reasonably available, or there is a realistic chance that treatment will be successful
- apply only for life-threatening situations.

Some submitters considered that PGD should be used only to treat a condition in a particular embryo; another considered that adult stem cell developments were sufficient to treat disease.

One submitter considered that the proposed guidelines were seriously lacking because they failed to limit the situations in which PGD may be used. This submitter stated that the use of PGD should be limited to situations where there is a high risk of serious abnormality and that it be prohibited for non-medical reasons. They considered that the guidelines should include requirements that:

- PGD be used only where there is a high risk of serious abnormality
- PGD may not be carried out for social reasons (including sex selection)
- PGD may not be carried out to alter the genetic constitution of an embryo.

Several other submitters expressed similar concerns, particularly that PGD must not be used for non-medical or social purposes.

Attitude towards disability

A few submitters considered that the language used by ACART is biased towards the medical model of disability, with the use of words like “disease” or “disorder” rather than “condition”, implying value judgements against those with disabilities.

One submitter considered that ACART should require that advice is provided to those undertaking PGD from people experienced in understanding disability knowledge and values. This would better prepare potential parents to decide whether to implant a certain embryo or not.

Counselling

Another submitter stated that medical advice and genetic counselling should be independent of the clinic, considering that some counselling is perceived as being more about selling the technology than facilitating truly informed decisions.

One submitter suggested that counselling provisions should be included in the guidelines because they are more specific than the Code of Health and Disability Services Consumers Rights and place responsibility for ensuring the provision of adequate information and genetic and psychosocial counselling on the provider.

Informed consent

One submitter considered that the information provided to ensure informed consent should be included in the guidelines.

One submitter suggested that informed consent guidelines should ensure that parents understand that treatment may not always be successful.

Rights of the child

Some submitters considered that the resulting child should have a legal advocate to consider their humanity and needs and rights. One submitter stated that the advocate should be familiar with the social model of disability and have a commitment to inclusion and diversity as reflected in the New Zealand Disability Strategy.

Several submitters suggested that the guidelines should include the proviso that the potential child will not be unduly harmed or disadvantaged.

Tikanga Māori and the use of PGD

One submitter considered that the full potential of the Tikanga was not reflected by ACART and that the guidelines should explicitly acknowledge relevant Tikanga to fully reflect the reality for people who need to make decisions around PGD, and who espouse these Tikanga principles.

Requirement that the procedure be used only to benefit a genetic sibling

One submitter suggested that restricting the treatment to full siblings was Eurocentric and that Māori would wish to see it extended to include cousins; another submitter stated that it wouldn't make genetic sense to expand the policy beyond siblings.

International benchmarking

Several submitters suggested that the guidelines should be consistent with the criteria in the United Kingdom as set by the Human Fertilisation and Embryology Authority.

Other issues

Sex selection

Two submitters stated that they were opposed to selection on the grounds of sex to address a familial disorder, seeing this as likely to lead to a more liberal policy on sex selection. Another submitter recommended a review of the prohibition on sex selection, considering that the public would be comfortable with this for the purposes of family balancing.

Low penetrance and late onset conditions

There were questions over whether lower penetrance diseases can be tested for, and whether it would be acceptable to use PGD to select against an embryo with genes that increase the risk of early onset breast cancer without going to ECART. One submitter proposed that consideration of the established procedure is necessary and, in particular, public dialogue is essential with respect to what might be seen as a wider range of uses of PGD than originally anticipated or intended.

Safety of PGD

A number of submitters raised concerns that recent research had found that PGD adversely affects the embryo, and considered that ACART should be monitoring this research and not extending the use of PGD in the meantime. Several submitters suggested the need for long-term follow up of children born following PGD. A couple of submitters considered that, because of these concerns, PGD should be used only on an embryo that would itself benefit from the procedure.

Public engagement

One submitter considered that further public engagement is needed about PGD, which involves complex decisions involving cultural, ethical and spiritual dimensions. Two submitters suggested that the Bioethics Council's dialogue on pre-birth testing would provide important information to assist ACART's decision-making.

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 New Zealand Canterbury
Fertility New Zealand 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 New Zealand
The Fertility Centre
The Interchurch Bioethics Council
The Nathaniel Centre – the New Zealand Catholic Bioethics Centre
Voice for Life Wellington
Voice for Life
Women's Health Action Trust

Appendix B: Draft Guidelines on PGD with HLA Tissue Typing

Preamble:

The Human Assisted Reproductive Technology Order 2005 (the Order in Council) describes preimplantation genetic diagnosis (PGD) as a procedure for genetically testing embryos for specific genetic conditions or chromosomal abnormalities prior to embryo transfer, including any of the following undertaken for, or in connection with, that procedure:

(a) biopsy of embryos to remove one or more cells

(b) transportation of the cells to an approved laboratory

(c) analysis of the genetic or chromosomal constitution of cells obtained by biopsy

(d) selection of embryos for transfer on the basis of the results from analysis.

Many uses of PGD are provided for in the established procedure, set out in the Order in Council, and, therefore, able to proceed under the management of providers of fertility services. Providers of fertility services must practise in accordance with the Code of Practice for Assisted Reproductive Technology Units or, when it comes into effect, the Fertility Services Standard. The established procedure for PGD is set out in appendix one.

Any other proposal for the use of PGD is not an established procedure and must be submitted to ECART for approval.

Procedures that are not permitted under the Human Assisted Reproductive Technology Act include sex selection for social reasons and the implantation of a genetically modified embryo.

These guidelines expand New Zealand's policy on PGD with HLA tissue typing to allow its use to find a tissue match for a close relative, generally a sibling, with a non-genetic disease.

Guidelines:

When considering applications for approval, ECART will be subject to the following guidelines.

1. When considering an application for PGD with HLA tissue typing, ECART must be guided by the principles of the Human Assisted Reproductive Technology Act 2004:

   All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function:

   (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure:

   (b) the human health, safety, and dignity of present and future generations should be preserved and promoted:

   (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures:

   (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent:

   (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins:

   (f) the needs, values, and beliefs of Māori should be considered and treated with respect:

   (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

2. When considering an application for PGD with HLA tissue typing:

(a) ECART must determine that:

(i) Genetic counselling has been received by the parties.

(ii) Medical advice has been received by the parties.

(iii) Each party has received counselling in accordance with the Code of Practice for Assisted Reproductive Technology Units or, when it comes into effect, the current Fertility Services Standard.

(iv) Medical and counselling reports satisfy ECART that the health and well-being of the resulting child is safeguarded.

(v) The condition for which HLA tissue typing is undertaken is judged by the clinical team and prospective parents to be of sufficient severity to justify undertaking the procedure.

(b) ECART must take into account all relevant factors, including:

(i) Whether the relationship between the parties safeguards the well-being of all parties and especially any resulting child.

(ii) Whether counselling has:

- Included implications counselling for all parties, including the possibility that treatment will not be successful.
- Been culturally appropriate.
- Provided for whānau/extended family involvement.

Appendix: Established Procedure

The Order in Council provides that the use of PGD for purposes of the prevention and treatment of a genetic disorder of disease is an established procedure where it involves:

(a) diagnosis of familial single-gene disorders where
    (i) the disorder has been identified in the family and whānau, and
    (ii) there is a 25 percent or greater risk of an affected pregnancy, and
    (iii) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
(b) sex determination where
    (i) a familial sex-linked disorder has been identified in the family or whānau, and
    (ii) there is a 25 percent or greater risk of an affected pregnancy, and
    (iii) no specific test for the particular mutation that causes the disorder is available, and
    (iv) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
(c) diagnosis of familial chromosomal disorders where
    (i) the disorder has been identified in the family and whānau, and
    (ii) there is a 25 percent or greater risk of an affected pregnancy, and
    (iii) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
(d) diagnosis of non-familial chromosomal disorders (aneuploidy testing) where
    (i) the woman is of advanced reproductive age; or
    (ii) the woman has had recurrent implantation failure or recurrent miscarriage.