Minutes of the Sixtieth Meeting of the Advisory Committee on Assisted Reproductive Technology

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Held on 8 April 2016 at the Wellington Airport Conference Centre, Wellington

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Present

Alison Douglass (Chair)

Mike Legge (Deputy Chair)

Karen Buckingham

Nikki Horne

Kathleen Logan

Sue McKenzie

Barry Smith

Non-members present

Adriana Gunder (ECART, from 9.30 am)

Betty-Ann Kelly (ACART Secretariat)

Martin Kennedy (ACART Secretariat)

Stella Li (ACART Secretariat)

Dev Oza (Manager, Business and Committee Services, Ministry of Health; 9.40 am to 1.30 pm)

1. Welcome

1.1 The Chair welcomed the Committee members and guests.

1.a Opening comments

1.2 Mike Legge gave the opening comments, speaking about genetic editing. He described CRISPR-Cas9, a new gene editing technique which has attracted international attention as a potential tool for editing DNA in embryos. The new technology is more precise than earlier techniques, and could eventually enable the treatment of genetic diseases at the early stages of embryo develoment. The long term effects of using the technology are not yet known.

Draft Briefing to the Associate Minister of Health

1.3 The committee discussed item 12 of the agenda, advice to Associate Minister Dunne on gene editing and the CRISPR-Cas9 technique.

1.4 The briefing notes recently approved research in the United Kingdom and discusses the implications for New Zealand of CRISPR-Cas9. The committee noted the broad application of gene editing technology, for example, from agricultural research to future clinical treatment purposes, and agreed to some amendments to the briefing.

Actions

- *Secretariat to amend the briefing and circulate to all ACART members.*
- *Secretariat to forward the finalised briefing to the Associate Minister.*
- *Secretariat to place the completed briefing on ACART's website.*

2. Apologies

2.1 An apology was received from Jonathan Darby.

3. Approval of the agenda

3.1 Members approved the agenda.

Action

- *Secretariat to place the April 2016 agenda on ACART's website.*

4. Declarations of Interests

4.1 There were no declarations of interests.

5. Minutes of ACART's meeting of 12 February 2016

5.1 The minutes were approved.

Action

- *Secretariat to place the February 2016 minutes on ACART's website.*

6. Actions arising from the previous minutes

6.1 Members noted the status of actions arising from the February 2016 meeting.

7. Work programme — current status

7.1 Members noted the status of the items on the programme.

8. Operations of the HART Act — reports on ECART decisions

8.1 Members noted the reports.

9. Informed consent — consider the draft advice to the Minister

9.1 Members and the Secretariat discussed the draft advice to the Minister about informed consent for human assisted reproduction, focusing on recommendations 5, 6, 7 and 9 (other recommendations were discussed previously at the February meeting). There was also discussion about recommendation 8 (the "cooling off period" and dispute resolution) and the introductory material.

9.2 Members agreed to add brief comments, to the introductory material, about the sub-project in 2014 into how clinics seek and obtain informed consent.

Draft recommendation 5 — donors should be able to continue to receive information on the use of their gametes and the outcomes of their donations

9.3 The discussion covered factors including how clinics seek and obtain consent for the different processes they carry out.

9.4 Members agreed that the recommendation should be that donors should be able to request and receive information on the outcome of their donation, with the onus on donors to request information. Members noted it would be too burdensome to require clinics to advise donors on any use of their gametes.

9.5 Members discussed the issue of providing information on the outcome of a donation. Members agreed the likely specific 'outcome' of interest to donors is whether there is a resulting live birth. However, clinics rely on consumers to share this information in order to fulfil their obligation to submit the donor and birth information to the HART Donor Register.

Draft recommendation 6 — gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation

9.6 Members agreed the recommendation should be that gamete donors should be able to withdraw or vary their consent to the use of their gametes up to the point of fertilisation (or the point of insemination as part of an assisted reproductive process).

9.7 Members requested some changes to the text and asked that it include more references to comments made by submitters.

Draft recommendation 7 — consent of partners or family/whanau should not be required where individuals donate gametes

9.8 Members discussed ACART's position on the importance of individual autonomy. The Committee confirmed it would like to proceed with its original proposed recommendation, that the consent of partners or family/whanau should not be required. Members noted that if the recommendation is accepted the Fertility Services Standard (the Standard) would need to be amended.

9.9 Members also discussed the importance of relationships, noting individuals seldom make decisions in isolation. The Committee was of the view that the recommendation should begin with an affirmative statement that donors should be encouraged to discuss with partners and, where appropriate, their family the proposed donation.

Draft recommendation 8 — a cooling off period for disputes over embryos

9.10 The Committee discussed its draft recommendation that a cooling off period be introduced to manage situations where disputes arise about the use (or otherwise) of an embryo. Members agreed to proceed with the recommendation.

9.11 Members also agreed it would recommend that a dispute resolution process could/should be established. Section 76(1)(a)(ii) of the HART Act expressly recognises that there is a need to provide a mechanism to address situations where the couple forming an embryo may separate or their relationship breaks down and one party withdraws consent and the other party wishes to use the embryo.

Draft recommendation 9 — requirements for informed consent should be set out in regulations where appropriate

9.12 Members concluded that the Standard could address some informed consent matters that are currently not included in the regulatory framework, if ACART's advice is accepted,

9.13 Members also considered ways of disseminating information about informed consent other than in the Standard. They noted that clinics provide the information about informed consent that parties will need to know. Members noted that recommendation 1 addresses access to information about assisted reproduction. Members agreed recommendation 1 should include a recommendation that there should be a Ministry-hosted website on assisted reproduction and that it should include a link to the donor registry information on the Department of Internal Affairs' website.

Action

- *Secretariat to amend the document as discussed for circulation to members.*

10. Review of the donation guidelines — Working Group report and recommendations

10.1 Members considered a report and recommendations by the Donation Guidelines Working Group, following a Working Group meeting on 16 March 2016. The Working Group sought the Committee's agreement on:

a. the future of the "biological link" policy, in guidelines, which requires that a resulting child must have at least one genetic parent or have been gestated by the intending mother
b. policy amendments to the Guidelines on Embryo Donation for Reproductive Purposes
c. correspondence to the Associate Minister of Health
d. preliminary discussions with ECART and fertility services providers.

10.2 Members noted that any changes to guidelines would require public consultation and consultation with the Minister of Health. ACART plans to undertake public consultation on proposed amended guidelines late in 2016. The current guidelines would continue to be in place until new guidelines are issued to ECART.

a) The biological link policy

10.3 ACART agreed that the lack of a "biological link" should not be a barrier to family formation. ACART considers that ECART should make decisions on a case-by-case basis when there is no biological link and whether the lack of such a link is justifiable.

Members noted:

- A lack of biological relatedness does not take away the importance of recognising the importance of a person knowing about their genetic history.
- Removing the "biological link" policy may encourage some people currently excluded from treatment by current guidelines to stay in New Zealand rather than seeking treatment overseas.
- The risks of additional complexity can be managed by ECART taking into account whether the lack of a biological link is justified.
- ACART would need to amend the *Guidelines on Surrogacy involving Assisted Reproductive Procedures*, since all cases without any biological link will be surrogacy arrangements.

b) Embryo donation guidelines policy

Eligibility to use a donated embryo

10.4 ACART agreed that the guidelines should provide for the use of a donated embryo without a medical justification. ECART must be satisfied that the proposed embryo donation must be the best or only opportunity for an intending parent or intending parents to have a child.

10.5 Members noted:

- While there was a risk that people might be coerced to donate or gestate an embryo in order to "save" an embryo from being discarded, coercion was a general risk in all assisted reproduction.
- The removal of medical criteria to use a donated embryo would provide for any cases where a lesbian couple or a single woman could not access donated sperm through a clinic but was offered a donated embryo.

Embryos able to be donated

10.6 ACART agreed that the guidelines should be extended to provide for the donation of surplus embryos created from donated eggs or sperm. In such cases ECART must obtain information about the way in which the parties involved planned to manage the complexity of the resulting relationships for the adults and children involved. ECART also must be satisfied about the adequacy of their plans.

10.7 ACART agreed that donated embryos must not be on-donated by the recipients.

10.8 Members noted there is interest in such donations. Some people currently prevented from donating want to help others by donating surplus embryos which would otherwise need to be discarded.

Consent by parties

10.9 ACART agreed that the parties who should give informed consent to embryo donation are:

- the person(s) for whose use the embryo was created (whether or not a donated gamete was used to create the embryo)
- the person(s) who will be the recipients
- any gamete donor whose eggs or sperm were used to create the embryo to be donated.

10.10 Members noted that while a couple donating an embryo created from donated eggs or sperm may see themselves as joint donors of the embryo, for the purposes of the HART Register, the donors will be recorded as the two people whose gametes were used to create the embryo that is then donated.

Form of consent

10.11 ACART agreed that all parties involved, including any gamete donor, should give written consent to embryo donation. Any gamete donor must give specific consent:

- at the time of gamete donation, to the potential future donation of an embryo created from their gametes; or
- when donation of embryos created from the donated gametes is contemplated.

10.12 In either case, implications counselling in regard to embryo donation should take place before the gamete donor gives consent.

10.13 Members noted that counselling at the time of gamete donation would not have encompassed implications arising from embryo donation, and therefore would not have enabled a gamete donor to give informed consent to the future donation of an embryo created from his/her gametes.

Joint counselling

10.14 ACART agreed that the parties to be part of joint counselling should be the person(s) for whom the embryos were created and the person(s) who are the potential recipients of the donated embryo.

10.15 Members noted that embryo donation establishes a link between two families that will probably each have full genetic siblings, and therefore joint counselling should take place between the parents in the two families.

Health and wellbeing of resulting children and adult parties

10.16 ACART agreed that the guidelines should include a preamble which notes:

- that embryo donation is ethically and socially complex, and involves risks for resulting children and adult parties
- that the guidelines require ECART to be satisfied that embryo donation is justified
- who is a donor for the purposes of the HART Act
- ACART's advice about cases that come under more than one set of guidelines.

10.17 Members noted that the preamble would give a context to the provisions in the guidelines, by setting out the risks to be managed.

"Residency" of the parties

10.18 ACART agreed to remove the reference to "residency" in the current guidelines.

10.19 Members noted that parties to embryo donation may live at a distance from each other in New Zealand, and families may be mobile. The focus in joint counselling should be

Number of families with full genetic siblings

10.20 ACART agreed that embryo donation should continue to be limited to producing full genetic siblings in no more than two families.

10.21 Members noted that the provision aims to reduce the risk of complexity of relationships resulting from the use of donated embryos.

Legal advice to parties

10.22 ACART agreed that the guidelines should no longer require that the parties have received independent legal advice.

10.23 Members noted that with embryo donation, in contrast to surrogacy, the intending mother is a legal parent, together with any partner, from the time a child is born (in accord with the Status of Children Act 1969).

Editorial amendment

10.24 ACART agree to remove the reference in the guidelines to Code of Practice for Assisted Reproductive Technology Units. Members noted that New Zealand fertility services providers are now covered by the New Zealand Fertility Services Standard.

c) Correspondence with the Associate Minister of Health

10.25 Principle (e) of the HART Act says that donor offspring should be made aware of their genetic origins and be able to access information about their origins. However, there is no legal requirement for parents to disclose such information to donor offspring.

10.26 Members noted that the 2005 Law Commission report *New Issues in Legal Parenthood* considered the disclosure issue. The Law Commission concluded that there should not be a duty in law for parents to disclose to children about their creation by gamete or embryo donation. Such a requirement would be an intrusive step to require one group of parents to disclose specific information to their children.

10.27 Instead, the Law Commission recommended that all birth certificates should be amended to include a statement indicating that the Births, Deaths and Marriages register contains other information that may be accessed by the person whose certificate it is. In addition, Births, Deaths and Marriages should consider allowing parents to choose to have an annotation stating that the child was born by "donor".

10.28 The Government said in its response that while the concerns prompting the recommendations are valid, further policy work and consultation was required before drawing conclusions on the concerns and any proposed solutions.

10.29 Members noted that ACART is not aware of any work on the matter.

10.30 ACART agreed to write to the Associate Minister of Health to express disappointment that the Government has not progressed consideration of the Law Commission recommendation.

Action

- The Secretariat to draft a letter to the Associate Minister of Health, for the Chair's signature.

d) Preliminary discussions with ECART and fertility services providers

10.31 Members noted that as part of the informed consent project, preliminary discussions with providers were useful to understand the processes used by providers and the challenges faced. For this current project, providers and ECART might have insights into any particular issues that can be managed by the donation guidelines, given their practical experience of using the guidelines.

10.32 ACART agreed that Working Group should draft a set of questions to be used in preliminary discussions with ECART and fertility services.

Actions

- The Working Group to meet in May 2016, to report back to ACART's June meeting with recommendations about:
  - any policy amendments to the family donation guidelines, taking into account the recent review of the eligibility criteria in those guidelines
  - any policy amendments to the donated eggs/donated sperm guidelines
  - policy amendments to the surrogacy guidelines, following ACART's agreement that the lack of a " biological link" should not be a barrier to forming a family, and
  - a draft set of questions to be used in preliminary discussions with ECART and fertility services about the donation guidelines.

11. ACART's monitoring role

11.1 Members agreed the committee needs a policy on its monitoring function and to make this policy available on ACART's website.

11.2 Members noted ACART's current monitoring practices include publishing documents on procedures and technologies (such as the guidelines, consultation documents, and advice to the Minister) and keeping up to date with literature and publications on assisted reproduction. Members did not consider and decide a policy statement.

12. Editing genes

12.1 See the opening comments (1.a).

13. ACART's annual report to the Minister

13.1 Members noted the draft annual report from ACART to the Minister of Health. They requested some changes to the text. Members noted that the profiles of some of the committee members need to be updated.

Action

- Secretariat to amend the report as requested.

14. Governance

a. Chair's report.

14.1 The committee noted the report.

15. Correspondence

15.1 Correspondence was presented with the Chair's report.

16. Secretariat report to ACART

16.1 The committee noted the report.

17. An ACART member to volunteer to be the "member in attendance" at the next ECART meeting

17.1 To be confirmed after the meeting.

Additional item 1 — Barry Smith — report from the Global Ethics Conference in Berlin

- The Global Summit 2016 was jointly organized by the German Ethics Council and the World Health Organization (WHO) in close collaboration with UNESCO. The organisation of the Summit was supported by a committee composed of representatives from national ethics councils and international experts.
- The matters addressed were those causing global ethical concern, such as gene editing, issues surrounding the use of 'big data', epidemics, and the link between ethics and the law. Discussions included examining the extent to which the public need to be aware of, and literate in, these matters.
- A common theme was that technology is developing more quickly than society can manage it, whether by regulations or other means. The importance of ethical policy and practice being suitable for the culture in which it is applied was also discussed at the conference.

Additional item 2 — Alison Douglass — new committee members

- The Chair advised members that new committee members have been appointed and will attend the June ACART meeting and the training day.

Additional item 3 — Sue McKenzie — report on attendance at ECART

- Sue attended the ECART meeting on 3 March. Members noted that some of the items on the agenda were discussed in closed sessions. This raised the

question of whether an ACART member should be allowed to observe those sessions, given that ACART's Terms of Reference require ACART to monitor ECART's decisions. Each committee has a member in attendance at each other's meetings, and ACART has never excluded an ECART member in attendance from discussion.

Action

- Secretariat to draft a letter to the Chair of ECART, for the Chair's signature, asking why discussion of some items on ECART's 3 March 2016 meeting was closed and to agree a reciprocal understanding of members attendance at meetings.

Additional item 4 — changes in the Committee and Ministry

- The Chair thanked and fare-welled Nikki Horne for her time on the Committee and her valuable contribution in bringing a consumer perspective to ACART's work.
- The Chair thanked Dev Oza for his support of the committee, noting his role as the manager of the ACART Secretariat was ending.

18. Conclusion of meeting

18.1 The work likely between meetings will be:

- finalising the advice to the Associate Minister on informed consent
- a meeting of the Working Group reviewing the donation guidelines
- beginning public consultation on the use of cryopreserved ovarian tissue
- a training day for new members of ACART and ECART on 9 June 2016.

18.2 The next ACART meeting is scheduled for 10 June 2016 and will be held at the Wellington Airport Conference centre.

18.3 The meeting closed at 2.30pm.