

ETHICS & LAW ADVISORY COMMITTEE

AT 21 BLOOMSBURY STREET

20 October 2009, 10.30am

Members present:

Richard Harries (Chair)
David Archard
Clare Lewis-Jones
Lisa Jardine
Jennie Hunt
Neva Haites (ex-officio)
Erica Haimes (external member)
Sam Abdalla

Executive present:

Danielle Hamm (Secretary)
Joanne Anton
Juliet Tizzard
Danny Edwards
David Gomez
Ellie Suthers
Alan Tipping
Darren Sawyer (work experience)
Ellen Adams (work experience)

Apologies:

Gemma Hobcraft
Mair Crouch

1. Apologies and declaration of interest

1.1. Apologies were received from Gemma Hobcraft and Mair Crouch.

1.2. Declarations of interests were declared by Jennie Hunt and Sam Abdalla, who both work in HFEA licensed centres.

2. Minutes of the previous meeting

2.1. The Executive noted that point 1.2 should be amended from 'conflict' of interest to 'declaration' of interest.

2.2. The minutes for 7 July 2009 were taken to be a true record of that meeting.

3. Matters arising

3.1. The Committee noted and agreed the Matters arising from the previous meeting.

4. Chairman's business

4.1. The Chair welcomed Erica Haimes, the new external member, to the Committee.

4.2. The Chair informed the Committee that Craig Westwood had recently taken over the post of Head of Embryology and Assisted Reproduction Policy at the Department of Health.

- 4.3. The Committee agreed the following Committee dates for 2010, which fall the day before Authority meetings:
- 23 March
 - 6 July
 - 12 October
 - 7 December

5. Secretary's business

5.1. The Secretary gave a brief update of a study on 'Trans-national Reproduction', following the second advisory group meeting. Members noted that the study aims to explore the motivations, understandings and experiences of UK based individuals who travel abroad for assisted reproductive treatment. The project is funded by the UK Economic and Social Research Council. Danielle Hamm represents the HFEA on the project advisory group. The Committee noted that Claire Lewis Jones was also a member of the advisory group.

ACTION: The Secretariat to continue to monitor the study and report the findings back to the Committee. DH/JA

5.2. Danny Edwards gave a short verbal update to the Committee on the policy review on the 'Licensing of lower penetrance/late onset conditions and tissue typing'

5.3. The Committee noted that the aim of the review is to evaluate licensing lower penetrance/late onset conditions and tissue typing decisions on a case-by-case basis. The review will be informed by the experience of the case-by-case process by licence committee members, by clinicians and by patient groups. The project will then assess whether licensing on a case-by-case basis for these conditions is proportionate when compared with PGD decision making in general.

5.4. The Committee noted that Danny Edwards would bring a paper to ELAC in December, followed by a paper to the Authority in January.

6. Paper: Ethics, Law and Social Science Briefing ELAC (07- 09) 1 – Joanne Anton

6.1. Joanne Anton introduced the briefing which followed the first Ethics, Law and Social Science Briefing presented to the Committee in January 2009. The Committee noted that the briefing included an update of the headline developments and projects in the fields of ethics, law and the social sciences from the previous nine months.

6.2. Members noted that this item was primarily for information, unless there were any specific areas Members would like to discuss.

6.3. The Chair welcomed the briefing and recommended that an updated version should be used to inform the Horizon Scanning meeting to be held in February 2010.

ACTION: The Secretary to update the Ethics, Law and Social Science Briefing to be integrated into the February 2010 Horizon Scanning meeting. JA

7. Paper: PGD with exclusion testing and non-disclosure ELAC (07-09) 2 – Joanne Anton

7.1. Joanne Anton presented a paper on the licensing of pre-implantation genetic diagnosis (PGD) with exclusion testing and non-disclosure.

7.2. The Committee discussed the licensing of PGD in January 2009. The paper provided the Committee with a brief description of exclusion testing and PGD with non-disclosure and explored the ethical and legal issues pertaining to the tests.

7.3. The Committee noted that the amended Act requires the Authority to only authorise the testing for a condition, rather than authorising the method of testing, i.e. for "Huntington's disease" rather than "Huntington's disease with exclusion testing." The Committee also noted that, if minded to do so, it may wish to discuss the possible alternative methods of regulation.

[Neiva Haites declared an interest in this paper as she works in a clinic which performs exclusion testing]

7.4. The Committee initially considered the specific ethical issues pertaining to exclusion testing. Members discussed the validity of a 'right not to know' principle and one member highlighted that this issue was deeply contentious from a philosophical perspective. However other members, suggested that patients were entitled 'not to know' and that this wish was respected within the field of genetics.

7.5. Another member felt that there was a distinction between a wish not to know and a right not to know and that there was a strong argument in support of respecting a patient's wish not to be informed. Most members recognised that there would be loss of healthy embryos for the patient (or partner) who did not inherit the condition but thought this was justifiable if there was a strong, fully informed wish of a patient not to be informed of their genetic status.

7.6. After this discussion, members concluded that the proposal set out in the paper to recommend to the Authority that exclusion testing is acceptable.

7.7. The Committee subsequently considered the ethical issues pertaining specifically to PGD with non-disclosure. Members heard that in rare

patient cases the tissue samples required to perform exclusion testing would not exist. Members expressed concern that if the HFEA were to prohibit PGD with non-disclosure, the options available to those patients would be reduced.

7.8. Members discussed the findings of the ESHRE taskforce which considered that PGD with non-disclosure imposed unethical behaviour on the practitioners and negatively affected their autonomy. Members discussed whether deceiving a patient to avoid disclosure equated to an unethical practice. Some members suggested that non-disclosure should not be defined as 'deception' as the clinicians would be acting upon the wishes of the patient. One member argued that secrecy in some cases is not unethical. In addition, it was held that if the HFEA were to prohibit this test, patients may seek treatment abroad.

7.9. Members also considered the implications of non-disclosure on clinical staff. Members agreed that this non-disclosure may be burdensome to professionals; however some Members drew similar parallels within other fields of medicine and thought that this issue had been overstated.

7.10. The Legal advisor highlighted that non-disclosure may be problematic in cases when unnecessary medical treatment is carried out, and especially problematic if payment were involved. Clinicians themselves may find this practice unethical and Members agreed that clinicians should be able to refuse to carry out dummy treatment.

7.11. The Committee agreed that there were additional considerations pertaining to non-disclosure, especially with regards to how a clinic would fire-wall the information from the patients and the importance of patients being aware of the risk of inadvertent disclosure.

7.12. The Committee agreed to recommend to the Authority that the HFEA issue strong guidance about the ethical considerations, leaving it to individual clinics to determine whether non-disclosure should be provided in particular cases. The Committee also recommended that the guidance contain stringent criteria and that PGD with non-disclosure should only be performed in exceptional circumstances.

DECISION: For recommendation to Authority:

1. That Exclusion testing is acceptable.

2. To issue strong guidance on PGD with non-disclosure, including:

- **that exclusion testing is preferable to PGD with non-disclosure**
- **that PGD with non-disclosure is acceptable only in exceptional circumstances**

- a list of stringent criteria which a clinic must meet if they choose to offer PGD with non-disclosure. This should include information regarding consent which illustrates that the patient understands all of the possible implications, and understands the risks of inadvertent disclosure

ACTION: For JA to draft and circulate draft guidance and to take a paper to the January Authority.

8. Paper: Intra-family gamete and embryo donation ELAC (07-09) 3 – Danielle Hamm

- 8.1. Danielle Hamm presented a paper on intrafamily gamete and embryo donation.
- 8.2. The Committee noted that the paper added to the information on intergenerational donation considered by the Committee in July 2009. The paper provided Members with additional material on the wider social and legal context surround prohibited relationships and a comparison with consent protocols in live organ donation. The Secretariat thanked Professor Martin Richards, a former ELAC member, for his contribution to the background of the paper. It was noted that a paper on intra-family gamete and embryo donation would be discussed by the Authority in December 2009.
- 8.3. Members discussed the issues raised by the mixing of gametes of close genetic relatives with reference to an Australian example set out in the paper. Members discussed the welfare of the child implications, with relevance to both the medical risks and the effect this may have on a child's identity.
- 8.4. Members agreed to recommend to Authority that the mixing of gametes of close genetic relatives should be prohibited through a licence condition. One member emphasised that guidance to clinics encouraging careful consideration before accepting gamete donation from relatives (as given in Australia) should be the minimum guidance provided.
- 8.5. Members discussed the role of Ethics Committees with reference to the New Zealand case study whereby gamete donation between family members were required to be referred for ethical review. Members agreed that it is the clinics that should make these decisions and when necessary they may wish to refer to their own ethics committee.
- 8.6. Members further discussed the issues raised by intra-family donation with particular relevance to sister to sister egg donation. Members discussed that although this would not involve mixing gametes of close genetic relatives (as the gametes would be from one sister and the brother in law) there may be sexual connotations and that familial

relations may be confused i.e. the child's social mother would be her biological aunt.

- 8.7. Members discussed the new storage regulations which allows for a parent to store gametes for the future use of their child i.e. mother to daughter donation. Members discussed that this could be disturbing for the child's identity; however it is not very uncommon for a mother to bring up her daughter's child. One member emphasised to the Committee that there already exists a wide range of family structures within British society.
- 8.8. Members discussed whether issues surrounding intra-family donation were of sufficient public concern to warrant open consultation. There were different feelings amongst the Committee as to whether a public consultation would be beneficial. Members discussed the advantages of public consultation for gathering a wide range of views, including views from different religious communities.
- 8.9. Members however were also concerned that a consultation may misrepresent the general public's view and that intra-family donation is already being carried out by clinicians. Members noted that further work on intra-family donation could be incorporated into the wider work on donation which will also be discussed by Authority in December.

DECISION: For recommendation to Authority:

- 1. That the mixing of gametes of close genetic relatives should be prohibited through a licence condition.**
- 2. To consider whether guidance relating to intra-family donation should be introduced**
- 3. To consider whether there are sufficient concerns to warrant open consultation**

ACTION: For DH to incorporate the above recommendations into the wider paper on intra-family gamete and embryo donation, to be taken to the Authority in December.

[Lisa Jardine exits the meeting]

[The Chair elected to discuss the item on ELAC Horizon Scanning prior to the evaluation of the HFEA donation policies as the later item would require a lengthier discussion].

9. Paper: ELAC Horizon Scanning Function and Open Meeting ELAC (07-09) 5 – Danielle Hamm

- 9.1. Danielle Hamm presented a paper on the ELAC horizon scanning function and Open Meeting.

- 9.2. The Committee noted and welcomed the proposal for a more developed ELAC horizon scanning function and agreed the proposed objectives. Members agreed to amend one of the objectives to read: *“To analyse legal and ethical issues where relevant to clinical practice”*
- 9.3. Members discussed the proposed format for the horizon scanning event and proposed that the Ethics, Law and Social Science Briefing should be incorporated into the event. It was agreed by most members that the meeting should be open invite and that key representatives from different stakeholders who hold a variety of views should be personally invited.
- 9.4. The Committee agreed that the meeting would be held in February 2010 to allow for the Executive to organise the meeting effectively and to ensure there is sufficient time to allow for invitees to attend.
- 9.5. David Archard and Erica Haines agreed to work with the Executive on the planning of the horizon scanning event. It was agreed that the new working group would agree a meeting date and list of invitees as soon as possible.

[It was later provisionally agreed amongst the working group to schedule the event for Wednesday 24th February 2010].

ACTION: For the executive and the two ELAC members to plan the horizon scanning event and bring an update to the Committee at the December meeting.

10. Paper: Evaluation of the HFEA donation policies ELAC (07-09) 4 – Danielle Hamm

- 10.1. Danielle Hamm presented a paper regarding the evaluation of HFEA donation policies. The HFEA is currently undergoing a review of its policies relating to sperm, egg and embryo donation, implemented following the SEED review in April 2006. The results of this evaluation will be presented to the Authority in December 2009.
- 10.2. One Member commented on the importance of gaining views from a number of different interest groups involved in donation. The Committee noted that the current paper summarises the emerging issues identified so far from interviews with clinicians and that the final paper, which will go to Authority in December, will incorporate information gathered from a wider set of different stakeholders and interest groups.
- 10.3. Members were asked to identify additional areas of ethical, legal and social concerns regarding the SEED policies. The following issues were identified:
- How donors are treated

- International comparisons
- Egg sharing outcomes
- Information on the number of IVF cycles from donations abroad; and
- Donor re-registration

10.4. Members noted the formation of a Nuffield Council on Bioethics Working Party which will begin work on relevant issues in donation in 2010.

Decision: For DH to consider the above issues and incorporate into the wider paper on the SEED Evaluation, to be taken to the Authority in December.

11. Any Other Business

None

12. Time and date of next meeting

12.1. The next meeting will be held on 15 December 2009, 10.30am.

Control sheet

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