

Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
26 March 2015

Minutes – item 6

Centre 0035 (Oxford Fertility Unit) – Special Directions to export sperm to IVI Alicante, Spain

Members of the Committee:	David Archard (Chair, lay) Sue Price (professional) Tony Rutherford (professional)
Legal Adviser:	Dawn Brathwaite – Mills and Reeve
Members of the Executive:	Sam Hartley – Head of Governance and Licensing Trent Fisher – Secretary

Declarations of interest: members of the committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the committee:

- executive update
- redacted consent form and medical practitioner statement
- additional information from centre (email)
- executive summary
- application form
- additional information form
- letter from proposed receiving centre
- article and abstract (studies of advanced paternal age and risk of autism)
- SAC minutes 26 February 2015
- SAC minutes 24 July 2014

The committee also had before it:

- HFEA protocol for the conduct of Licence Committee meetings and hearings

- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA directions 0000 – 0012
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers.

Discussion

1. The committee noted that the centre applied for Special Directions to export two straws of patient gametes to IVI Alicante. This was considered by the Statutory Approvals Committee on 15 January 2015.
2. The committee noted the decision was to adjourn until further information could be obtained in relation to the storage consent and explanation of the criteria the patient couple have for a donor.
3. The committee noted the responses contained in the additional information provided by the centre set out below:
 - a. a signed consent form from the centre stating the patient's sperm can be stored for a period in excess of ten years:
the committee noted receipt of the HFEA GS Form with consent signed for a specified period of 15 years
 - b. the accompanying written opinion, from within the initial ten year period, from a registered medical practitioner regarding the male partner's infertility:
the committee noted the receipt of the signed medical practitioner's statement
 - c. an explanation of the criteria the patient couple have for a donor
the committee noted the explanation received from the centre on the criteria the couple have for a donor
4. The committee noted that the HFE Act 1990 (as amended) permits the Authority to issue directions to allow the export of gametes or embryos to countries outside the United Kingdom. Furthermore, the committee noted that if a licenced centre meets all requirements set out by section 1 of schedule 2 of General Directions 0006, of which there are ten, export is permitted without the need for Special Directions.

5. The committee noted that this application for Special Directions is being made because the centre is unable to export the sperm samples under the auspices of General Directions because they are not able to meet the requirements of
 - a. section 1(d) of schedule 2 of General Directions 0006: no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;
 - b. section 1(e) of schedule 2 of General Directions 0006: The gametes or embryos are not exported if they cannot be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre.
6. In this case the Committee noted that the partner's sperm, once exported, will be used in the fertilisation of donor eggs that have been procured from an anonymous Spanish egg donor and that the egg donor could be compensated above the level as set out in General Directions 0001.
7. The committee noted creating an embryo from sperm and an anonymously donated egg in the UK would not be lawful. The committee regarded the UK requirements for identifying donors to be important. Special directions would not be granted routinely, or where the purpose or dominant effect appeared to be to circumvent those requirements.
8. The Authority's policy on donor compensation aims to balance the desire to treat donors fairly with the need to avoid a financial inducement to donate. Special directions would not be granted routinely, or where the purpose or dominant effect appeared to be to circumvent these requirements.
9. The committee noted that the couple have undergone seven fresh IVF cycles and one frozen embryo replacement cycle – all being unsuccessful. The committee noted that the number and quality of the patient's eggs and resulting embryos is declining.
10. The committee noted that male partner is azoospermic and underwent surgical sperm retrieval (SSR) in 2004 with the resulting sperm being used for their fertility treatments to date.
11. The committee noted that currently there is an 18-month waiting time at the Oxford Fertility Unit and that there is anecdotal evidence from other patients that this is comparable to other centres in England.
12. The committee noted that the couple now wish treatment in Spain for IVF using the male partner's sperm with donor eggs. Reasons given for not

remaining in the UK and receiving treatment were that waiting times in Spain are considerably shorter and success rates are said to be higher.

13. The committee note that the couple wish to use the sperm collected by the SSR in 2004, as any sperm collected now is likely to be of poorer quality than what is currently in storage and that the male partner would avoid undergoing an additional SSR
14. The committee noted that the patient couple wish to have a donor who is young, with a proven fertility and is a close physical match for the female patient. It is said that the clinic in Spain has over one hundred egg donors which allows it not only to meet the couple's criteria but also to match them with a second donor in the event that this is necessary.
15. The committee were reminded by their legal adviser that whilst it needed to have regard to its previous decision, each application must be decided on its own set of facts.

Decision

16. In considering whether Special Directions should be issued in this case the committee looked at the other options open to the patient couple, including staying in the UK and waiting, or travelling to Spain and the male partner undergoing the SSR procedure.
17. The committee determined that the fact that there is an 18-month waiting list does not, without more, justify the grant of special directions.
18. The committee also considered the explanation of the criteria the patient couple have for a donor. There is no suggestion that the couple are looking for a 'unique' sub-type. There are also other clinics in the UK who have more available donors. The Committee was not persuaded that this factor should be given significant weighting when considering whether a Special Direction should be granted.
19. The committee concluded that if they were to refuse the application for Special Directions then the couple would either have to wait, when the female partner was already approaching the end of her reproductive window, or the male partner would have to undergo a further SSR in Spain. A second procedure, carried the associated risks of any surgery, and there would now be a low guarantee of viable sperm some 10 years later. The Committee noted that the evidence provided regarding increased risk of autism linked to paternal age was not a relevant consideration.
20. By a majority decision, the committee decided to issue Special Directions in this case for the export of two straws of the patient's sperm to IVI Alicante, Spain on the grounds that a combination of the female partner approaching

the end of the reproductive window and the risks should the male have to undergo a further SSR, made this exceptional.

21. The committee concluded that the current case involves a highly exceptional set of circumstances. Accordingly, granting Special Directions for the application would not represent an undesirable precedent, which would undermine the imperative requirements identified. Alternatively, a refusal to grant would not be a proportionate means of upholding the legitimate aims having regard to the impact on the individual.

Signed:

Date: 7 April 2015

A handwritten signature in black ink, appearing to read 'DWA' followed by a stylized flourish.

David Archard (Chair)