Statutory Approvals Committee – minutes

Centre 0078 (IVF Hammersmith) – application for Special Directions to export gametes to New York Fertility Services, New York, USA

Friday, 5 August 2016
HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Rebekah Dundas (Chair) Anne Lampe Margaret Gilmore Anthony Rutherford	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
Legal Adviser	Sarah Ellson	Fieldfisher LLP
Observers	none	

Declarations of interest:

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

The committee had before it:

- 8th edition of the HFEA Code of Practice
- standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Executive summary
- Submissions on behalf of Mr and Mrs M dated 26 July 2016
- Witness statement of AM's aunt
- Decision from the Court of Appeal – R(on the application of IM and MM) v HFEA C1/2015/2189 – 30-06-2016
- Decision of the High Court – R(on the application of IM and MM) v HFEA CO/3077/2014 – 15-06-2015
- HFEA Statutory Approvals Committee minutes from 28 August 2014
- Dickson v United Kingdom [2007] ECHR 44362/04
- H and others v Austria (2011) 31 BHRC 443
- L v Human Fertilisation and Embryology Authority and another [2008] EWHC 2149 (Fam)
- Documents presented to the Statutory Approvals Committee on 28 August 2016 including:
  - Executive Summary
  - Application Form for Special Directions to Export
  - Letter from PR dated 09-10-2013
  - Emails from PR dated 18-11-2013
  - Letter from New York Fertility Services undated
  - Emails between NGA and Lister Fertility Clinic dated 16-04-2013
  - Minutes of SAC meetings on 28-11-2013 and 27-03-2014
  - Submissions of Jenni Richards QC on behalf of Mr and Mrs M dated 01-08-2014
  - Letter from NGA dated 15-10-2013
  - Letter from NGA dated 11-02-2014
  - Witness statement of IM dated 23-06-2014 and exhibits
  - Witness statement of MM undated
  - Emails from PR dated 04-08-2014
  - Supplemental Submissions of Jenni Richards QC dated 15-08-2014
  - Executive Comments on Supplementary Submissions dated 20-08-2014
  - General Direction 0006
  - Centre for Reproductive Medicine v U [2002] EWCA Civ 565
  - R v HFEA ex parte Blood [1997] 2 All ER 687
  - Evans v UK [2007] All ER (D) 109 (Apr)

1. Background

1.1. The Committee noted that this is an application for Special Directions (under section 24(4) of the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act')) to export three cryopreserved oocytes from a deceased patient ('AM') to New York Fertility Services, to enable IM and MM to use their daughter's ('AM's') gametes in treatment by A's mother ('IM').

1.2. AM was diagnosed with bowel cancer in November 2005 when she was 23 years old. AM stored three eggs at IVF Hammersmith in 2008. At the time, AM signed forms which can be found within exhibit IM2 attached to the statement of IM. These forms included:

- A form devised by IVF Hammersmith entitled "Consent to treatment involving egg retrieval and/or embryo replacement"
- HFEA form 'WS Form' (consent to the storage of eggs)
- A form devised by IVF Hammersmith entitled "Agreement to oocyte freezing"

1.3. In completing the WS form, AM consented to her eggs being stored for later use in the event of her death (see section 3 of WS form). Section 3 of the WS form states 'There is a separate form on which you can say how you want your eggs to be used. Your eggs can only be used if you have also completed the other form'. AM did not complete a form relating to the use of her gametes, such as a WD form.

1.4. AM died on 12 June 2011. At the time of storage and at the time of her death AM was single. IM and MM wish to use their daughter's eggs for the creation of an embryo(s) using donor sperm (see paragraphs 26 to 31 of the statement of IM) for use in IM's own treatment. Although it is stated that the chances of IM becoming pregnant are 'very small' and that 'any complications could be life threatening,' IM and MM say that they are determined to 'honour (AM's) wishes.'

1.5. IM and MM state that they wish to export the gametes to New York Fertility Services. A letter from the proposed receiving centre is attached within the bundle of documents. IM and MM state that the US clinic has provided details of two sperm bank websites with donor profiles from which they would select a donor who is as close to A's origins as possible.

2. Previous considerations of the application

2.1. In October 2013, IVF Hammersmith made an application to the Authority for a special direction permitting the export of A's eggs. The application was first considered by the Statutory Approvals Committee (SAC) on 28 November 2013 and was declined.

2.2. MM and IM asked for the matter to be reconsidered. A second application was made and further evidence was provided including a statement from IM. The second application was considered by the SAC on 27 March 2014 and again declined in a decision dated 2 April 2014.

2.3. The couple issued Judicial Review proceedings on 26 June 2014 challenging the decision of 2 April 2014. Following the issue of those proceedings, SAC reconsidered the application on 28 August 2014 but again declined to make the special direction recording its decision in the minutes dated 3 September 2014.

2.4. Permission to proceed with a judicial review claim was granted by the High Court on 26 November 2014. Following a hearing on 8 May 2015, Mr Justice Ouseley dismissed the claim for Judicial Review and refused permission to appeal in a decision dated 15 June 2015.

2.5. MM and IM made an application to the Court of Appeal for permission to appeal the High Court decision. Following a hearing on 4 February 2016, permission to appeal was granted on 24 February 2016. The appeal hearing took place on 25 May 2016 and in its judgment of 30 June 2016, the Court of Appeal upheld the appeal, quashed SAC's decision and remitted the application for a special direction back to the Authority for consideration.

3. Consideration of application

3.1. The committee noted that the HFEA 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 in relation to the export of gametes outside the EEA the conditions set out by schedule 4 of General Directions 0006, of which there are nine, are all satisfied, export is permitted without the need for a Special Direction.

3.2. The committee noted that this application for Special Directions is being made because the centre is unable to export the eggs under the auspices of General Directions 0006 because it is unable to meet the requirements of Schedule 4, Section 1 in particular:

- (d) the person who provided the gametes has given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated;
- (e) before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom, and they have been given any further information which they may require; and
- (h) the gametes or embryos are not exported if they could not lawfully be 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.

3.3. The committee noted that Special Directions should not be granted routinely, or where the purpose or dominant effect appears to be to circumvent these requirements.

3.4. The committee's legal adviser informed the committee that even though this is a matter which has come before the committee in the past, this would be a fresh decision on whether or not special directions should be issued. The legal adviser made clear that the committee is not bound by any of its previous decisions. It should on this occasion be careful to approach the decision making as the Court has indicated is required and to provide reasons for its decision.

3.5. In considering the present application, it was important to bear in mind how the Court of Appeal viewed the SAC decision of 3 September 2014. In summary, the Court found that there were three flaws in the decision (see paragraph 7 of the judgment):

- SAC had misstated material evidence about AM's consent (see detailed discussion at paragraphs 69 to 73 of the judgment);
- SAC failed to explain why AM needed to receive information on particular matters in order to give proper consent (see paragraphs 74 to 76); and
- SAC failed to decide what information the 1990 Act required AM to be given in the particular circumstances (see paragraphs 77 to 84).

3.6. The legal adviser directed the committee to the additional documents which were now before them including the decision to the Court of Appeal, the further submissions from the applicants' legal representatives which included a statement from A's aunt and the new Executive Summary.

3.7. The legal adviser suggested that the Committee adopt a structured approach and that, in addition to following its decision tree the Committee should, when considering whether to vary the General Directions GD0006 to give a Special Direction to allow export, ask itself

- Is there "effective consent" in relation to a number of areas?

  [Following Centre for Reproductive Medicine v U [2002] EWCQ 565 "effective consent" usually has to be signed and set out in writing and should be informed consent which implicitly requires the patient to be properly informed],

  those areas, in this case, being*:*

  - The export of the gametes
  - The mixing of the gametes with donated anonymous sperm
  - The use of a surrogate
  - The use of the gametes in the treatment of another (in this case A's mother)

- Given that the absence of "effective consent" is not determinative the next step would be to consider whether there is "sufficient evidence" of informed consent to the above? In particular:

  - What evidence is there of AM's wishes?

    (considering the totality of the evidence)

  - What did she (genuinely) need to be informed about to give informed consent? What relevant information was AM required to have?

    [The question from the Court of Appeal of what information had to be provided needs to be supported by reasons "consideration and articulation in the decision"]

  - Did she have the necessary/required information?

- If AM did not have the necessary/required information is it inherently probable that AM would have refused consent had she been given further information (in relation to any of the above topics) to inform her decision? The Court of Appeal agreed that the Committee should not make inferences which are not fairly capable of being made but said it could make appropriate inferences from the evidence or on the basis of the inherent probabilities of the case.

- If the Committee was minded to give a Special Direction can it do so in a way that serves and promotes the objects of the HFE Act?

- If the Committee was not minded to give a Special Direction - would refusal interfere with an individual's human rights? If yes it would interfere, can such interference be justified and said to fulfil a pressing social need, legitimate aim and be proportionate and non-discriminatory?

3.8. The committee noted that in the exhibit 2 of MM's statement, in the consent form signed by AM prior to undergoing egg collection and freezing in 2008, and in the accompanying WS form, AM had consented to the continued storage of her eggs in the event of her death. These are the only formal consent forms in this case, the details of which are set out at paragraph 10 of the Court of Appeal decision.

3.9. The committee emphatically emphasised the importance and central role of consent, and effective and informed consent, in the Human Fertilisation and Embryology Act (HFE Act) and the way in which Parliament has resolved or balanced the various sensitive and complex medical, social, ethical and legal issues arising over the collecting, storage and use of gametes and embryos.

3.10. The committee agreed that fully informed, effective consent to treatment and the provision of relevant information are cornerstones of the HFE Act. The committee therefore welcomed the Court of Appeals comments in this regard:

- *"Consent means "effective consent" and so the HFE Act provides that, before treatment, a person must be given "such relevant information as is proper", and offered counselling. Effective consent to treatment and the disclosure of relevant information are cornerstones of this carefully calibrated legislation."*

3.11. The committee also reminded itself of the summary in *U v Centre for Reproductive Medicine* [2002] EWCA, that

- "*The whole scheme of the 1990 Act lays great emphasis upon consent. The new scientific techniques which have developed since the birth of the first IVF baby in 1978 open up the possibility of creating human life in ways and circumstances quite different from anything experienced before then. These possibilities bring with them huge practical and ethical difficulties. These have to be balanced against the strength and depth of the feelings of people who desperately long for the children which only these techniques can give them, as well as the natural desire of clinicians and scientists to use their skills to fulfil those wishes. Parliament has devised a legislative scheme and a statutory authority for regulating assisted reproduction in a way which tries to strike a fair balance between the various interests and concerns. Centres, the HFEA and the courts have to respect that scheme, however great their sympathy for the plight of particular individuals caught up in it*."

3.12. The committee considered very carefully all of the other evidence which has been provided in this case, including the statement of MM with exhibits, emails from the PR at IVF Hammersmith about his initial discussion with AM in 2006 which included a very hypothetical discussion of her mother (or a second person) carrying a child as a surrogate for AM, if her treatment meant she would be unable to do this. The PR confirmed that AM was advised to have counselling although the Committee understood, from the aunt's statement, that in fact AM never took up the offer of counselling. The Committee recognised the importance of counselling particularly in donation cases, to emphasise the lifelong nature of the decision and the implications for any child born as a result of the donation.

3.13. The committee noted that there was no evidence provided that AM had ever provided written consent to the export of her gametes for use in treatment of IM.

3.14. However the committee went on to analyse the sufficiency of the informed consent, drawing on all of the available evidence as directed by the Court of Appeal.

3.15. The committee discussed whether or not AM's wishes were for her gametes to be used in treatment of IM in the event of her death and whether AM would have understood that IM would not in those circumstances be a surrogate, and would in fact be the legal mother of any resulting children. The committee noted that the Court of Appeal criticised the previous committee for failing to consider the possibility that AM consented to her mother's use of the eggs for the purpose of bearing a child.

3.16. The committee noted that there was evidence that AM had made statements about the role her mother might take in the event of AM's death. In IM's statement, IM recounts that AM had (in 2008) contemplated the use of her eggs after her death and in January 2010 had asked her to "carry my babies" (after her death). The committee also now had the benefit of the aunt's statement which records conversations, with AM again recorded as having contemplated IM carrying her babies after AM's death.

3.17. The committee found no evidence that AM would have known or had discussion in relation to the fact that she would not be considered the legal parent of any resulting child and therefore the committee was concerned about whether consent to use the eggs in this way was properly

informed. It had regard to the IVF Hammersmith consent form which AM had signed which indicated that, in the circumstances contemplated by the form, AM understood "I will become the legal mother of any resulting children".

3.18. However, the committee referred to the judgement of the Court of Appeal at paragraph 83 which suggested that the legal implication of a posthumous child might not be a matter of such significance as to outweigh the evidence that the only person other than AM who might be the legal mother could be IM, and that the proposal was that the child would be recognised in everyday life to be AM's baby with IM and MM bringing the child up as their grandchild.

3.19. The committee noted that in the absence of explicit consent, and notwithstanding its concerns about informed consent, the Court of Appeal had made clear an obligation on the committee to consider whether it was inherently probable that AM would have refused consent had she been given further information about legal parentage in the event of the eggs being used after her death.

3.20. The committee noted that the HFE Act 1990 (as amended) requires that a person be given (a) a suitable opportunity to receive proper counselling about the implications of taking the proposed steps and (b) such relevant information as is proper. It noted that the Court of Appeal made reference to this requirement at paragraph 78 of its judgement, and went on to indicate that the test of materiality in consent to medical treatment, is whether in the circumstances of the particular case, a reasonable person would be likely to attach significance to the risk. The Court of Appeal made clear that the HFEA legislation recognises that what information is "proper" may vary according to the particular circumstances of the case.

3.21. The committee discussed the requirements set out by the HFEA on what information a donor would need to be presented with in order to give consent for their gametes to be used in treatment of another. The committee noted that Standard Licensing Condition (SLC) T58 requires amongst other things, that prior to giving consent gamete providers must be provided with information about:

- the nature of the treatment
- its consequences and risks
- the right to withdraw or vary their consent.

3.22. The committee placed great importance on a donor being informed of the consequences of donation and understanding that they will be undertaking a lifelong commitment in providing their gametes for donation. The committee was clear that the requirements for consent for donation should be upheld with the upmost importance.

3.23. The committee carefully reviewed all of the evidence in relation to AM having given sufficient, informed consent in relation to the mixing of her gametes with donor sperm. Having regard to the totality of the evidence even though AM had not consented to mixing her eggs with donor sperm, the committee recognised (as highlighted in the Court of Appeal decision at paragraph 71) that there was from MM's statement and the aunt's statement that AM understood that donor sperm would have to be used to create a child or children from her frozen eggs.

3.24. In relation to the lack of consent to export, the fact that AM would never have been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom, and that fact that AM could not have been given any further information which she may have required , the Committee understood that Court of Appeal decision invited it to conclude that these requirements were not necessary in the particular circumstances of this case as this would be an issue for IM (as the legal parent) rather than AM.

4. Decision

4.1. The committee had regard to its decision tree. It noted that this was an application to export AM's eggs to a receiving centre in New York and that the centre is unable to export the eggs under General Directions 0006 because

- AM did not give consent in writing to her gametes being exported to the USA;
- AM was not given written notice about governing laws to use and parentage in the USA potentially not be the same as in the UK; and
- AM's gametes could not lawfully be used in licensed treatment services in the UK, in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre, given the absence of effective, informed consent signed and set out in writing.

4.2. The committee noted that this case contains an extremely exceptional set of circumstances and recognised in these unique circumstances it has been directed by the Court of Appeal judgement, on the totality of evidence, to decide in the absence of effective and informed consent to consider the inherent probability of certain facts; something that it is not usually appropriate or necessary to do. The committee was very clear that the granting of Special Directions in this case could not be regarded in any sense as routine nor as an attempt to circumvent the central requirements of consent.

4.3. The committee decided that, although there was no effective or informed consent from AM to the export of her embryos, and indeed the need for export had almost certainly never been contemplated, following the Court of Appeal indication it could conclude that it was inherently improbable that AM would have refused such consent had she been given proper information about the proposal to export.

4.4. In relation to the lack of information about export and notice about governing laws, the committee accepted the indication of the Court of Appeal, that in the very particular circumstances of this case, these requirements were not necessary.

4.5. The committee decided it was inherently improbable that AM would have refused consent for the use of the eggs after her death, had she been given further information on legal parentage either in the UK or overseas. Applying the test required by the Court of Appeal it was also inherently improbable that AM would have not consented to the eggs being donated for her mother's treatment using anonymous donor sperm, having regard to the reports of what she said to her mother, aunt, cousin and a friend and the issues raised with healthcare professionals.

4.6. The committee decided that, in relation to Standard Licensing Condition (SLC) T58, AM, as a gamete provider, would have been provided with information about (and the opportunity to receive counselling in relation to), the nature of the treatment she would undergo as a donor, its consequences and risks and her right to withdraw or vary her consent.

4.7. Having:

- reviewed the totality of the evidence in this case, including the new evidence from AM's aunt and the decision of the Court of Appeal,
- challenged itself to consider not just effective consent but the sufficiency of the evidence of informed consent and what AM genuinely needed to be informed about; and
- asked itself, as the Court of Appeal required, whether, if AM did not have the necessary/required information it was inherently probable that she would have refused consent had she been given further information to inform her decision

– and strongly emphasised the importance of the consent process as a cornerstone of the HFEA Act

the committee agreed, in the exceptional and unique circumstances of this case, to grant Special Directions for centre 0078 (IVF Hammersmith) to export three eggs to New York Fertility Services.

4.8. Having granted the Special Directions, the committee did not need to consider any issues in relation to potential interference with any individual's human rights.

5. Chair's signature

5.1. I confirm this is a true and accurate record of the meeting

Signature

Name

Rebekah Dundas

Date

19 August 2016