



Statutory Approvals Committee – minutes

Item 9

Centre 0061 (CARE Sheffield)

Special Directions application to export sperm to Italy for patient couple's own use

Thursday, 26 July 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Ruth Wilde	
Members of the Executive	Dee Knoyle Richard Chamberlain Paula Robinson Catherine Burwood	Committee Secretary Temporary Committee Clerk (Observer) Head of Planning and Governance (Observer) Senior Governance Manager (Observer)
External adviser		
Legal Adviser	Graham Miles	Blake Morgan LLP
Apologies	Anthony Rutherford Anne Lampe	

Declarations of interest

- Members of the panel 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.
- General Directions 001 (2015)
- General Directions 006 (2018)
- General Directions 013 (2018)

The following papers were considered by the committee:

- Executive Summary
- Application for the export of sperm to The Centre for Assisted Fertilisation (CRM-Napoli), Italy
- Further Information form
- Additional information regarding human rights
- Letter/transfer form from the proposed receiving centre confirming acceptance of sperm

1. Background

- 1.1.** The Person Responsible (PR) at CARE Sheffield, centre 0061 has applied for Special Directions to export six straws of the patient's own sperm to the Centre for Assisted Fertilisation (CRM-Napoli) in Italy.
- 1.2.** The patient couple have moved to Italy and are permanent residents. They are seeking to continue their treatment to pursue a family as their treatment in the UK has not been successful after a cycle of egg donation with a frozen embryo replacement. It is understood that the male had a vasectomy. The patient couple's intention is to proceed with donated eggs in Italy.
- 1.3.** The original ten-year statutory storage period for the sperm samples ended on 4 September 2013. Under the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations') it is possible to extend storage beyond the statutory 10 year period provided that the relevant provisions of the Regulations can be met. In addition to the requirement for consent, a medical practitioner's opinion given on any day 'within the relevant period' i.e. before expiry of the statutory ten-year storage period, is also required that one of the 'relevant persons' or 'the person to be treated' is prematurely infertile. In this case, a Medical Practitioners Statement (MPS) was not completed until 24 June 2016 i.e. two years and nine months after the original ten-year statutory storage period had expired. The circumstances surrounding this occurrence are being investigated as an active HFEA incident. The clinic has therefore been unable to satisfy the requirement for a Medical Practitioner's opinion within the relevant period. The ongoing storage of the gametes in the UK is not compliant with the 2009 Regulations given the fact that the Medical Practitioner's opinion was provided outside of the relevant period and as such, the use of the gametes in treatment in the UK would not be lawful.
- 1.4.** The centre is unable to export the patient's sperm under the auspices of General Direction 0006 because the following requirements cannot be fully met:
- [Schedule 2 - Export of gametes and embryos to Gibraltar and the European Economic Area \(EEA\)](#)
- Part 1**
- (f) 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.*
- 1.5.** Treatment in the UK would not be lawful given that the storage period for sperm has expired and the clinic has not been able to satisfy the requirements of the 2009 Regulations for storage beyond the statutory period of 10 years.
- 1.6.** This application was initially considered by the Statutory Approvals Committee on 28 June 2018. The committee adjourned making a decision because the original application did not make reference to egg donor anonymity in Italy. The centre has since provided relevant information confirming that the couple would be using an anonymous egg donor in Italy due to restrictions in Italian law on releasing donor identity.

2. Consideration of application

Application

- 2.1.** The committee noted that the PR at centre 0061 has applied for Special Directions to export six straws of the patient's own sperm to Italy. An application form has been received.

Human Fertilisation and Embryology Act 1990 (as amended) Section 24(4)

- 2.2.** The committee noted that section 24(4) of the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the export or import of gametes or embryos to or from countries inside and outside of the European Economic Area and Gibraltar. Such directions may provide for modification of the requirements in sections 12 to 14 of the Act in relation to the particular gametes or embryos to be imported or exported.

- 2.3.** The committee further noted that, in relation to the import and export of gametes and embryos, transactions can be permitted without the need for Special Directions if the conditions outlined in General Directions 0006 are satisfied.

General Directions 0006, Schedule 2

- 2.4.** The committee noted that this application for Special Directions is being made because the centre is unable to export the sperm under the auspices of General Directions 0006 as it is unable to meet the requirements of Schedule 2:

Part 1

(f) 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.

- 2.5.** The committee noted that treatment in the UK would not be lawful as the storage period for the sperm has expired and the clinic has not been able to satisfy the requirements of the 2009 Regulations for storage beyond the statutory period of 10 years.
- 2.6.** In addition, the proposed treatment in Italy would not be lawful in the UK in view of the proposed use of an anonymous egg donor. In the UK, in relation to gametes donated after 1 April 2005, any person born as a result of the donation will be able to obtain identifying information about the gamete donor when they reach 18 years of age. This information would not be available to any person born as a result of the proposed treatment in Italy where the law on anonymity is not the same as in the UK.
- 2.7.** In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in *Blood* and from rights arising under the Human Rights Act 1998.

Principle 1

- 2.8.** The committee noted that the centre is unable to import the gametes under General Directions 0006 because requirements of part 1(f) of Schedule 2 cannot be met:

Principle 2

- 2.9.** The committee noted that Articles 49 and 50 of the EC Treaty are concerned with the prohibition of restrictions on the obtaining of services by a national of one member state from another member state within the European Community.

2.10. In this case, the couple are seeking to obtain medical treatment services in another member state and the gametes of the male patient are essential in order to achieve a pregnancy with a genetic link to the couple. The committee was satisfied that a refusal to make Special Directions in this case would amount to an interference with the couple's rights under EU law to obtain medical treatment services in another member state.

Principle 3

2.11. The committee recognised that the couple's rights under the European Convention of Human Rights (ECHR) are separate and distinct from those arising under EU law. Furthermore, those rights under the ECHR will apply regardless of whether the proposed destination of the gametes is another member state within the European Community.

2.12. The committee noted the rights to a private and family life under Article 8 and to marry and found a family under Article 12 of the ECHR. The committee was satisfied that a refusal to issue Special Directions in this case would be likely to amount to an interference with the couple's rights under Articles 8 and/or 12.

Principles 4 and 5

2.13. The committee then considered whether interference with the couple's rights under EU law and/or under the ECHR would be justifiable and proportionate.

2.14. The committee recognised the importance of the statutory requirements relating to the storage of gametes and extending the period for which gametes may be stored. The committee considered whether these requirements might be undermined by issuing Special Directions in this case.

2.15. The committee noted that the failure to ensure that the extended storage of the gametes in the UK was not attributable to any fault on the part of the couple, but was due to a failure on the part of the centre which is being investigated by the HFEA as an active incident. The committee recognised that this investigation and any regulatory action will be aimed at preventing any future similar incidents. The committee regarded such action as important in terms of the upholding of the law and recognised that any such action was separate and distinct from the committee's decision as to whether to issue Special Directions.

2.16. The committee also had regard to the particular circumstances of the couple. The committee noted that the male patient is azoospermic following a vasectomy. Furthermore, the time since the vasectomy would lower the chance of retrieving sperm from the testicles. Furthermore, the age of the patient is now in a higher aneuploidy risk than when the samples were frozen. Given that donated eggs had to be used in treatment in the UK, the use of the stored sperm is the only realistic prospect of achieving a pregnancy with a genetic link to the couple.

2.17. As to the proposed use of eggs from an anonymous donor, the committee had regard to the interests of any person who might be born as a result of licensed treatment. Under UK law, subject to limited exceptions, a person born as a result of licensed treatment will become entitled to identifying information about the donor on reaching the age of 18. Any person born as a result of the proposed treatment of the couple in Italy would not acquire this entitlement. Whilst taking these potential future interests into account, the committee recognised that such interests would only arise in the event of successful treatment and the committee had to weigh in the balance the rights of the couple under the EU law and under the ECHR.

- 2.18.** Treatment could not lawfully take place in the UK because the requirements of the 2009 Regulations cannot be met. Accordingly, the couple could only receive treatment services using the stored gametes if Special Directions are issued. The committee considered whether the concerns about the use of an anonymous egg donor might be addressed if the export was to another country where an identifiable donor might be used. However, the committee also had regard to the fact that the couple have chosen to receive treatment in Italy as they now permanently reside in that country.
- 2.19.** Taking all of these circumstances into account, the committee concluded that a refusal to make the direction sought would amount to interference with the couple's rights under EU law and under the ECHR which could not be justified and which would not be proportionate. In reaching this conclusion, the committee was satisfied that there were exceptional circumstances based on the particular facts of this case which justified the issuing of Special Directions without creating an undesirable precedent.
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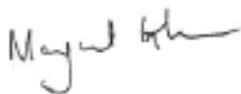
3. Decision

- 3.1.** The committee agreed to grant the application for Special Directions to export six straws of the patient's own sperm to the Centre for Assisted Fertilisation (CRM-Napoli) in Italy.
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4. Chair's signature

- 4.1.** I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

30 August 2018