Statutory Approvals Committee – minutes

Centre 0105 (London Women's Clinic)

Special Direction application to export sperm to Eurocare IVF Clinic, Nicosia, North Cyprus.

Thursday, 27 February 2020

HFEA, Spey Meeting Room 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Emma Cave Anne Lampe Tony Rutherford Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Legal Adviser	Tom Rider	FieldFisher - LLP
Observer	Emily Tiemann (Induction)	Policy Officer

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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee:

- Executive Summary
- Special Directions Application Form
- Further information form
- Letter from the proposed receiving centre confirming acceptance of gametes
- 'Letter of justification' for export from centre 0105
- E-mail correspondence between centre 0105 and proposed receiving centre
- Expired ISO certificate
- Proposed receiving centre certificate from North Cyprus Ministry of Finance
- Proposed receiving centre certificate of Authorization from the municipality of Kyrenia
- Proposed receiving centre certificate North Cyprus Ministry of Health

1. Background

1.1. The Person Responsible (PR) at Centre 0105 (the applicant) has applied for a Special Direction for the export of five ampoules of sperm from London's Women Clinic, United Kingdom (UK) to Eurocare IVF Clinic, Nicosia, North Cyprus.

1.2. The committee noted that the sperm provider (the patient's husband) is deceased, and if exported the sperm will be stored and used to fertilise donor oocytes to produce embryos for use in further treatment.

1.3. The committee noted that the patient has undertaken five treatment cycles in several different clinics in the UK. Three have been with her own eggs and two have been with donor eggs. The patient is currently using donor eggs in the UK for her fertility treatment.

1.4. The committee noted the consent to storage expires on the 12 April 2020, and after that date the gametes can no longer be stored legally in the United Kingdom.

1.5. The committee noted that at the time of storage, it was not anticipated that the gametes would be exported to another country, therefore the patient's husband was not able to provide his consent in writing to allow the gametes to be exported to the country in which the receiving centre is situated.

2. Consideration of application

Application

2.1. The committee considered the application, which included an executive summary, a Special Direction application form and Further Information form.

2.2. The committee noted that the Human Fertilisation and Embryology Act (as amended) permits the Authority to issue directions to allow exports of gametes or embryos to countries outside of the United Kingdom. Furthermore, the committee noted that in relation to the import and export of gametes and embryos to Gibraltar and the European Economic Area (EEA), movement can be permitted without the need for a Special Direction if the conditions outlined in General Directions 0006 are satisfied.

2.3. The committee noted that this application for a Special Direction is being made as the centre is unable to export the five ampoules of sperm to Eurocare IVF Clinic, Nicosia, North Cyprus, under General Directions 0006, since the following requirements of paragraph 1(b), (d), (e), (h) and (i) of Schedule 4 of General Directions 0006 cannot be met:

(b) the receiving centre has a quality management system in place which has been certified by an internationally recognised body.

(d) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) 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.

(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.

(i) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 14 (3) or (4) or by Regulations made under section 15 (5) of the HFE Act 1990 amended, and the period for which the gametes and embryos may remain stored in accordance with the consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.

2.4. The committee noted the information that had been provided to support the Special Direction application. This included a letter from Eurocare IVF Clinic, Nicosia, North Cyprus, which confirms that they are willing to accept the five ampoules of frozen sperm for storage.

2.5. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in R v HFEA ex parte Blood (1997) 2 All ER 687 and from rights arising under the Human Rights Act 1998.

2.6. **Principle 1**

The committee recognised the centre is unable to export the frozen sperm under General Direction 0006 because treatment in the UK would not be lawful given that the statutory storage period will soon lapse and the clinic has not been able to satisfy the requirements of the 2009 Regulations in order for storage to lawfully be extended beyond the statutory period of ten years.

In addition, given that the statutory storage period expires on 12 April 2020, the centre is unable to comply with the requirement that the period for which the gametes remain stored in accordance with the consent of the relevant gamete provider, is not less than six months from the date on which they are to be exported.

The committee also recognised that the centre is unable to export the gametes under General Directions 0006 of Schedule 4 as the gamete provider did not provide consent to export his gametes to another country before he died. It is also not documented that he was provided with information about or was aware that the laws in the country that his gametes will be exported to (North Cyprus), may be different to those in the UK.

The committee discussed compliance with section 1(h) of Schedule 4 of the General Directions 0006 which requires that 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. The committee noted that it was intended for the gametes to be used to created embryos with anonymous donor oocytes.

The committee also discussed the centre's compliance with section 1(b), Schedule 4 of the General Directions 0006.The clinic the patient wishes to transfer the gametes to does not have a certified quality management system. However, the committee noted that the receiving centre is licensed

under the quality and safety laws of North Cyprus and that the quality management system is inspected as part of the process to receive this licence.

2.7. Principle 2

The committee considered whether a refusal would amount to an interference with the patient's rights under the EC Treaty to obtain medical treatment services in another member state. The committee acknowledged that the proposed transfer was to a country outside the EU where the applicant could in future seek treatment services.

2.8. Principle 3

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the EC Treaty. Based on the patient's particular personal circumstances, the committee accepted that a refusal to allow her deceased husband's frozen sperm to be exported would amount to an interference with the patient's rights to respect her private and family life under Article 8 and to found a family under Article 12 of the ECHR and that any refusal to grant the application would need to be justified.

2.9. Principle 4

The committee considered whether interference with the patient's rights under the ECHR could be justified and whether a refusal to grant the application would be disproportionate. In doing so, the committee had regard to the patient's particular circumstances. The committee considered the effect of a refusal on the patient and whether this represented an isolated case or an undesirable precedent.

3. Decision

3.1. The committee took into consideration the fact that the patient had been undergoing fertility treatment in the UK using her own eggs, but more recently donor eggs. The committee also recognised that following the death of the patient's husband, there were now limited options available to her to start a family using her own husband's sperm.

3.2. The committee also took into consideration that consent to store the sperm expires on the 12 April 2020, meaning there is less than six months remaining of the storage period. As such, the patient must export her deceased husband's sperm if she wishes to continue fertility treatment. The committee acknowledged that the couple had not anticipated that the gametes would need to be exported and were satisfied that consent for posthumous use was in place.

3.3 However, the committee raised serious concerns that the receiving centre, Eurocare IVF, did not have a fully up to date quality licence and strongly recommended that the patient should be informed of and understand the implications of this, and the impact it may have on the quality of care she receives in future treatment at this centre.

3.4. The committee also noted the letter from Eurocare IVF stating they 'confirm receiving' the patient's deceased husband's sperm. The committee assumed this was an incorrect translation, and that the centre had not already received the sperm. It was therefore prepared to base its decision on the fact that the clinic has not received the sperm and that it is still in storage in the UK.

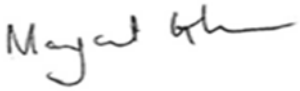
3.5. Taking all of these particular circumstances into account, including the needs of a future child to have an identifiable donor and the right of the patient to seek treatment appropriate to her own unique circumstances, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was also satisfied that granting the application in the exceptional circumstances of this particular case would not set an undesirable precedent.

3.6. The committee therefore agreed to issue a special direction in the case of London's Women Clinic, 113-115 Harley Street, London, W1G 6AP United Kingdom (UK) to export five ampoules of frozen sperm to Eurocare IVF Clinic, Sehit Mustafa Russo Str.No.151 Kucuk Kaymakli, Nicosia, North Cyprus, for treatment.

.4. Chairs signature

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

Signature



Name

Margaret Gilmore

Date

17 March 2020