

Statutory Approvals Committee – minutes

Centre 0057 (Wessex Fertility Limited)

Application for Special Directions to export sperm and an embryo for patient's own use to Bangladesh

Thursday, 22 February 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Anthony Rutherford Ruth Wilde	
Members of the Executive	Dee Knoyle Paula Robinson Clare Ettinghausen	Committee Secretary Head of Planning & Governance (Observing) Director of Strategy & Corporate Affairs (Observing)
External adviser		
Legal Adviser	Graham Miles	Blake Morgan LLP
Observers		

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
- Application form to export embryo
- Application form to export sperm
- Further information form
- Letter from proposed receiving centre
- Proposed receiving centre licence
- Proposed receiving centre renewals of licence

1. Background

- 1.1.** The Person Responsible (PR) at Wessex Fertility Limited, centre 0057 has applied for Special Directions to export two straws of sperm and one embryo to Harvest Infertility Care, Dhaka, Bangladesh for a patient couple's own use. The patient couple started their treatment in the UK and are unable to obtain replacement visas to travel back to the UK for further treatment. Therefore, they wish to continue treatment in Bangladesh, their home country. The sperm is the male patient's own and the embryo was created using the patients' own gametes.
- 1.2.** The centre has assessed that it is unable to export the sperm and embryo under the auspices of General Direction 0006 because the following requirement of Schedule 4 cannot be fully met:
- Section 1(b), the receiving centre has a quality management system in place which has been certified by an internationally recognised body.

2. Consideration of application

- 2.1.** The committee noted that centre 0057 has applied for Special Directions to export two straws of sperm and one embryo to Bangladesh for a patient couple's own use. A suitably completed application form and further information form was received by the HFEA Executive.

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

General Directions 0006, Schedule 4, Part 1(b)

- 2.2.** The committee noted that Section 24(4) of the 1990 Act provides a power to make Directions and confers a broad power on the Authority to permit the export of a person's gametes. Pursuant to this power the Authority has issued General Direction 0006 ('the General Direction'). However, this application arises because all of the requirements of the General Direction cannot be met and therefore the committee is asked to consider whether, in the particular circumstances of this case, there are grounds to exercise the power under section 24(4) to permit the export of these two straws of sperm and embryo to Bangladesh for a patient couple's own use.
- 2.3.** The committee noted that the centre is unable to export the two straws of sperm and embryo under General Direction 0006 because the requirements of Part 1(b) of Schedule 4 cannot be met.

Part 1(b) of Schedule 4 of the General Direction provides as follows:

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

Quality Management System (QMS) – No QMS in place

- 2.4.** The committee noted that the centre is unable to comply with Part 1(b) of Schedule 4 to the General Direction. Centre 0057 contacted the clinic in Bangladesh concerning the presence of a quality system, in order to determine that the processing and treatment undertaken in the receiving centre meet the HFEA standards. They have confirmed that no such quality system is in place. The patient has specified this clinic for treatment, having had to switch from a previously selected clinic due to "unavoidable circumstances". This is now the couple's preferred centre to continue treatment.

2.5. Despite the absence of a certified quality management system, the committee noted that the centre staff have confirmed to the Executive that the clinic in Bangladesh has a current valid licence. The committee was presented with a copy of a licence issued by the licensing authority in Bangladesh. However, according to the copy of the licence provided, the licence expired on 3 April 2017. The committee recognised that, if the clinic in Bangladesh is not currently licensed, this would be a further requirement of the General Direction that could not be met in relation to this proposed export. Part 1(a) of Schedule 4 to General Direction provides as follows:

a) The centre to which the gametes or embryos are to be exported ('the receiving centre') is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated.

2.6. In the light of the statement from the centre that the clinic in Bangladesh does have a current valid licence, the committee determined that it would be appropriate to consider the application on the basis that a current licence exists, subject to the centre providing written confirmation of the same to the HFEA Executive.

3. Decision

3.1. The committee had regard to General Direction 0006.

3.2. The committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.

3.3. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in the *Blood* case and from rights arising under the Human Rights Act 1998.

3.4. The committee noted that Special Directions have been applied for because Part 1(b) of Schedule 4 of the General Directions could not be met.

3.5. The committee noted that the couple had treatment in the UK and have two straws of sperm and one embryo in storage at centre 0057. The patient couple live in Bangladesh and are unable to obtain replacement visas to return to the UK for further treatment. Therefore, the couple would like to export the sperm and embryo to Bangladesh for their own use. The sperm is the patient's own and the embryo was created from the patients' own gametes. The couple find the use of donor gametes unacceptable.

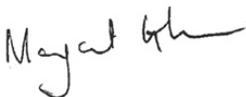
3.6. The committee noted that it is highly unlikely that the patient and partner would be able to receive successful fresh treatment abroad, due to the particulars of their medical history. The frozen embryo that centre 0057 is storing represents the patient's best chance of conceiving and is therefore essential to their treatment in their home country. Should the patient wish to attempt any further fresh treatment, they would need to utilise the sperm samples that are currently in storage. The male partner has a very low sperm count and underwent a microscopic TESE procedure by a urologist, under general anaesthetic, in 2011 to obtain sperm for his treatment. Given the male patient's very low testosterone levels and the time that has elapsed since the successful recovery of sperm, it is highly unlikely that further sperm would be capable of being retrieved should the patient attempt to undertake a completely new fresh cycle in Bangladesh.

- 3.7.** The patient couple's treatment was further complicated by the female patient's diagnosis of Polycystic Ovaries and a very high ovarian reserve, meaning that she was at risk of OHSS and had to be very carefully managed. The combined diagnoses of these patients makes a very complex case and would suggest that the likelihood of success in any potential future fresh cycles abroad would be minimal. The couple has had three unsuccessful embryo transfer attempts in addition to their live birth.
- 3.8.** The committee considered whether a refusal to make Special Directions would be an interference with the patients' rights under Articles 8 and/or 12 of the European Convention on Human Rights and whether such interference would be justified and proportionate. The committee decided that refusal is likely to amount to interference in that the patient couple wish to export their sperm and embryo, which are essential to their treatment, to Bangladesh for their own use. The committee considered that a refusal to issue Special Directions to export the patient couple's sperm and embryo to the clinic in Bangladesh would not be proportionate.
- 3.9.** The committee concluded that, taking all the factors into account, the current case involves a highly exceptional set of circumstances and agreed to issue Special Directions to allow the export of the patients' two straws of sperm and one embryo to Harvest Infertility Care, Dhaka, Bangladesh subject to the Executive satisfying itself that this centre currently holds an active licence as outlined in Part 1(a) of Schedule 4 of the General Directions.
- 3.10.** The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.
- 3.11.** The committee, therefore, determined that Special Directions should be granted, subject to the centre providing to the HFEA Executive written confirmation that the receiving centre meets the requirements of paragraph 1(a) of Schedule 4 to the General Direction. If the centre is unable to provide such confirmation, the committee determined that the application should be referred back to the committee for further consideration.

4. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

7 March 2018