HFEA Statutory Approvals Committee

20 November 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Undiagnosed X-linked Fetal Hydrops / Fetal Akinesia

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Trent Fisher
Rebekah Dundas (lay)	
Jane Dibblin (lay)	Legal Adviser:
Debbie Barber (professional)	Ros Foster, Browne Jacobson
Advisor: Dr Anne Lampe	Also in attendance: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: The Members declared no conflicts in relation to this item

The following papers were considered by the Committee:

- Executive Summary
- Application form and additional information
- Clinician's letter
- Redacted peer review
- Genetic Alliance opinion

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) ("the Act")
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of 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 Publication of Authority and Committee Papers
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note For Licence Committee

Discussion

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre is licensed to carry out PGD. The Committee was also satisfied that the Centre has experience of carrying out PGD and that generic patient information about its PGD programme and associated consent forms had previously been received by the HFEA.

2. The Committee noted that the proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(c) of schedule 2 of the Act, i.e. 'where there is a particular risk that the embryo may have or develop a gender-related serious physical or mental disability'.

3. The Committee noted that the supporting information provided with this application suggests that the prospective patient has an undiagnosed, X-linked condition causing fetal hydrops / fetal akinesia which means there is a 1 in 4 chance of having an affected child in each pregnancy with male offspring having a 1 in 2 chance of being affected.

4. The Committee noted that the supporting information shows a family history of three male foetuses conceived by two sisters have been affected by this condition whereas conceived females appear to not be affected, leading to the conclusion that the condition is inherited in an X-linked recessive pattern.

5. The Committee noted that embryos affected by this undiagnosed condition which is lethal before birth suffer fetal hydrops where fluid accumulates in two or more foetal compartments caused by a prenatal form of heart failure and show signs of fetal akinesia, i.e. severely reduced foetal movement.

6. The Committee noted that the application is consistent with the Peer Review.

7. The Committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that the condition was as described in the papers. Dr Lampe further confirmed that on the balance of probability and based on the supporting information presented by the applying centre in its original application as well as further clarification supplied subsequently in response to Peer Review it is

most likely that the inheritance pattern for this family would be X-linked recessive. She confirmed that the Committee was not dealing with a clearly defined diagnostic condition, rather a combination of symptoms that affect male embryos in the case of this specific family, given the evidence presented. The Committee accepted the advice.

8. The Committee noted the advice of its Legal Adviser, Ros Foster, who confirmed that in accordance with the Act and the Authority's Standing Orders, the Committee had the power to authorise sex testing for this particular family, and that the authorisation of this case was not an authorisation for the condition to appear on the HFEA's PGD list of authorised conditions. The Committee accepted the advice.

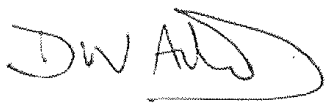
9. The Committee considered that the condition is serious because of the development of fetal hydrops and fetal akinesia leading to death in-utero.

10. The Committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The Committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(c) and (3) of Schedule 2 to the Act.

11. The Committee agreed to authorise the sex testing of embryos for the avoidance of Undiagnosed X-linked Fetal Hydrops / Fetal Akinesia in the applicant family only. The Committee urged the applying centre to ensure that the family had access to counselling and were aware of their options and all implications of the testing.

12. The Committee noted that as this condition relates to a specific family the condition would therefore not appear on the general list for authorised PGD conditions.

Signed: Date: 3 December 2014



David Archard (Chair)