Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
30 April 2015

Minutes – item 7

Centre 0006 (Lister Fertility Clinic) – PGD application for epidermolysis bullosa, lethal acantholytic OMIM #609638

Members of the Committee	David Archard (Chair, lay) Sue Price (professional) Tony Rutherford (professional) Margaret Gilmore (lay)
Legal Adviser	Sarah Ellson, Fieldfisher
Specialist Attending	Professor Mary Porteous
Members of the Executive	Sam Hartley, Head of Governance and Licensing Trent Fisher, Secretary

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

The following papers were considered by the committee:

- executive summary
- PGD application form
- redacted peer review
- Genetic Alliance opinion
- redacted public opinion in support of the application

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)
- HFEA decision trees

- 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

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 condition being applied for is not on the approved PGD condition list.

3. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, i.e. 'where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'.

4. The committee noted that epidermolysis bullosa, lethal acantholytic OMIM #609638 is inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected where both parents are carriers.

5. The committee noted that individuals with epidermolysis bullosa, lethal acantholytic OMIM #609165 suffer from extremely fragile skin that at the slightest touch can tear and blister. Painful open wounds and sores form causing secondary infections and fluid loss, internal linings and organs are similarly affected. The condition is fatal during infancy.

6. The committee noted other symptoms that may develop are transcutaneous fluid loss, shedding of nails, dysmorphic ears and deformed hands.

7. The committee noted that the condition demonstrates a complete penetrance and that symptoms are present from birth.

8. The committee noted that there is no curative treatment for the condition.

9. The committee noted that the application is consistent with the Peer Review.

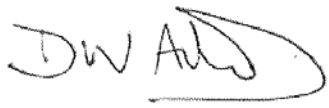
10. The committee welcomed the advice of its advisor, Professor Mary Porteous, who confirmed that the conditions are as described in the papers adding that it is a very rare condition and that infants born with this condition may receive little or no emotional comfort due to the difficulties in nursing and parents holding the infants.

11. The committee considered that the condition is serious due to severe symptoms that present at birth and affected infants die in the first few days following birth.

12. The committee had regard to its decision tree 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 conditions meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 to the Act.

13. The committee agreed to authorise the testing of embryos for epidermolysis bullosa, lethal acantholytic OMIM #609638.

Signed: Date: 12 May 2015



David Archard(Chair)