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 4

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for microcephaly with or without chorioretinopathy, lymphoedema or mental retardation (MCLMR) OMIM #152950

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

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 MCLMR OMIM #152950 is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected.

5. The committee noted that the condition presents with a variable spectrum of the central nervous system and lymphatic anomalies. Ocular abnormalities can occur and in some cases cause blindness. Affected individuals may have microcephaly associated with reduced mental function, chorioretinopathy that causes changes in the brain leading to visual impairment and severe learning difficulties.

6. The committee noted other symptoms that may develop include lymphoedema often in the legs, cardiac defects and sensorineural hearing loss.

7. The committee noted that the there was evidence that there was a high risk of any child who inherited this genetic mutation developing this condition. Physical symptoms may present at birth with intellectual impairment becoming apparent later in life.

8. The committee noted that there is no curative treatment for the condition and the only treatment options available are those to manage the symptoms that arise from the condition.

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

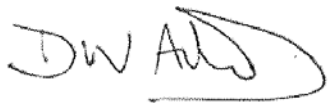
10. The committee welcomed the advice of its advisor, Professor Mary Porteous, who confirmed that the condition is as described in the papers adding that the condition is extremely variable.

11. The committee considered that the condition is serious due to early onset of symptoms, apparent high risk of inheritance, severity of the symptoms that present and the lack of any curative treatment.

12. The committee had regard to its decision tree and 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)(b) and (2) of Schedule 2 to the Act.

13. The committee agreed to authorise the testing of embryos for microcephaly with or without chorioretinopathy, lymphoedema or mental retardation OMIM #152950.

Signed: Date: 12 May 2015



David Archard(Chair)