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 July 2015

Minutes – item 3

Centre 0119 (Centre) – PGD application for lissencephaly type 3 (LIS3) OMIM #611603

Members of the Committee	David Archard (Chair, lay) Rebekah Dundas (Deputy Chair, lay) Sue Price (professional) Margaret Gilmore (lay) Lee Rayfield (lay)
Legal Adviser	Jane Williams, Mills & Reeve
Specialist Attending	Professor John Walter
Members of the Executive	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
- clarification letter from the centre's clinical geneticist

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 lissencephaly type 3 OMIM #611603 is inherited in an autosomal dominant pattern and there is up to a 1 in 2 chance of an embryo being affected with the condition where one parent is a carrier in some cells.

5. The committee noted that the condition is a neurological disorder characterised by structural problems in the brain that can cause mental retardation, early-onset epilepsy, severe developmental delay and visual impairment.

6. The committee noted that other symptoms may include involuntary eye movement, low muscle tone in the trunk of the body and the absence of one or both testes.

7. The committee noted that the condition demonstrates a high penetrance with symptoms likely to develop from birth.

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 John Walter, who confirmed that the condition is as described in the papers and confirmed that it was a severe neurological disorder.

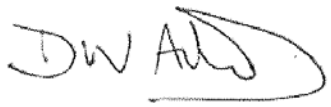
11. The committee considered that the condition is serious due to the severity of the symptoms, early onset of symptoms and lack of any curative treatment.

12. 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)(b) and (2) of Schedule 2 to the Act.

13. The committee agreed to authorise the testing of embryos for lissencephaly type 3 OMIM #611603. The committee noted the Peer Reviewer's suggestion that the condition is also listed under this OMIM number as TUBA1A-related cortical dysgenesis.

14. The committee took the opportunity to reflect on the fact, and to remind centres, that even though a condition is listed on the HFEA PGD condition list, centres are under a statutory obligation to evaluate the significance of the 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 in each individual case.

Signed: Date: 12 August 2015



David Archard(Chair)