Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

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

Minutes – item 2

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for X-linked lissencephaly OMIM #300067

Members of the Committee:	David Archard (Chair, lay) Sue Price (professional) Debbie Barber (professional) Tony Rutherford (professional)
Legal Adviser:	Dawn Brathwaite, Mills & Reeve
Specialist Attending:	Dr Anne Lampe
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 email correspondence with peer reviewer
- email from centre confirming specific mutation responsible

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)
- 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

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 X-linked lissencephaly OMIM #300067 is inherited in an X-linked pattern and there is a 1 in 2 chance of a male embryo being affected with DCX related lissencephaly and a 1 in 2 chance of a female embryo affected by varying degrees of DCX related subcortical band heterotopia where the mother has the DCX mutation.

5. The committee noted that those affected by the condition display psychomotor retardation, cerebral palsy and can suffer from seizures. A proportion of children affected will die before the age of 10 from issues due to aspiration or severe seizures.

6. The committee noted that other symptoms that may develop are swallowing issues and deformities of the hands, figures and toes. Neurodevelopment issues vary greatly, with some children affected showing no significant development above that of a three to five month old, whereas some females with the DCX mutation may have normal development and intelligence.

7. The committee noted that the condition demonstrates a near complete penetrance in males and symptoms in females range from mild to severe form. Symptoms are present from birth and can be identified as early as week 20 of gestation.

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

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

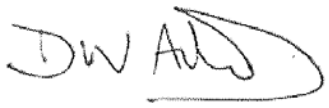
10. The committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that the condition is as described in the papers and added that symptoms affecting females can be learning difficulties and seizures. Dr Lampe also stated that the symptoms are much more variable in females.

11. The committee considered that the condition is serious due to the reduced life expectancy, that symptoms can be present from birth and the lack of any curative treatment for the condition.

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 X-linked lissencephaly OMIM #300067.

Signed: Date: 13 April 2015



David Archard(Chair)