Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

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

Minutes – Item 3

Centre 0321 (New Life Centre) – PGD application for frontotemporal dementia with Parkinsonism OMIM #607485

Members of the Committee:	David Archard (Chair, lay) Rebekah Dundas (lay) Jane Dibblin (lay) Sue Price (professional) Debbie Barber (Professional) Anthony Rutherford (Professional)
Legal Adviser:	Ros Foster, Browne Jacobson
Specialist Attending	Dr Anne Lampe
Members of the Executive:	Siobhain Kelly 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
- Additional document containing answers to questions 2-3 of 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)
- 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 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'.

3. The Committee's Adviser pointed out that paragraph 4.3 of the Executive Summary was inaccurate as regards the information provided in relation to motor disorders in that they do not directly relate to the condition.

4. The Committee noted that frontotemporal dementia with Parkinsonism is inherited in an autosomal dominant manner and there is a 1 in 2 chance of an embryo being affected with the condition when one parent is affected.

5. The Committee noted that frontotemporal dementia with Parkinsonism causes damage to the frontal and temporal lobes which may cause several forms of pre-senile dementia. Changes can be seen in a person's personality and behaviour with loss of inhibitions, sympathy and empathy. Individuals may also develop language problems and loss of speech. As the conditions progress the symptoms will become more severe and in the latter stages full time care is needed as the individuals will lose the ability to care for themselves.

6. The Committee noted that the condition was extremely rare, and discussed the psychological impact of the condition on the affected individual, in terms of the knowledge that they would ultimately become a burden on their family.

7. The Committee noted that there is a high penetrance with the condition and it can be present from middle age and later in life however some cases present in those less than 40 years of age.

8. The Committee noted that there is no curative treatment for frontotemporal dementia with Parkinsonism.

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

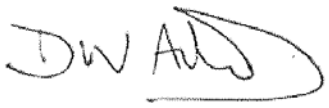
10. The Committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that, subject to the matter referred to in paragraph 3 above the condition was as described in the papers and that those who have the condition may become very disinhibited and behave in socially inappropriate ways.

11. The Committee considered that the condition is serious due to pre-senile onset of dementia which causes extreme personality changes which become more severe as the condition progresses and the need for full time care as the individual loses the ability to care for them-selves.

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 frontotemporal dementia with Parkinsonism OMIM #607485.

Signed: Date: 12 February 2015



David Archard (Chair)