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 1

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Usher Syndrome type one (including OMIM #276900 #276904 #601067 #602083 #606943 #614869) and type two (including OMIM #276901 #605472 #611383)

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
- redacted peer review comments
- correspondence with centre re applying for additional subtypes
- 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 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 Usher syndrome types 1 and 2 (including listed subtypes) are inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers.

5. The committee noted that those affected by the condition have hearing and vision impairment. Type 1 causes profound deafness from birth and visual loss by the age of 10. Type 2 is more variable where symptoms can range from mild to severe.

6. The committee noted that as individuals born deaf would become a lot more dependent on their sight for communication with this condition the deterioration of their sight has an extremely negative impact on their life.

7. The committee noted that the Usher syndrome type 1 demonstrates a complete penetrance while type 2 penetrance appears high but not complete with large and unpredictably variation in severity between and within families. The onset of symptoms in both types is from birth.

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

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

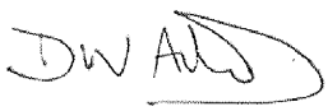
10. The committee welcomed the advice of its advisor, Dr Anne Lampe, who confirmed that the condition is as described in the papers .clarifying that onset of symptoms in both types is from birth. She also advised that the description contained at paragraph 4.3 of the Executive Summary was inaccurate with the reference to *'Sufferers tend to be hard of hearing rather than deaf and they generally have normal balance'* in that type 2 symptoms can vary making it hard to predict how an individual will be affected with hearing loss ranging from mild to severe.

11. The committee considered that the condition is serious due to the potential loss of two essential senses and the extraordinary effect that this would have on an individual's life.

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 Usher syndrome type one (including OMIM #276900 #276904 #601067 #602083 #606943 #614869) and type two (including OMIM #276901 #605472 #611383).

Signed: Date: 13 April 2015



David Archard (Chair)