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 6

Centre 0102 (Guys Hospital) – PGD application for arthrogryposis renal dysfunction and cholestasis (ARC) type 1 and type 2 OMIM #208085 #613404

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
- five medical articles provided by the centre

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 conditions being applied for are 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 ARC type 1 and type 2 are inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected where both parents are carriers.

5. The committee noted that individuals with these conditions suffer from renal and liver problems with affected children becoming jaundiced. Incomplete formation of the brain and congenital cardiovascular anomalies can be present. Recurrent infections and internal bleeding is common and most infants die within the first year of life.

6. The committee noted other symptoms that may develop are contractures at joints, ichthyosis, platelet anomalies and deafness.

7. The committee noted that the conditions demonstrate a complete penetrance and symptoms are present from birth.

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

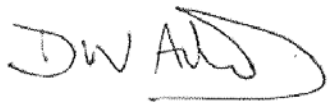
10. The committee welcomed the advice of its Advisor, Professor Mary Porteous, who confirmed that the conditions are as described in the papers adding that it is a devastating condition.

11. The committee considered that the conditions are serious due to symptoms being present at birth and death in early infancy death.

12. The committee had regard to its decision tree and explanatory note and noted that on the basis of the information presented, given the conditions' 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 conditions meet 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 arthrogryposis renal dysfunction and cholestasis type 1 and type 2 OMIM #208085 #613404.

Signed: Date: 12 May 2015



David Archard(Chair)