Statutory Approvals Committee - minutes

Centre 0119 (Birmingham Women's Hospital) – PGD application for Myotonic Dystrophy type 2 OMIM #602668

Thursday, 25 February 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Committee members	David Archard (Chair) Anne Lampe Margaret Gilmore Anthony Rutherford	
Members of the Executive	Trent Fisher	Secretary
External adviser	Professor John Walter	
Legal Adviser	Dawn Brathwaite	Mills & Reeve
Observers	None	

Declarations of interest:

- members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- executive summary
- PGD application form
- redacted peer review
- Genetic Alliance opinion
- seven redacted public comments

1. Consideration of application

1.1. The committee noted the advice of its specialist advisor, Professor John Walter, who confirmed that the condition is as described in the papers.

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

1.3. The committee noted that there were seven public comments submitted with the application. The committee welcomed the comments from the public as they assisted the committee to gain a better understanding of the condition from a patient's point of view.

1.4. 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.

1.5. The committee noted that the condition being applied for is not on the approved PGD condition list.

1.6. 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'.

1.7. The committee noted that the condition is inherited in an autosomal dominant pattern which means there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected by the condition.

1.8. The committee noted that the condition causes affected individuals to have muscle problems. Symptoms include involuntary contraction of muscle and an inability of the muscle to relax, muscle weakness, stiffness and pain. This may involve facial muscles, the neck, fingers and hip flexor muscles. By middle age, 30 percent of individuals will display progressive hip muscle weakness and may require a wheelchair.

1.9. The committee noted other symptoms can include cardiac arrhythmias, development of cataracts or development of insulin-insensitive diabetes. Males may also suffer from testicular failure.

1.10. The committee noted that the symptoms can be variable even within the same family but penetrance is regarded as being 100%. Onset of symptoms can be from teenage years to early adulthood.

1.11. The committee noted that there is no curative treatment for the condition, only treatment for symptoms that present.

2. Decision

2.1. The committee considered that the condition is serious as it is a physically debilitating condition.

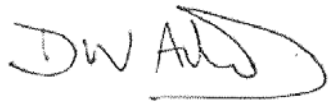
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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.

2.3. The committee agreed to authorise the testing of embryos for Myotonic Dystrophy type 2 OMIM #602668.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

David Archard

Date

10/03/2016