Statutory Approvals Committee - minutes

Centre 0006 (The Lister Fertility Clinic) – PGD application for Lubs X-linked mental retardation syndrome MRXSL (MECP2 Duplication syndrome) OMIM #300260

Friday, 24 June 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Margaret Gilmore Anthony Rutherford Anne Lampe Ruth Wilde	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Jenny Carmichael	
Legal Adviser	Dawn Brathwaite	Mills & Reeve LLP
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
- a letter from a clinical geneticist treating a carrier of MECP2 Duplication syndrome

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Dr Jenny Carmichael, who confirmed that the condition is as described in the papers. Dr Carmichael informed the committee that the condition causes severe syndromic disability.

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

1.3. The committee noted the Genetic Alliance opinion which helped the committee gain an understanding of the condition from the patient perspective.

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 X-linked pattern which means there is a 1 in 2 chance of having a child who will inherit the mutation when the female partner carries the mutation.

1.8. The committee noted that the condition is a neurodevelopment disorder in which males are more severely affected than females. Females carriers may be unaffected or may present with mild neuropsychiatric symptoms such as anxiety, depression and exhibit autistic features. However, the committee noted the experience of the specialist adviser of a female affected patient who presented with severe global developmental delay early on in childhood.

1.9. The committee noted that three out of five affected males will die of secondary complications before the age of ten. Also, one third of affected individuals will never develop the ability to walk independently and a majority of individuals do not develop speech.

1.10. The committee noted that symptoms include profound mental retardation, infantile hypotonia, progressive spasticity, autistic features, seizures which can be very difficult to treat, recurrent infections, poor speech development, limited physical movement and swallowing difficulties.

1.11. The committee noted that the condition shows complete penetrance in males. Symptoms can be present from birth or develop within the first few months of life.

1.12. The committee noted that there is no curative treatment for the condition. Treatment for management of some of the symptoms does exist.

2. Decision

2.1. The committee considered that the condition is serious due to early onset of the condition, wide range of severe symptoms and the life limiting features of the condition.

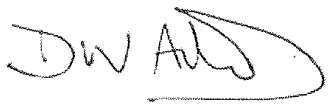
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Lubs X-linked mental retardation syndrome MRXSL (MECP2 Duplication syndrome) OMIM #300260.

3. Chair's signature

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

Signature



Name

David Archard

Date

11 July 2016