Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital) – PGD application for Aicardi Goutieres syndrome type 2 OMIM #610181

Thursday, 29 September 2016

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

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Margaret Gilmore Anne Lampe Ruth Wilde	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Jenny Carmichael	
Legal Adviser	Jane Williams	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
- email communication from Person Responsible
- Licence Committee minutes, 26 August 2010

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.

1.2. The committee noted that the application is consistent with the Peer Review. Within the review, the reviewer stated that there are five additional variants of Aicardi Goutieres Syndrome (AGS) type 1 OMIM #225750, type 3 OMIM #610329, type 4 OMIM #606034, type 5 OMIM #606754, and type 6 OMIM #146920.

1.3. The committee noted that the reviewer also stated that although there are 6 different genetic causes, there is no significant phenotypic difference in the majority of affected Aicardi Goutieres syndrome cases. This was also confirmed by the committee's specialist advisor.

1.4. The committee noted from the executive that type 1 has previously been authorised for testing and is currently on the HFEA PGD condition list. The committee members were provided with an email from the PR of the applying clinic confirming his agreement to extend his application to include subtypes 3 – 6 of AGS.

1.5. The committee decided that as there are no significant phenotypic differences between the different genetic variants of AGS, it would continue to consider the application for AGS subtypes 2, 3, 4, 5 and 6.

1.6. 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.

1.7. The committee noted that the subtypes of the condition being applied for are not on the approved PGD condition list.

1.8. 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'.

1.9. The committee noted that AGS subtypes 2 – 6 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.

1.10. The committee noted that the AGS is a severe, childhood onset, neurodegenerative condition which often results in death during early childhood.

1.11. The committee noted that symptoms may include profound intellectual disability, epilepsy, chilblain lesions, scoliosis, insulin dependent diabetes, hypothyroidism, glaucoma, severe irritability, crying for hours at a time, poor sleep, fevers without infection, loss of developed skills, stiff limbs, poor head control and abnormal limb movements.

1.12. The committee noted that the condition is highly penetrant and onset of symptoms may be soon after birth.

1.13. The committee noted that there is no curative treatment for AGS and only symptomatic treatment is available at present.

2. Decision

2.1. The committee considered that the AGS is serious due to the early onset and extreme severity of symptoms which can result in death in early childhood in the majority of cases.

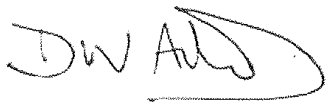
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Aicardi Goutieres syndrome type 2, 3, 4, 5 and 6 OMIM #610181, #610329, #606034, #606754 and #146920.

3. Chair's signature

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

Signature



Name

David Archard

Date

13 October 2016