Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital) – PGD application for Atrioventricular Septal Defect 4 (AVSD4) (GATA4 gene), OMIM #614430

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

1. Background

1.1. The committee noted that the condition was previously heard by the Statutory Approvals Committee on 28 April 2016. At the time of consideration, the committee's specialist advisor stated that it was only possible to determine the risk of a patient inheriting the condition if there was a confirmed family history of the condition.

1.2. The committee had adjourned its decision in receipt of further legal advice as the legal adviser stated he would require further time to consider the wording of paragraph 1ZA(2) of Schedule 2 to the Human Fertilisation and Embryology Act 2008 and to provide advice to the committee on its application in these circumstances.

1.3. The committee noted that after receipt of legal advice and consideration of the issues, it would be able to license a condition as 'familial' in just those cases where determination of the particular risk of inheritance of a condition could only be determined if there was a familial history; and, further, that it might, but only in exceptional circumstances, receive and consider an individual application on behalf of an affected family.

2. Consideration of application

2.1. The committee welcomed the advice of its specialist advisor, Dr Jenny Carmichael, who confirmed that the condition is as described in the papers.

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

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

2.2. 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.

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

2.4. 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'.

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

2.6. The committee noted that the condition is characterised by individuals presenting with congenital heart malformations.

2.7. The committee noted that the congenital heart malformations can lead to complications such as heart failure, enlargement of the heart, pulmonary hypertension, pneumonia and death. Cardiac failure is likely to occur within the first few months of life. Without surgery, many patients develop pulmonary vascular disease and die from Eisenmenger syndrome.

2.8. The committee noted that the condition demonstrates a high penetrance.

2.9. The committee noted that congenital abnormality of heart development may be detected during a scan in utero, present at birth or later with signs of heart disease.

2.10. The committee noted that there is no curative treatment for the condition. The treatment available involves surgical invention which is recommended soon after diagnosis. Some patients have lifelong complications which will require further cardiac surgeries.

3. Decision

3.1. The committee considered that the condition is serious due to increased risk of death caused by the condition and need for repeat major cardiac surgical interventions.

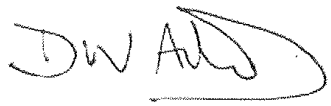
3.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious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

3.3. The committee agreed to authorise the testing of embryos for Atrioventricular Septal Defect 4 (AVSD4) (GATA4 gene), OMIM #614430 in cases where a family history of the condition has been identified.

4. Chair's signature

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

Signature



Name

David Archard

Date

22 July 2016