Statutory Approvals Committee - minutes

Centre 0339 (CREATE, St Paul's London) – PGD application for Loeys-Dietz syndrome Type I OMIM #609192

Thursday, 28 April 2016

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

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Margaret Gilmore Anthony Rutherford Ruth Wilde Anne Lampe	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Mary Porteous	
Legal Adviser	Philip Grey	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
- Two redacted peer reviews
- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Professor Mary Porteous, who confirmed that the condition is as described in the papers. Professor Porteous informed the committee that Loeys-Dietz syndrome type 1 and type 2 were clinically almost indistinguishable.

1.2. The committee considered whether, in those circumstances, it would be appropriate for it to consider licensing both Loeys-Dietz syndrome types 1 and 2 for PGD. The legal advisor advised the committee that if, in the light of the specialist adviser's advice, it was content that it had sufficient information available, it would be lawful for it to do so.

1.3. The committee decided that with the advice they had received from their specialist and legal advisers, it was content to continue to consider whether to licence both Loeys-Dietz syndrome types 1 and 2 OMIM #609192 #610168.

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

1.5. 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.

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

1.7. 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'.

1.8. 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.

1.9. The committee noted that the condition causes aortic aneurysm which can lead to rupture and a life-threatening emergency. Aneurysms can be aggressive in nature and can occur at very early ages and can affect other major arteries. In females the condition can cause complications during pregnancy.

1.10. The committee noted that other symptoms can include unusually wide spaced eyes, cleft palate, a partially cleft soft palate, and an unusual head shape.

1.11. The committee noted that the condition demonstrates a high penetrance and age of onset is variable however symptoms can occur from birth.

1.12. The committee noted that there is no curative treatment for the condition. Surgical intervention may succeed in lessening the risks of aneurysms rupturing but will carry additional risks.

2. Decision

2.1. The committee considered that the condition is serious as while it is difficult to predict the exact age of onset and presentation of symptoms, the symptoms which do present can be very severe and wide-ranging, having a severe impact on the quality of life of an affected individual. The condition is also life threatening.

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

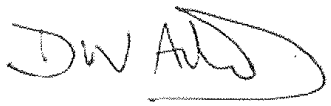
the condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 to the Act.

2.3. The committee agreed to authorise the testing of embryos for Loeys-Dietz syndrome types 1 and 2 OMIM #609192 #610168.

3. Chair's signature

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

Signature



Name

David Archard

Date

13 May 2016