Statutory Approvals Committee - minutes

Centre 0078 (IVF Hammersmith) – PGD application for Dilated cardiomyopathy (DCM) caused by a mutation in the Tropomyosin alpha-1 chain gene OMIM #611878

Thursday, 27 August 2015

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

Committee members	David Archard (Chair, lay) Rebekah Dundas (Deputy Chair, lay) Margaret Gilmore (lay) Anthony Rutherford (professional) Sue Price (professional)	
Members of the Executive	Jo McAlpine	Secretary
External advisor	Professor Peter Turnpenny	
Legal Advisor	Tom Rider	Fieldfisher
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. Consideration of application

1.1 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.

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

1.3 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'.

1.4 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.

1.5 The committee noted that the condition is a form of cardiomyopathy, a disease of the muscle tissue of the heart, characterised by the enlargement of the heart, often affecting all four chambers. DCM is associated with early onset stretching of the ventricle and congestive heart failure in children and young adults. This disease can be discovered from early infancy to adulthood, though the condition when found in adults tends to be less severe. DCM is a leading cause of heart failure and in severe cases is a strong indication for heart transplantation.

1.6 Symptoms vary depending on the age of disease onset, but worse outcomes have been seen early in life. These include heart failure, multisystem organ failure and sudden death without prior evidence of heart disease in young children and teenagers. Symptoms in adults include temporary loss of consciousness caused by a fall in blood pressure, rapid heartbeat, mild to moderate impaired emptying and enlargement of the left ventricle, and irregular or abnormal heart rhythm.

1.7 The committee noted that the condition is likely to demonstrate a high penetrance by late adult life. Onset of symptoms can be from infancy.

1.8 The committee noted that there is no curative treatment for the condition, but that treatment for symptoms includes ACE inhibitors to control blood pressure and beta blockers, with therapy also available to control irregular heartbeat, for instance pacemakers or implantable cardiac defibrillators. Treatment may be introduced once heart abnormalities are found but before symptoms develop. This may result in remission of DCM or may delay the onset of symptoms and improve survival and quality of life. Cardiac transplantation is the definitive treatment for progressive DCM and heart failure that cannot be solved using other available therapies.

1.9 The committee is mindful of the anxiety in families with unpredictable cardiac risk.

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

1.11 The committee welcomed the advice of its specialist advisor, Professor Peter Turnpenny, who confirmed that the condition is as described in the papers.

2. Decision

2.1 The committee considered that the condition is serious due to the lack of curative treatment and the risk of sudden death or heart/multi-organ failure.

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.

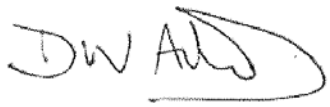
2.3 The committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 to the Act.

2.4 The committee agreed to authorise the testing of embryos for Dilated cardiomyopathy caused by a mutation in the Tropomyosin alpha-1 chain gene, OMIM #611878.

3. Chair's signature

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

Signature



Name

David Archard

Date

10 September 2015