Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Dilated Cardiomyopathy Type 1A OMIM #115200

Thursday, 24 September 2015

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

Committee members	David Archard (Chair, lay) Rebekah Dundas (Deputy Chair, lay) Sue Price (professional) Margaret Gilmore (lay)	
Members of the Executive	Sam Hartley Trent Fisher	Head of Governance and Licensing Secretary
External adviser	Dr Anne Lampe	
Legal Adviser	Ros Foster	Browne Jacobson
Observers	Erin Barton	Projects, Inspections and Logistics Officer

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committe 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 to the Human Fertilisation and Embryology Act 1990 (as amended) ("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 of an embryo being affected with the condition where one parent is affected.

1.5. The committee noted that the condition is one of the many causes of familial dilated cardiomyopathy ("DCM") and it carries a higher risk of sudden death than most other forms of genetic DCM..

1.6. The committee noted that the condition is characterised by enlargement of the left ventricle of the heart with reduced systolic function (i.e. reduced ability to pump blood out of the ventricles leading to heart failure), preceded or accompanied by significant conduction system disease (i.e. blockage of the electrical impulse transmission within the heart) and / or abnormal heart rhythms. Symptoms may include palpitations or episodes of collapse, heart failure with symptoms of breathlessness and fatigue or embolus from a blood clot forming in the left ventricle causing a stroke. Sudden death is not uncommon

1.7. The committee noted that the condition is likely to demonstrate a high penetrance by late adult life. Onset is typically in the third or fourth decades but may be earlier and by the seventh decade penetrance is greater than 90%.

1.8. The committee noted that for those presenting in heart failure standard treatment is used. Cardiac transplantation or other advanced therapies may be required with progressive DCM and advancing heart failure. Because of the risk of malignant heart rhythms, an ICD (implantable cardiac defibrillator) is recommended if the left ventricular function falls below a certain threshold.

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

1.10. The committee welcomed the advice of its specialist advisor, Dr Anne Lampe, who confirmed that the condition is as described in the papers and that the condition is extremely variable and there is a risk of sudden cardiac arrest causing death. Dr Lampe also confirmed that the condition that the application was based on was caused by a mutation in the LMNA gene.

2. Decision

2.1. The committee considered that the condition is serious due to the extreme variability and increased risk of sudden death.

2.2. The committee had regard to its explanatory note and on the basis of the information presented, given the condition's worst symptoms, 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.

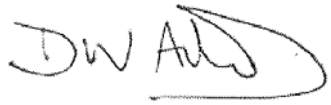
2.3. The committee decided that to avoid any confusion the condition for which testing had been authorised will appear as ‘Dilated Cardiomyopathy type 1A caused by a mutation in the LMNA gene’ on the HFEA approved PGD conditions list.

2.4. The committee agreed to authorise the testing of embryos for Dilated Cardiomyopathy type 1A caused by a mutation in the LMNA gene OMIM #115200.

3. Chair’s signature

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

Signature



Name

David Archard

Date

8 October 2015