Statutory Approvals Committee - minutes

Centre 0102 (Guy's Hospital) – PGD application for Dyskeratosis Congenita OMIM #127550

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 & Logistics Officer

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 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 risk of an embryo being affected with the condition where one parent is affected.

1.5. The committee noted that this condition is a rare multisystem disorder that causes numerous complications including bone marrow failure leading to a reduction in normal blood cells, or abnormal blood cell production that can lead to leukaemia. There is a high risk of developing other cancers of the head and neck, anus and genital regionThe committee noted further that scar tissue can form in the lungs which affects the oxygen absorption into the blood. Other symptoms that may present are low bone mineral density, liver disease, narrowing of the urethra, dental problems, blocked tear ducts and hair loss.

1.6. The committee noted that severity varies widely and may possibly increase in successive generations.

1.7. The committee noted that there is no curative treatment for this condition. The only treatment available is to treat the symptoms that arise.

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

1.9. 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 Dyskeratosis Congenita is a very heterogenous condition and the condition type applied for is caused by a mutation in the TERC gene.

2. Decision

2.1. The committee considered that the condition is serious due to the range and severity of symptoms and lack of treatment for the underlying condition.

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.

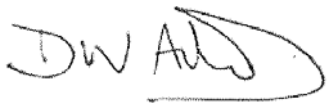
2.3. The committee decided that to avoid confusion the condition will appear as 'Dyskeratosis Congenita due to TERC mutation' on the HFEA approved PGD conditions list.

2.4. The committee agreed to authorise the testing of embryos for Dyskeratosis Congenita due to TERC mutation, OMIM #127550

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