Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital)

Pre-implantation Genetic Diagnosis (PGD) application for

Leigh Syndrome, French Canadian type (LSFC) OMIM #220111

Monday, 23 January 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford	
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser	Dr Ed Blair	
Legal Adviser	Tom Rider	Field Fisher
Observers	Bobby Farsides Bernice Ash	Member (Induction) Committee Secretary

Declarations of interest

- Members of the panel 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
- Additional paper submitted with the application
- Redacted peer review
- Minutes of the Licence Committee on 26 August 2010 which approved Leigh Syndrome (Infantile Subacute Necrotising Encephalopathy), OMIM #185620, as a condition for which PGD can be applied.
- Redacted Public Opinion
- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Dr Ed Blair, who confirmed that the condition is as described in the papers.

1.2. The committee noted that the description in the PGD application for LSFC is consistent with the Peer Review.

1.3. 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.

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

1.5. LSFC is a severe neurological disorder with onset in infancy. The condition is characterised by a progressive loss of mental and physical ability and may result in death within two years due to respiratory failure. Children surviving the neonatal period exhibit global developmental delay and crises, often triggered by infection, causing seizures, hypotonia, multiple organ failure and death. Median age of death in one study was 1.6 years.

1.6. The committee noted that there is no curative treatment for the condition. Treatment is supportive of the symptoms only.

1.7. The committee noted the inspectorate's recommendation to consider the approval of LSFC to be included on the PGD List.

2. Decision

2.1. The committee had regard to its decision tree.

2.2. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph IZA(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'.

2.3. The committee noted that the condition is inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers of relevant mutations.

2.4. The committee noted that the condition demonstrates a 100% penetrance and the onset of symptoms occurs during infancy.

2.5. The committee considered that the condition is serious due to developmental delay and crises, often triggered by infection, causing seizures, hypotonia, multiple organ failure and death. The committee considered the poor quality of life of an affected child and the effect on the family caring for a child with this condition. The committee considered the progressive loss of mental and physical ability and that death may occur within two years due to respiratory failure.

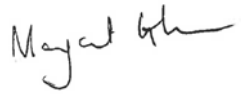
2.6. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition meets the criteria for testing under paragraph IZA(1)(b) and (2) of Schedule 2 of the Act.

2.7. The committee agreed to authorise the testing of embryos for Leigh Syndrome, French Canadian type (LSFC) OMIM #220111.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

10 February 2017