Statutory Approvals Committee – minutes

Centre 0105 (London Women's Clinic)

Pre-implantation Genetic Diagnosis (PGD) application for

Parkinson's Disease, Type 8, OMIM #607060

Thursday, 23 February 2017

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford Bobbie Farsides	
Members of the Executive	Dee Knoyle Siobhain Kelly Erin Barton	Secretary Interim Head of Corporate Governance Governance Manager
External adviser	Dr Mary Porteous	
Legal Adviser	Shelley Edwards	Fieldfisher
Observers		

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
- Redacted peer review
- Genetic Alliance opinion
- Statutory Approvals Committee Minutes of meeting held on 30 April 2015

1. Consideration of application

1.1. The committee welcomed the advice of its specialist adviser, Dr Mary Porteous, who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the PGD application for Parkinson's disease, type 8, OMIM #607060 is consistent with the Peer Review.

1.3. The committee noted that the Genetic Alliance opinion provided a patient's perspective and supported the application.

1.4. 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.

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

1.6. 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'.

1.7. 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 if either parent is a carrier of a relevant mutation.

1.8. The committee noted that Parkinson's disease, type 8 is a slowly progressive disorder of the nervous system in which affected individuals experience variable problems with balance, movement and cognition. Parkinson's disease, type 8 is considered a late onset condition with symptoms starting after the age of 50. The mean age at onset is approximately 60 years, however, in the earliest reported case, the age of onset was 28 years.

1.9. Parkinson's disease typically starts as tremors, slow movement, gait disturbances, mood and sleep disorders, dementia and cognitive decline. Over time, this can progress to severe problems moving, which can result in falls.

1.10. Many affected individuals will become wheelchair bound due to the lack of ability to get around independently. In the most severe forms of the condition, symptoms include losing the ability to care for oneself, not being able to live alone, behavioural disorders, aspiration when eating, deep vein thrombosis, pulmonary embolism and getting to the point when treatment is no longer helpful as the side effects are more damaging to daily quality of life than the benefits gained from the medication.

1.11. The committee noted that there is no curative treatment for the condition but there are therapies which aim to relieve symptoms.

1.12. The committee noted the inspectorate's recommendation to consider the approval of Parkinson's disease, type 8 to be included on the PGD List. The committee agreed to consider the application on this basis.

2. Decision

2.1. The committee considered that the condition is serious due to physical disability, problems with balance, movement and cognition, slowly losing independence and becoming wheelchair bound, affecting an individual's quality of life. The committee also considered the age of onset which can be as early as 28 years. The committee considered the affected individual knowing they have a progressive condition with no cure and how this can lead to depression. The committee also considered the psychological impact on parents carrying the mutation predisposing to the condition themselves, who might experience a sense of guilt when knowingly exposing their children to the risk of inheriting this from them.

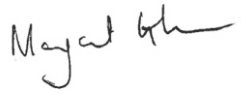
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 of the Act.

2.3. The committee agreed to authorise the testing of embryos for Parkinson's disease, type 8, OMIM #607060.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

10 March 2017