Statutory Approvals Committee – minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Pre-implantation Genetic Diagnosis (PGD) application for

Neuropathy, distal hereditary motor, Type IIA (HMN2A), OMIM #158590

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
- Licence Committee minutes of meeting held on 19 July 2012: Charcot Marie Tooth type 1A
- Licence Committee minutes of meeting held on 28 June 2012: Charcot Marie Tooth type 1A
- Licence Committee minutes of meeting held on 26 January 2012: Charcot Marie Tooth type 2
- Licence Committee minutes of meeting held on 31 March 2011: Charcot Marie Tooth type 1A
- Licence Committee minutes of meeting held on 28 March 2002: Charcot Marie Tooth X-linked

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 Neuropathy, distal hereditary motor, type IIA (HMN2A), OMIM #158590 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 HMN2A is a progressive disorder that affects nerve cells in the spinal cord. The age of onset ranges from the teenage years through to mid adulthood.

1.9. The initial symptoms of HMN2A are cramps or weakness in the muscles of the big toe and, later, the entire foot. Over a period of 5 to 10 years, affected individuals experience a gradual loss of muscle tissue in the lower legs which may lead to trouble walking and running, and eventually complete paralysis of the lower legs. Some individuals may have weakening of the muscles in the hands and forearms.

1.10. The committee noted that there is no curative treatment for the condition.

1.11. The committee noted the inspectorate's recommendation to consider the approval of Neuropathy, distal hereditary motor, type IIA (HMN2A) 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 reduced mobility, a gradual loss of muscle tissue in the lower legs which may lead to trouble walking and running and associated pain, and eventual complete paralysis of the lower legs. In addition, when hands and arms are affected, this could impact on ability to work, future career options and has an impact on daily life. The committee considered the age of onset which could be as early as the teenage years which could have psychological impact at a critical point in the affected individual's life.

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

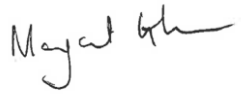
the condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act.

2.3. The committee agreed to authorise the testing of embryos for Neuropathy, distal hereditary motor, type IIA (HMN2A), OMIM #158590.

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