Statutory Approvals Committee - minutes

Centre 0102 (Guy's Hospital) – PGD application for Methylmalonic Acidemia (MMA), OMIM #251000

Thursday, 24 November 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Rebekah Dundas (Deputy Chair) Anne Lampe Ruth Wilde Anthony Rutherford	
Members of the Executive	Siobhain Kelly Trent Fisher	Head of Corporate Governance (interim) Secretary
External adviser	Professor Mary Porteous	
Legal Adviser	Graham Miles – Blake Morgan LLP	
Observers	None	

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
- one additional academic paper submitted with the application
- redacted peer review

- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Professor Mary Porteous, who confirmed that the condition is as described in the papers.

1.2. The committee noted that the application is consistent with the Peer Review and Genetic Alliance opinion.

1.3. 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.

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

1.5. 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'.

1.6. The committee noted that the condition is inherited in an autosomal recessive manner which means there is a 25% chance of having an affected child in each pregnancy, if each parent is a carrier of a relevant mutation.

1.7. The committee noted that the condition is an inborn error of metabolism in which the body is unable to process certain proteins and fats. Symptoms usually appear in early infancy and can vary considerably. Affected babies can experience difficulty gaining weight, vomiting, dehydration, weak muscle tone, excessive tiredness, an enlarged liver and developmental delay.

1.8. The committee also noted that long term problems include intellectual disability, chronic kidney disease, pancreatitis, severe liver damage and metabolic stroke. In the most severe form death can occur within the first four weeks of life.

1.9. The committee noted that treatment includes management of metabolic crises in intensive care at specialist centres, with reduced protein diet and strictly regulated fluids. In spite of intensive care, the majority of individuals will have long term neurological problems and a shorter life expectancy.

1.10. The committee noted that the onset of symptoms is usually from early infancy but individuals with less severe forms can present later in life.

1.11. The committee noted the information included in the application which stated that there were two further conditions Methylmalonic Acidemia cb1A type #251100 and Methylmalonic Acidemia cb1Btype #251110 which are indistinguishable from the condition applied for.

1.12. The committee agreed that there was sufficient evidence within the papers with further corroboration from the External Adviser, to include these further two conditions in their deliberations.

2. Decision

2.1. The committee considered that the conditions are serious due to risk of stroke, kidney failure, early death and almost all individuals sustaining neurological problems.

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

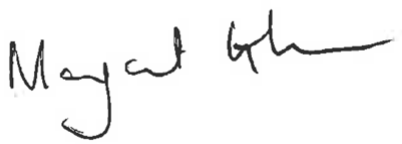
serious illness or any other serious medical condition. The committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 to the Act.

2.3. The committee agreed to authorise the testing of embryos for Methylmalonic Acidemia (MMA), OMIM #251000, Methylmalonic Acidemia cb1A type #251100 and Methylmalonic Acidemia cb1B type #251110 .

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

09 December 2016