Statutory Approvals Committee - minutes

Centre 0035 (Oxford Fertility) – PGD application for Familial Hyperinsulinism OMIM #256450

Friday, 24 June 2016

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

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Margaret Gilmore Anne Lampe Ruth Wilde	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Jenny Carmichael	
Legal Adviser	Dawn Brathwaite	Mills & Reeve 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
- redacted peer review
- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Dr Jenny Carmichael, who confirmed that the condition is as described in the papers. Dr Carmichael stated that within the paperwork there were additional forms of congenital Hyperinsulinism identified that were not listed in the original application.

1.2. The legal adviser confirmed that the committee were not restricted by the conditions listed in the application form. The committee, if it felt it had sufficient information for related conditions to assess the statutory test, could consider additional forms of the condition. To avoid complication, the legal adviser advised that the committee should specifically outline what it would be considering before continuing with the consideration of the application.

1.3. The committee, with the assistance of the specialist adviser, agreed that it had sufficient information to consider the Autosomal Recessive forms of Congenital Hyperinsulinism OMIM #601820 #256450.

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

1.5. The committee noted the Genetic Alliance opinion which helped the committee gain an understanding of the condition from the patient perspective.

1.6. 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.

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

1.8. 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'.

1.9. 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.

1.10. The committee noted that the condition causes the body to produce abnormally high levels of insulin which leads to frequent episodes of low blood sugar.

1.11. The committee noted that as a result of the low blood sugar episodes there is an increased risk for serious complications such as seizures, intellectual disabilities, breathing difficulties, long term neurological damage, coma and brain death.

1.12. The committee noted that the condition is extremely variable with individuals presenting as asymptomatic to presenting with severe episodes.

1.13. The committee noted that the condition is likely to demonstrate a complete penetrance in those with homozygous/compound heterzygous mutations in ABCC8/KNJ11 where the variations are confirmed to cause Congenital Hyperinsulinism. Symptoms present from birth or during infancy.

1.14. The committee noted that there are treatment options available, including intravenous medical therapy, but if this fails subtotal pancreatectomy may be the only option for treatment. This is accompanied by the risk of developing insulin dependent diabetes in later life. Severely affected individuals require constant care and frequent hospital admissions.

2. Decision

2.1. The committee considered that the condition is serious due to the risks of brain damage as well as risks associated with the surgical treatment.

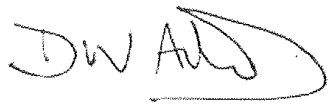
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Autosomal recessive congenital hyperinsulism OMIM #256450 #601820.

3. Chair's signature

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

Signature



Name

David Archard

Date

11 July 2016