Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital) – PGD application for Split hand/foot malformation 3 (SHFM3) OMIM #246560

Thursday, 26 May 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	Edward Blair	
Legal Adviser	Shelley Edwards	Fieldfisher
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
- two reference papers

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Dr Edward Blair, who informed the committee that he has extensive professional experience of this condition. Dr Blair stated that in his experience he had found that the condition presented with a near complete penetrance and that those who inherited the condition would exhibit symptoms of this condition.

1.2. Dr Blair offered one qualification of the peer review in that he did not believe that symptoms such as intellectual disability, hearing problems and renal hypoplasia are associated with this condition and that if these symptoms did appear they would have some other underlying cause.

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 approved PGD condition list.

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 where one parent is affected.

1.8. The committee noted that the condition causes abnormal limb development, which can manifest as extra digits, missing digits and split hands and feet. This can cause a significant disability from reduced hand function and difficulty walking.

1.9. The committee noted that individuals with this condition can suffer from stigmatisation, bullying, low self-esteem and a failure to integrate as they will be less able to enter into a range of activities with their peers.

1.10. The committee noted that the condition is likely to demonstrate a high. Abnormal development occurs in utero and is therefore present at birth.

1.11. The committee noted that the only treatment that is available is treatment for some of the symptoms that present which may include surgery, the need for prosthetic limbs and specialist shoes.

2. Decision

2.1. The committee considered that the condition is serious due both to the severe physical impact of the condition on a range of activities and its damaging psychological effects on the individual.

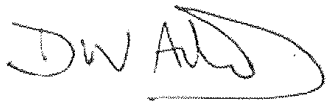
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Split hand/foot malformation 3 (SHFM3) OMIM #246560.

3. Chair's signature

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

Signature



Name

David Archard

Date

10 June 2016