Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital) – PGD application for Kallmann Syndrome type 1 OMIM #308700

Friday, 5 August 2016

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

Committee members	Rebekah Dundas (Chair) Margaret Gilmore Anne Lampe	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Peter Turnpenny	
Legal Adviser	Sarah Ellson	Fieldfisher 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 supporting research publication 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 Peter Turnpenny, 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 the 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 x-linked recessive pattern and there is a 1 in 4 chance of a female carrier having an embryo being affected with the condition.

1.7. The committee noted that the condition affects the production of hormones that direct sexual development.

1.8. The committee noted that males born with this condition may present with an unusually small penis and undescended testicles. At puberty most affected males will not develop secondary sexual characteristics such as facial hair, and deepening of the voice. Also an affected individual's sense of smell can be diminished or absent. Untreated adult males usually have decreased bone density and muscle mass, decreased testicular volume, erectile dysfunction, diminished libido and infertility.

1.9. The committee noted that the condition demonstrates complete penetrance and the onset of symptoms is from birth.

1.10. The committee noted that treatment for the condition involves hormone treatment and if started early enough the treatment can correct the symptoms that present but can not restore smell.

2. Decision

2.1. The committee noted that in those families who would be presenting for PGD for this condition affected individuals may be diagnosed early as the condition can be screened for in males where the underlying gene change has previously been identified. This early diagnosis would enable treatment to be started prior to puberty which would address the most serious symptoms of this condition.

2.2. As there is currently available treatment for many of the symptoms of the condition the committee was not 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.

2.3. The committee therefore decided that the condition did not meet the statutory test of seriousness and refused to authorise the condition for PGD testing.

3. Chair's signature

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

Signature

Name

Rebekah Dundas

Date

19 August 2016