Statutory Approvals Committee - minutes

Centre 0101 (CARE Nottingham) – PGD application for partial androgen insensitivity syndrome OMIM #312300

Thursday, 29 October 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Sue Price Margaret Gilmore Anthony Rutherford	
Members of the Executive	Trent Fisher Sam Hartley	Secretary Head of Governance and Licensing
External adviser	Dr Alan Fryer	
Legal Adviser	Graham Miles	Blake Morgan
Observers	Anna Quinn	Scientific Policy Officer

Declarations of interest:

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel 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
- email clarification from the centre regarding the X-linked risk factors for PAIS carriers

1. Consideration of application

1.1. 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.

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

1.3. 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'. The committee noted that this is not an application for sex testing.

1.4. The committee noted that the condition is inherited in an X-linked pattern and there is a 1 in 2 chance of a male embryo being affected and a 1 in 2 chance of a female embryo being a carrier where the mother is a carrier of the condition.

1.5. The committee noted that the condition is a sex development disorder caused by a mutation in the androgen receptor gene. This causes males to be partially insensitive to androgen the hormone responsible for the development of male genitals during pregnancy.

1.6. The committee noted that males with this condition will have a highly variable genital appearance where severity is graded from having fully masculinised external genitals to fully feminised external genitals. Other characteristics include separation of the two sides of the scrotum, development of breasts during puberty. Males can present with a large clitoris or a micropenis and either descended or undescended testes. Infertility is common. Females will be completely asymptomatic.

1.7. The committee noted that the condition is likely to demonstrate a high penetrance and is extremely variable even within the same family. Onset of symptoms can be detected from birth or may become apparent during puberty.

1.8. The committee noted that there is no curative treatment for the underlying condition. Treatment of symptoms will depend of the sex of rearing that the parents and healthcare professionals assign. An individual may need corrective surgery, hormone therapy, and psychological support.

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

1.10. The committee welcomed the advice of its specialist advisor, Dr Alan Fryer, who confirmed that the condition is as described in the papers adding that regardless of sex of rearing a male with this condition would need to go under a great deal of corrective surgery.

1.11. The committee discussed at length whether the significant and serious test could be met as female carriers present as asymptomatic. The committee's legal advisor reminded the committee that they only needed to judge the condition based on the worse case scenario.

2. Decision

2.1. The committee considered that the condition is serious due to the severity and variability of the symptoms of the condition impact on a male's quality of life.

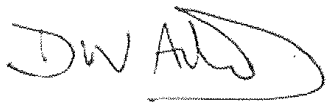
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a male with the abnormality will have or develop a serious physical or mental disability, a serious 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 partial androgen insensitivity syndrome due to defects in the androgen receptor gene, OMIM #312300.

3. Chair's signature

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

Signature



Name

David Archard

Date

11 November 2015