Statutory Approvals Committee – minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Pre-implantation Genetic Diagnosis (PGD) application for

Feingold Syndrome 1, OMIM #164280

Thursday, 29 June 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Bobbie Farsides	
Members of the Executive	Bernice Ash Paula Robinson	Secretary Head of Planning & Governance
External adviser	Dr Alan Fryer	
Legal Adviser	Ros Foster	Browne Jacobson LLP
Observers		

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 adviser, Dr Alan Fryer, who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the application for Feingold Syndrome 1, OMIM #164280 is consistent with the Peer Review.

1.3. The committee noted that the Genetic Alliance opinion provided a patient 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 list of approved PGD conditions.

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 which means there is a 50% chance of having an affected child in each pregnancy, if either parent has a relevant mutation.

1.8. The condition is a rare genetic disorder affecting many parts of the body, including the digestive, cardiac and renal systems. The condition can vary considerably, even within the same family.

1.9. The committee noted that individuals with the condition are typically born with a blockage in one, part of their digestive system, abnormalities of the fingers and toes, small head size (microcephaly) and mild to moderate learning disability. Affected individuals may also have hearing loss, restricted growth, vertebral anomalies and kidney and heart abnormalities.

1.10. The committee noted the peer review which noted that Feingold et al (1997) had reported that 87% of those with Feingold Syndrome 1 had ‘mental retardation or learning difficulties'; Frydman et al (1997) had also reported that 80% had microcephaly and 25% had blockages of the food pipe between the mouth and stomach or the intestine (oesophageal or duodenal atresia).

1.11. The committee noted there is currently no cure for Feingold Syndrome 1. The condition is often serious and affected patients may have a significantly reduced life expectancy, particularly if they require surgery.

1.12. The committee noted the inspectorate’s request to consider whether Feingold Syndrome, OMIM #164280 should be approved for inclusion on the PGD List. If approved, the condition would be named as Feingold Syndrome 1, OMIM #164280 which is consistent with the information published by OMIM. The committee agreed to consider the application on this basis.

2. Decision

2.1. The committee considered that Feingold Syndrome 1, OMIM #164280 is serious given the early onset and the impact on quality of life of this condition, including the possibility of heart and kidney malformations, the prospective number of surgeries required and any associated complications, learning difficulties, risk of reduced life expectancy and the lack of a cure. The committee considered the impact on the family caring for affected individuals.

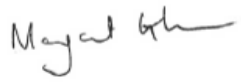
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition of Feingold Syndrome 1, OMIM #164280 does meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act.

2.3. The committee agreed to authorise the testing for Feingold Syndrome 1, OMIM #164280.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

25 July 2017