Item 3

Statutory Approvals Committee – minutes

Centre 0102 (Guys Hospital)

Pre-implantation Genetic Diagnosis (PGD) application for MYH associated polyposis (MAP), OMIM #608456

Thursday, 27 July 2017

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

Committee members	Margaret Gilmore (Chair) Anne Lampe Tony Rutherford Ruth Wilde Bobbie Farsides	
Members of the Executive	Dee Knoyle Paula Robinson	Committee Secretary Head of Planning & Governance
External adviser	Dr Peter Turnpenny	
Legal Adviser	Dawn Brathwaite	Mills & Reeve 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
- Licence Committee minutes from 23 September 2004, licence variation application by centre 0044 to include Familial Adenomatous Polyposis as a condition for which PGD can be applied

1. Consideration of application

1.1. The committee welcomed the advice of its specialist adviser, Dr Peter Turnpenny, who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the application for MYH associated polyposis (MAP), OMIM #608456, 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 recessive pattern and there is a 25% chance of an embryo being affected with the condition if each parent has a relevant mutation.

1.8. The committee noted that MAP is characterised by an increased lifetime risk of colorectal cancer of between 43% and almost 100%, in the absence of careful surveillance, and polyposis (presence of numerous internal polyps). Symptoms normally manifest between 45-60 years of age.

1.9. The committee noted that MAP has also been linked to other related cancers of the thyroid, duodenum, stomach, ovary, bladder and skin. There is also evidence of a slightly increased risk of breast and endometrial cancer. It can be difficult to reliably screen for all these other related cancers. MAP can be variable, even within the same family but is a highly penetrant disorder.

1.10. The committee noted that treatment will include lifelong surveillance for the development of tumours and usually affected individuals will require major surgery for polyp removal, and in many cases complete removal of the bowel. Depending upon the extent and impact of the polyps and whether they develop into malignancies, other cancer therapies may be required.

1.11. The committee noted the inspectorate's request to consider whether MAP, OMIM #608456, should be approved for inclusion on the PGD List. The committee agreed to consider the application on this basis.

2. Decision

2.1. The committee considered that MYH associated polyposis (MAP), OMIM #608456, is serious, given the significant risk of developing colorectal cancer and polyposis. Symptoms normally manifest between 45 to 60 years of age but could occur much earlier in their twenties and thirties and there is no cure. The condition has also been linked to other related cancers. The committee considered the impact on the lives of affected individuals undergoing invasive screening for the development of tumours and major bowel surgery. The committee also considered the difficulties of screening for different types of cancer and that even with screening the risk of developing cancer remains high.

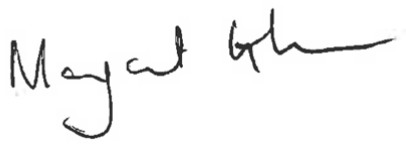
2.2. The committee had regard to its decision tree and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition of MYH associated polyposis (MAP), OMIM #608456, 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 MYH associated polyposis (MAP), OMIM #608456.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

24 August 2017