Statutory Approvals Committee – minutes

Centre 0102 (Guys Hospital)
Pre-implantation Genetic Diagnosis (PGD) application for Focal Segmental Glomerulosclerosis 7 (FSGS7), OMIM #616002

Thursday, 27 April 2017

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

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Anthony Rutherford Bobbie Farsides	
Members of the Executive	Dee Knoyle Paula Robinson Bernice Ash	Secretary Head of Planning & Governance Committee Officer
External adviser	Professor Peter Turnpenny	
Legal Adviser	Graham Miles	Blake Morgan
Observers		

Declarations of interest

- Members of the panel 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 1 March 2012 - approved Renal Coloboma Syndrome, OMIM #120330

1. Consideration of application

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

1.2. The committee noted that the description in the PGD application for Glomerulosclerosis (focal segmental) with kidney failure, OMIM #616002 is consistent with the Peer Review.

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 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. Patients with this condition have significant proteinuria and some will also have features of nephrotic syndrome. Some go on to develop end stage renal disease and require a renal transplant. This condition has a variable age of onset from late childhood to adulthood. This condition is fully penetrant, although there is variability in severity.

1.9. Treatment aims to reduce blood pressure, oedema and proteinuria through diet and medication. Treatments include anti-hypertensive drugs, a low protein diet, dialysis and some patients require a kidney transplant.

1.10. The committee noted that there is no curative treatment for the condition.

1.11. The committee noted the inspectorate’s recommendation to consider the approval of Glomerulosclerosis (focal segmental) with kidney failure, OMIM #616002 to be included on the PGD List, named as Focal Segmental Glomerulosclerosis 7 (FSGS7), OMIM #616002, which is in line with the information published by OMIM. The committee agreed to consider the application on this basis.

2. Decision

2.1. The committee considered whether Focal Segmental Glomerulosclerosis 7 (FSGS7), OMIM #616002 is a serious condition. The onset of the condition may be as early as childhood. Affected individuals have problems with kidney function which is progressive and some go on to develop end stage kidney disease and require a transplant and dialysis. The condition is managed through diet, anti-hypertensive drugs and dialysis, however there is no cure. This is a life threatening condition with associated complications including strokes. The committee considered the psychological effects on the parents, knowing that their children could inherit this condition. The committee also considered the impact on the quality of life of affected individuals.

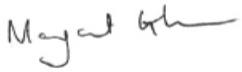
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition Focal Segmental Glomerulosclerosis 7 (FSGS7), OMIM #616002 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 of embryos for Focal Segmental Glomerulosclerosis 7 (FSGS7), OMIM #616002 and agreed that the condition should be included on the PGD List on the HFEA website named as Focal Segmental Glomerulosclerosis 7 (FSGS7), OMIM #616002.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

15 May 2017