Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Congenital Dyserythropoietic Anaemia, types 1a, 1b, 2 and 3 OMIM #224120 #615631 #224100 #105600

Thursday, 26 November 2015

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

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Sue Price Anthony Rutherford Bishop Lee Rayfield	
Members of the Executive	Trent Fisher Sam Hartley	Secretary Head of Governance and Licensing
External adviser	Professor Mary Porteous	
Legal Adviser	Jane Williams	Mills & Reeve
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
- redacted peer review
- OMIM entries for CDAN types 1a, 1b, 2 and 3
- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Professor Mary Porteous, who informed the committee that the paperwork for the application referred mainly to Congenital Dyserythropoietic Anaemia types 1a, 1b and 2. Professor Porteous advised the committee that there may be insufficient information before it today to make an informed decision on type 3.

1.2. The committee, noting that the application had been made for the authorisation of PGD testing for 4 types of Congenital Dyserythropoietic Anaemia but that the centre had a particular patient awaiting PGD testing for only type 1a, sought the advice of its legal adviser. On the basis of the advice received, the committee, noting the observations of Professor Porteous on the adequacy of the paperwork before it, decided that there was insufficient information to reach a decision in respect of Congenital Dyserythropoietic Anaemia type 3. The committee accordingly decided to decline the application in respect of type 3 as it would be unable to reach a fully informed decision. The committee decided, however, that it had sufficient information before it to continue to consider the application in respect of Congenital Dyserythropoietic Anaemia types 1a, 1b and 2.

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 (types 1a, 1b and 2) 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 (types 1a, 1b and 2) is inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers.

1.7. The committee noted that the condition is characterised by moderate to severe forms of anaemia. In its most severe form the anaemia can result in the fetus developing hydrops fetalis (accumulation of fluid in one or more areas of the foetus) causing swelling and often resulting in death shortly before or after birth.

1.8. The committee noted that symptoms can include swelling of the liver, enlargement of the spleen, jaundice and delayed growth. Individuals will also need life-long monitoring for iron overload resulting from multiple transfusions which in its most severe form can cause shortness of breath, arthritis, liver disease, diabetes and heart failure. Additionally, a proportion of individuals with type 1 are born with anomalies of the distal limbs.

1.9. The committee noted that the condition demonstrates complete penetrance; age at onset is variable, ranging from before birth through to adolescence and young adulthood.

1.10. The committee noted that there is no curative treatment for the condition but management of the condition may include regular blood transfusions and, in extreme cases, bone marrow transplant which carries risks of infection and graft versus host disease.

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

2. Decision

2.1. The committee considered that the condition is serious due to the severity of presenting symptoms and lack of any curative treatment.

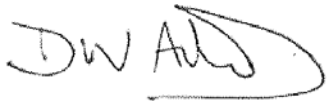
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition 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 Congenital Dyserythropoietic Anaemia, types 1a, 1b and 2, OMIM #224120 #615631 #224100.

3. Chair's signature

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

Signature



Name

David Archard

Date

10/12/2015