Statutory Approvals Committee – minutes

Centre 0102 (Guy's Hospital)
Pre-implantation Genetic Diagnosis (PGD) application for Immunodeficiency 44 (IMD 44), OMIM #616636

Thursday, 13 December 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Anthony Rutherford Emma Cave	
Members of the Executive	Dee Knoyle Catherine Burwood Paula Robinson	Committee Secretary Senior Governance Manager (Observer) Head of Planning and Governance (Observer)
Legal Adviser	Eve Piffaretti	Blake Morgan LLP
External adviser	Dr Jenny Carmichael	
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 UK statement
- Licence committee minutes 11 Sept 2008; application for PGD-HLA for Wiscott-Aldrich syndrome.
- Supporting paper - Hambleton S et al 2013
- Supporting paper - Shahni R et al 2015

1. Consideration of application

1.1. The committee welcomed the advice of its Specialist Adviser, Dr Jenny Carmichael who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the application for PGD for Immunodeficiency 44 (IMD 44), OMIM #616636 is consistent with the peer review.

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

1.4. The committee noted that the Genetic Alliance opinion provided a patient perspective and supported the application.

1.5. 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.

1.6. 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 which means there is a 25% chance of an embryo being affected with the condition in each pregnancy, if both parents have a relevant mutation. The penetrance of the condition is not known however the medical literature, and the fact the condition is autosomal recessive, suggest it is high.

1.8. The committee noted that IMD 44 is a variable condition, however those affected cannot respond appropriately to viral or bacterial infections. Affected individuals are at risk of severe multisystem disorder resulting from overwhelming viral or bacterial infections such as meningitis and septicaemia or some vaccinations. The sequelae from the viral infection may be variable but have included death and severe neurological impairment.

1.9. The committee noted that treatment for the condition is supportive and there is no curative treatment. Individuals with neurological deficit are more likely to have developmental problems and require lifelong medical treatment and care. Children may need intensive care.

1.10. The committee noted the inspectorate's request to consider whether Immunodeficiency 44 (IMD 44), OMIM #616636 should be approved for inclusion on the list of conditions approved for PGD.

1.11. The committee noted that IMD 44 is one of a number of inherited Immunodeficiency (IMD) syndromes and that the inspectorate also requests that other types of IMD, which have a similar clinical outcome as IMD 44 are considered for inclusion on the list of conditions approved for PGD. The committee accepted the advice from its Specialist Adviser who confirmed the similarities and agreed to consider the following conditions on this basis:

- Immunodeficiency 44 (IMD 44)
- Immunodeficiency 9, OMIM #612782
- Immunodeficiency 19, OMIM #615617
- Immunodeficiency 24, OMIM #615897
- Immunodeficiency 31B, OMIM #613796
- Immunodeficiency 40, OMIM #616433

2. Decision

2.1. The committee considered that, in the worst case scenario Immunodeficiency (IMD) is a serious condition. Babies are born healthy and as a result of a viral or bacterial infection or vaccination could develop a severe multisystem disorder affecting many parts of the body including multiorgan failure. Individuals that survive infections resulting in neurological disorder require lifelong support. There is no cure for this condition which is life-threatening and could cause death in infancy.

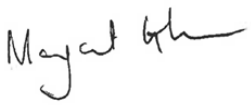
2.2. The committee had regard to its explanatory note and confirmed that, on the basis of the information presented, it was satisfied that there is a particular risk that an embryo may have the abnormality in question and that there is a significant risk, given the condition's worst symptoms, that a 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 following conditions meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act and agreed to authorise testing:

- Immunodeficiency 44 (IMD 44)
- Immunodeficiency 9, OMIM #612782
- Immunodeficiency 19, OMIM #615617
- Immunodeficiency 24, OMIM #615897
- Immunodeficiency 31B, OMIM #613796
- Immunodeficiency 40, OMIM #616433

3. Chairs signature

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

Signature



Name

Margaret Gilmore

Date

17 January 2019