HFEA Licence Committee Meeting

24 February 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0044 (The Centre for Reproductive and Genetic Health) PGD for Haemoglobin E/ beta-thalassaemia

Members of the Committee: David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Sue Price (professional)	Committee Secretary: Terence Dourado Legal Adviser: Sarah Ellson, Field Fisher

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Executive Summary
- PGD Application Form
- Oliveri N F et al (2008) Studies in haemoglobin E beta-thalassaemia. *British Journal of Haematology* 141: 388-397
- Vichinsky E (2007) Haemoglobin E syndromes. *Haemotology: The American Society of Haemotology*. 2007: 79-83

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy

- Policy on Publication of Authority and Committee Papers
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note for Licence Committee

1. The Committee noted that it had been asked to consider whether PGD for Haemoglobin E/ beta-thalassaemia may be carried out under the title of beta-thalassaemia (OMIM +141900) and; whether other variations on beta-thalassaemia, for example sickle cell/ beta-thalassaemia, may also be carried out under the title of beta-thalassaemia (OMIM +141900).

2. The Legal Adviser reminded the Committee that the HFEA convention of licensing PGD by reference to OMIM numbers was simply a convention and a robust way of clearly indicating and identifying the gene abnormality for which it was authorising the testing of embryos. The provisions of paragraph 1ZA of Schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended) do not refer to OMIM numbers.

3. Leaving aside other circumstances where testing may be authorised, the legislation makes clear that before authorising the testing of an embryo in a case where there is a particular risk that the embryo may have a gene abnormality, the Committee must be 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.

4. The Committee's preliminary discussions for this item indicated that Beta-thalassaemias, haemoglobin E and conditions predisposing to a combination of Beta-thalasaemia with sickle cell disease were all conditions which could arise from an abnormality on the gene identified by OMIM number +141900.

5. In considering this application the Committee would need to determine how the Authority wanted to approach the situation of having a wide range of conditions which could arise as a consequence of an abnormality which would be identified by testing +141900. Although not strictly a legal matter the Legal Adviser suggested that because the legislation did not define how authorisations might be referenced there were at least two options. One option would be to clarify that once PGD was authorised for OMIM +141900 testing for any condition arising from an abnormality of that gene would be permitted for suitably licensed centres, subject to the provisions of the Code of Practice and in particular 10.6. [Paragraph 10.6 requires centres to consider a number of factors when deciding if PGD is appropriate in a particular case including the degree of suffering, speed of degeneration etc.]

6. If the Committee were minded to take this route it might wish to refer to its guidance note at paragraph 5.5 (although this refers to a "condition" not a gene abnormality), and explain (if this was the case) that authorisation was being granted (or confirmed) given the worse possible symptoms of a condition arising from an abnormality of this gene.

7. An alternative option would be to authorise PGD by reference to specific and separate conditions and to clarify that different conditions, arising from abnormalities of the same gene, each required their own authorisation.

8. The Committee were minded to decide that once PGD was authorised for OMIM +141900 testing for any condition arising from an abnormality of that gene should be permitted for suitably licensed centres, subject to the provisions of paragraph 10.6 of the Code of Practice. However, the Committee request that it receives the minutes of the meeting or meetings where the PGD conditions arising from OMIM +141900 was/were first considered by a committee, before it is able to make a fully informed decision.

9. The Committee adjourned consideration of the item and request that the Executive submit the documentation requested in paragraph 8 for consideration at the next available licence committee meeting.

Signed ..... Date 9/8/2011.

David Archard (Chair)