HFEA Licence Committee Meeting

29 November 2012

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

Minutes – Item 2

Centre 0078 (IVF Hammersmith) – PGD for Hereditary Haemorrhagic Telangiectasia or Rendu-Osler-Weber Syndrome (OMIM #187300)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Sue Price (professional) Jane Dibblin (lay) Rebekah Dundas (lay) – (Videoconference)	Lauren Crawford Legal Adviser: Sarah Ellson, Field Fisher Waterhouse

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

- Cover sheet
- Executive Summary
- PGD Application form
- Genetic Alliance Opinion

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

Discussion

1. 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.

2. The Committee noted that the supporting documents with this application did not contain a Peer Review. The committee were satisfied that the application form and the Genetic Alliance opinion contained sufficient information on which to make a decision.

3. The Committee noted that the Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, ie. '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'. The Committee did not accept that the purpose of testing was to establish whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capability to result in a live birth (as also suggested in the application form).

4. The Committee noted Hereditary Haemorrhagic Telangiectasia or Rendu-Osler-Weber Syndrome (OMIM #187300) is a disorder that is inherited in an autosomal dominant manner. Therefore there is a 1 in 2 chance that an embryo will inherit the condition from an affected parent..

5. The Committee noted that although the severity of the disease can vary within each family and symptoms can increase over a lifetime, it is not possible to predict how severe the presentation will be. Hereditary Haemorrhagic Telangiectasia or Rendu-Osler-Weber Syndrome is highly penetrant and the vast majority of people born with the gene will develop symptoms of some kind.

6. Patients have very frequent blood vessel malformations. These range from problems in the smallest vessels, the capillaries, which cause nose bleeds and cosmetic problems (telangiectases); to large malformations in larger blood vessels; large arteriovenous malformations (AVMs). The most common AVM location is the lungs. These occur in approximately half of all patients

with the condition. The effect of these malformations in the blood vessels in the lungs is that blood is not properly oxygenated and the arterial system is exposed to infection and blood clots. The lack of oxygenation in the blood leads to shortness of breath and difficulty with exercising. Cerebral AVMs occur in patients with the condition (according to the literature in 1 in 10 cases). Cerebral AVMs may cause strokes, headaches, fits and abscesses. The liver, spine and intestines can also be affected causing anaemia and, in rare cases, liver failure. Complications like bleeding or shunting may be sudden and catastrophic.

7. The Committee noted that treatment options include humidification, nasal lubricants or surgery for recurrent nosebleeds, iron replacement therapy or endoscopic surgery for intestinal bleeding and liver transplantation for the patients who cannot be treated medically. Malformations in larger blood vessels in the brain are treated with surgery, embolotherapy or radiation therapy. Women may have particular problems during pregnancy because of the raised circulation and bleeding at delivery.

8. Treatment options are not curative and are invasive, involving major surgery with risks.

9. The Committee considered the condition is serious noting in particular the most serious symptoms described above.

10. The Committee noted that the application is supported by the Genetic Alliance UK.

11. The Committee agreed to authorise the testing of embryos for Hereditary Haemorrhagic Telangiectasia or Rendu-Osler-Weber Syndrome (OMIM #187300). The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 10/12/2012

David Archard (Chair)