HFEA Statutory Approvals Committee

30 October 2014

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

Minutes – Item 4

Centre 0006 (The Lister Fertility Clinic) – PGD application for Alport Syndrome OMIM #203780

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Lauren Crawford, Committee Officer
Sue Price (professional)	
Debbie Barber (professional)	
Rebekah Dundas (lay)	Legal Adviser:
Jane Dibblin (lay)	Dawn Brathwaite, Mills & Reeve
Advisor: Dr Peter Turnpenny	

Declarations of Interest: The Members declared no conflicts in relation to this item.

The following papers were considered by the Committee:

- Executive summary
- PGD application form
- Redacted Peer Review 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) ("the Act")
- 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 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'.

3. The Committee noted that Alport Syndrome OMIM #203780 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.

4. The Committee noted that Microscopic haematuria (blood in the urine) is the first clinical sign, always present by the age of 5 years, usually becoming macroscopic (visible to the naked eye) during intercurrent infections. Patients then develop proteinuria and hypertension. They need regular review in paediatric renal clinics from presentation as gradual progression to end stage renal failure is inevitable, although the age at which dialysis or transplantation is required can be postponed by an average of 13 years if treatment with ACE inhibitors is initiated as soon as there is significant proteinuria or hypertension. The age at which patients require renal replacement therapy ranges from 9 years to 35 years. Some patients die before a suitable kidney is found for them and some die from complications of the required post-treament. Unlike other inherited kidney conditions, carriers of autosomal recessive Alport's are not usually regarded as potentially suitable kidney donors as they have a 15% lifetime risk of developing renal impairment themselves and should also be offered lifelong follow-up with early consideration of ACE inhibition. Patients with Alport Syndrome usually also have progressive sensorineural deafness and may develop characteristic eye signs, including anterior lenticonus requiring surgical lens extraction.

5. The Committee noted that there is no known cure for Alport Syndrome and any available treatment is for the symptoms of the conditions. Proteinuria (the presence of protein in the urine, indicative of kidney problems), is often treated with ACE inhibitors, which are used mainly in the treatment of high blood pressure. Once kidney failure has developed, patients are given a dialysis or a kidney transplant. This is not always successful as the new kidney may be recognised as foreign by the body and its immune system. Alport Syndrome is a chronic progressive disease in which sufferers will require lifelong medical investigation, intervention and often significant surgery which still may not improve the long-term prognosis. Quality of life for those affected is also significantly impaired throughout the course of the disease due to the ocular, renal and auditory symptoms.

6. The Committee welcomed the advice of its advisor, Dr Peter Turnpenny. Dr Turnpenny confirmed that the condition is as described in the papers. He also added that with this type of Alport Syndrome renal failure is not late onset.

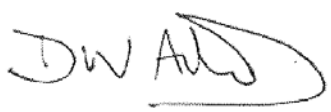
7. The Committee noted that the application is consistent with the Peer Review and is also supported by the Genetic Alliance.

8. The Committee considered that the condition is serious because it is an incurable condition that, taken in its worst form, would have a profound effect on the patient's quality of life.

9. 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.

10. The Committee agreed to authorise the testing of embryos for Alport Syndrome OMIM #203780.

Signed: Date: 13/11/2014



David Archard (Chair)