HFEA Statutory Approvals Committee

27 February 2014

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

Minutes – Item 8

Centre 0006 (The Lister Fertility Clinic) – PGD application for Congenital Secretory Chloride Diarrhoea OMIM #214700

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Mary Porteous	Committee Secretary: Lauren Crawford Legal Adviser: Stephen Hocking, DAC Beachcroft Also in attendance: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: Hossam Abdalla left the meeting before this item as he is the PR (Person Responsible) at this centre. The Members present declared no conflicts in relation to this item.

The following papers were considered by the Committee

- Executive summary
- Application form
- Redacted peer review

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 Congenital Secretory Chloride Diarrhoea (OMIM #214700) 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 symptoms of Congenital Secretory Chloride Diarrhoea include persistent watery diarrhoea resulting in dehydration, poor muscle tone, abnormal gut motility and a large abdomen.

5. The Committee noted the effects in specific age ranges:

   Newborn - premature birth and complications of prematurity;
   Infancy - chronic watery diarrhoea that may require hospital admission to address dehydration and electrolyte imbalance. These children have low potassium and sodium and this can cause low muscle tone and poor development. If the dehydration and electrolyte imbalance is not managed aggressively, it can result in death;
   Childhood - chronic ill health and social impact as a consequence of long standing diarrhoea and frequent soiling. Frequent hospital admissions. Also adverse impact on growth;

As an adult - Secondary gut inflammation and renal failure has been reported as a complication of congenital secretory chloride diarrhoea. Chronic kidney disease develops in nearly 30% of the affected individuals. In males, there is subfertility.

6. The Committee noted that the age of onset of Congenital Secretory Chloride Diarrhoea is early and some features can be observed prenatally. Infants are usually born premature.

7. The Committee noted that there is no curative treatment for this disorder. Treatment is supportive with lifelong diet monitoring and aggressive salt replacement therapy. If not treated aggressively the condition can cause death by 6 months of age.

8. The Committee noted that the application is supported by the Peer Reviewer.

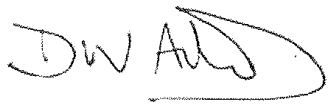
9. The Committee welcomed the advice of its Advisor, Mary Porteous, who confirmed that the condition was as described in the papers.

10. The Committee considered that the condition is serious because it is a lifelong disorder which severely impacts on the quality of life.

11. 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.

12. The Committee agreed to authorise the testing of embryos for Congenital Secretory Chloride Diarrhoea (OMIM #214700).

Signed: Date: 11/03/2014



David Archard (Chair)