HFEA Licence Committee Meeting

28June 2012

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

Minutes – Item 1

Centre 0102 (Guy's Hospital) – PGD for Early-onset Alzheimer disease Type 3 & 4 (OMIM #607822 & #606889)

Members of the Committee: David Archard (lay) Chair Anna Carragher (lay) Sue Price (professional) Rebekah Dundas (lay) - VC	Committee Secretary: 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
- Redacted Peer Review
- 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 considerable 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 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'.

3. The Committee noted Early-onset Alzheimer disease (types 3 and 4 OMIM #607822 & #606889) is a disorder that is inherited in an autosomal dominant manner. There is a 1 in 2 chance of an embryo being affected by this condition where a parent is affected.

4. The Committee noted symptoms of the disease include adult-onset progressive dementia associated with cerebral cortical atrophy, beta-amyloid plaque formation, and intraneuronal neurofibrillary tangles. This typically begins with subtle memory failure that becomes more severe and is eventually incapacitating. Other common findings include confusion, poor judgment, language disturbance, agitation, withdrawal, hallucinations, seizures, Parkinsonian features, increased muscle tone, myoclonus, incontinence, and mutism. Death usually results from malnutrition and pneumonia.

5. The Committee noted that the degree of penetrance is consistently high but varies slightly depending on the gene mutation. Type 3 is almost 100% penetrant by 65 years of age and type 4 is 95 % penetrant. Type 3 age of onset is typically 30-55 years and with type 4 it is typically 40-65 years.

6. The Committee noted that there is no cure for this disease and treatment is supportive only. Affected individuals will eventually require assisted living arrangements and/or nursing home care. Treatment includes medical and behavioural management of depression, aggression, sleep

disturbance, seizures, and hallucinations. Depression and seizures should be treated with appropriate medications. Physical and occupational therapy may help manage gait problems and daily living activities.

7. The Committee noted that the condition is serious because ~~the~~ disease progression is often rapid (< 5 years), life expectancy is significantly reduced and there is no curative treatment. Early-onset Alzheimers disease is devastating ~~to~~ for both patients and their families. The impact of the condition begins before onset and continues throughout the lives of all of the family members, especially the patient's children, who will have witnessed the profound deterioration this condition causes.

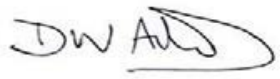
8. The Committee noted that the application is supported by the Peer Reviewer as well as by Genetic Alliance UK.

9. The Committee 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. Accordingly, it was appropriate to grant the application under paragraph 1ZA(1)(b) of Schedule 2 to the Act.

10. The Committee noted that while they may grant approval, the centre providing PGD for the condition must also ensure that each individual case treated fulfills the severity criteria of Schedule 2 paragraph 1ZA of the HFE Act 1990 (as amended).

11. The Committee agreed to authorise the testing of embryos for Early-onset Alzheimer disease (OMIM #607822 & #606889). The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 03/07/2012



David Archard (Chair)