HFEA Statutory Approvals Committee

30 October 2014

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

Minutes – Item 5

Centre 0119 (Birmingham Women's Hospital) – PGD application for Finnish Nephrotic Syndrome Type 1 OMIM #256300

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 Finnish Nephrotic Syndrome Type 1 OMIM #256300 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 Finnish Congenital Nephrotic Syndrome, Type 1; NPHS 1 OMIM #256300 is a rare form of kidney failure (nephrotic syndrome), which is characterised by the appearance of protein in the urine. In the worst case scenario, affected babies are born prematurely and have large placentas which account for up to 25% of their total body weight. Babies are puffy and swollen at birth (oedematous) or become so shortly afterwards and in most cases, abdomens are enlarged due to retention of fluid. Scans usually reveal enlarged kidneys. Babies can develop chronic renal failure which is fatal if left untreated. Other symptoms of the condition include a propensity to infections and blood clots and higher than normal levels of lipids in the blood which can increase the risk of heart disease.

5. The Committee noted that symptoms of the condition are apparent from birth.

6. The Committee noted that children may require one or both kidneys to be removed in order to prevent protein loss and continuous dialysis is

required until the child reaches a weight at which a kidney transplant may be considered, assuming a suitable donor can be found. Children with Finnish Congenital Nephrotic Syndrome, as opposed to other forms of the condition, do not respond to steroid treatment

7. The Committee welcomed the advice of its advisor, Dr Peter Turnpenny. Dr Turnpenny advised that with this condition the kidney failure is the most risk to a young infant. The availability of child-sized organs for transplant are minimal.

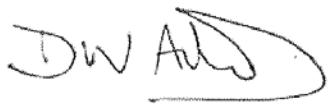
8. The Committee noted that the application is consistent with the Peer Review and is also supported by the Genetic Alliance.

9. The Committee considered that the condition is serious because affected babies fail to thrive and are particularly prone to infections and blood clots. Children who survive these early complications progress to renal failure and, without treatment, die in early childhood.

10. 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.

11. The Committee agreed to authorise the testing of embryos for Finnish Nephrotic Syndrome Type 1 OMIM #256300.

Signed: Date: 13/11/2014



David Archard (Chair)