HFEA Licence Committee Meeting

12 August 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

The Assisted Conception Unit (UCH) (0044) – Addition of PGD for occulopharangeal muscular dystrophy (OPMD; OMIM 164300) to the licence

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) -- Chair Rebekah Dundas (lay) Richard Harries (lay) Emily Jackson (lay)	Kristen Veblen Legal Adviser: Stephen Hocking, Beachcroft LLP
Apologies: William Ledger (clinician)	

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:

- papers for licence committee (18 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

1. The Committee considered the papers, which included an Executive Summary, application form, peer review and a paper on the condition, provided by the peer reviewer.
2. The Committee noted that OMPD was a form of late-onset, progressive muscle weakness, characterised by eyelid drooping, difficulty swallowing and, sometimes by other head and limb muscle involvement. The disorder presents in the fourth to sixth decade with progressive, often symmetrical eyelid droop, resulting in a compensating contraction of the forehead muscle and therefore a backward tilt of the neck. Difficulty swallowing is also an early symptom and can lead to nasal regurgitation and severe episodes of aspiration. Limb-girdle muscle weakness, especially in the pelvic girdle, is often noted but varied and proximal limb-muscle weakness may lead to some patients becoming wheelchair dependant.
3. Additionally, the Committee noted that this was an autosomal dominant condition; therefore embryos have a 1 in 2 chance of being affected.
4. The Committee noted that some supportive treatment was available and consists of eyelid surgery and myotomy of the cricopharyngeal muscle, but that this is only available in carefully selected cases. However, the Committee considered that the course of the disease affects people differently and that the available therapy was not sufficient given the potential speed of degeneration.
5. The Committee noted that the peer-reviewer supported the application and considered OPMD to be a serious genetic condition. The Committee agreed that the peer reviewer had turned his or her mind specifically to the question of whether this disease was serious in the context of an application for PGD, and had concluded that it was.

<u>The Committee's Decision</u>

6. The Committee considered the guidance given in the 7th Code of Practice at G.12.3.3 (c), (d) and (e) and agreed based on the discussion above that there was a high degree of likely suffering associated with the disease, that the available therapy was insufficient and that the speed of degeneration may, in some cases be quite rapid.
7. The Committee agreed that the patient information and generic PGD forms, which the peer reviewer had previously reviewed, were satisfactory and that counselling arrangements, as judged by the peer reviewer were satisfactory.

8. The Committee was satisfied that a licence should be granted to carry out PGD selection for the purpose of avoiding OPMD, being a practice designed to secure that embryos were in a suitable condition to be placed in a woman, as outlined in Schedule 2, paragraph 1(1)(d) of the HFE Act 1990 (as amended).
9. The Committee considered that in accordance with Schedule 2, paragraph 1(3) of the HFE Act 1990 (as amended), a treatment licence could not authorise any activity unless it appeared to the Committee to be necessary or desirable. The Committee agreed, on the basis of the above discussion and the support of the peer reviewer that PGD for the avoidance of OPMD was necessary and desirable for the purpose of providing treatment services.
10. The Committee decided to vary the Centre's licence to add PGD for the avoidance of occulopharangeal muscular dystrophy (OMIM 164300).

Signed..Anna Carragher..... Date..25.8.2009
Anna Carragher (Chair)