HFEA Licence Committee Meeting
22 June 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

The Bridge Centre (0070) – Variation to add PGD condition: multiple exostoses

Members of the Committee:	Committee Secretary:
	Kristen Veblen
David Archard (lay) – Chair	
Jennifer Hunt (counsellor)	Legal Adviser:
Hossam Abdalla (clinician)	Mary Timms, Field Fisher Waterhouse
	Observers:
	Mark Bennett, HFEA
	Peter Thompson, HFEA

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 (51 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 to vary the licence, letter from Professor Patton, peer review and article about the condition.

2. The Legal Adviser reminded the Committee 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 for the purpose of providing treatment services.

3. The Committee noted that hereditary multiple exostoses (HME) was a rare medical condition in which multiple bony spurs or lumps developed on the bones of a child in areas of active bone growth, particularly the metaphysic of the long bones. HME could lead to the shortening and bowing of bones, and depending on location, the exostoses could cause pain or numbness from nerve compression, vascular compromise, inequality of limb length, irritation of tendon and muscle, as well as limited range of motion at the joints upon which they encroached. Additionally, the most serious side effect of HME was an increased risk of developing chondrosarcoma, a rare form of bone cancer, as an adult.

4. The Committee noted that this condition is inherited in an autosomal dominant manner. Therefore offspring of an affected individual had a 50 per cent risk of inheriting the disease-causing mutation and penetrance was approximately 96 per cent. Additionally, the Committee noted that the risk of bone cancer was 0.5 to 5 percent.

5. Further, the Committee noted that HME patients struggled with pain, fatigue and mobility problems throughout their lives and most patients underwent numerous surgical procedures throughout their lives to remove painful or deforming exostoses, correct limb length discrepancies or improve the range of motion.

6. The peer review expressed the opinion that this is a genetic condition for which PGD could be supported and the Committee bore in mind this recommendation in making its decision.

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

7. The Committee considered the guidance given in the 7th Code of Practice at G.12.3.3 (c) and (d) and agreed that there was a high degree of suffering associated with this condition and that currently there was no

effective cure available, and no evidence that there would be an effective cure for this condition in the foreseeable future.

8. The Committee agreed that based on the information before it, it considered HME a serious genetic condition, which posed a significant risk of being present in the embryo, as described by 7th Code of Practice section G.12.3.2. The Committee considered it a serious genetic condition because at its worst it may cause pain, fatigue, mobility problems and require numerous surgical procedures, and also carried a small risk of cancer.

9. The Committee was satisfied that those seeking treatment and their family had access to proper counselling about the implications of the procedure.

10. The Committee was satisfied that a licence should be granted to carry out PGD selection for the purpose of avoiding HME, being a practice designed to secure that embryos were in a suitable condition to be placed in a woman (Schedule 2, paragraph 1(1)(d) of the HFE Act 1990 (as amended)) and agreed that, taking into account all the matters set out above, this practice was necessary and desirable for the purpose of providing treatment services (Schedule 2, paragraph 1(3) of the HFE Act 1990 (as amended)).

11. The Committee decided to vary the Centre's licence to add PGD for avoidance of HME (OMIM 133700).

Signed..... Date...7/July/09
David Archard (Chair)

Addendum

1. Subsequent to the Committee's decision, the Committee considered whether the minutes of this meeting should be published, because of concerns regarding the maintenance of patient confidentiality.

2. Further to this concern, the Chair sought expert advice from Professor Neva Haites, Consultant Clinical Geneticist, University of Aberdeen.

3. Professor Haites gave the following advice:

   Hereditary multiple exostoses affects about 1 in 50,000 people, so will be regarded as a relatively common condition and as such, I would not see a problem with it being mentioned as a decision.

4. Taking into consideration this advice, as well as the information about the prevalence of the disease presented in the papers, the Committee agreed that HME may be considered relatively common and as such, the release of these minutes for publication would present no danger of patient identification.

5. The Committee decided not to withhold these minutes from publication.