

HFEA Licence Committee Meeting

22 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 7

Guys Hospital (0102) – Variation to add PGD condition – Autosomal recessive polycystic kidney disease (OMIM 263200)

Members of the Committee:

Committee Secretary:

Kristen Veblen

Present:

Anna Carragher (lay) – Chair
Rebekah Dundas (lay) – by videolink
Richard Harries (lay)

Legal Adviser:

Mary Timms, Field Fisher
Waterhouse

Apologies:

Emily Jackson (lay)
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 (35 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 additional information about autosomal recessive polycystic kidney disease (ARPKD).
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 ARPKD lies on Chromosome 6 and was called PKHD1. The Committee noted that a couple seeking treatment will have a 1 in 4 chance of having an affected child in any pregnancy.
4. Further, the Committee noted that this was a rare disorder characterised by the development of cysts in the kidney and often the liver. The condition can cause large kidneys with multiple cysts, high blood pressure and urinary tract infections as well as portal hypertension, biliary duct infection, and renal function. The Committee heard that end-stage renal failure generally occurred after 15 years, but could occur within 5 to 10 years and that the only available treatment was dialysis or renal transplantation.
5. The Committee noted that the Peer Reviewer was of the opinion that this was a genetic condition for which PGD could be supported and the Committee bore in mind this recommendation in making its decision.

The Committee's Decision

6. 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, the only treatment being dialysis or renal transplantation.
7. The Committee agreed that based on the information before it, it considered ARPKD a serious genetic condition, as described by 7th Code of Practice section G.12.3.2, which posed a significant risk of being present in the embryo,. The Committee considered it a serious genetic condition taking into consideration the symptoms discussed above and that the only long term treatment option was transplantation.
8. The Committee was satisfied from the Peer Review that those seeking treatment would have access to proper counselling about the implications of the procedure and that the Patient Information leaflet was good.
9. The Committee was satisfied that a licence should be granted to carry out PGD selection for the purpose of avoiding ARPKD, 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, in accordance with Schedule 2, paragraph 1(3) of the HFE Act 1990 (as amended).

Signed.....**Approved by the Chair**..... Date.....**5 August 2009**.....
Anna Carragher (Chair)