

Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital) – PGD application for Ichthyosis hystrix of Curth-Macklin OMIM #146590

Thursday, 26 November 2015

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

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Sue Price Anthony Rutherford Bishop Lee Rayfield	
Members of the Executive	Trent Fisher Sam Hartley	Secretary Head of Governance and Licensing
External adviser	Professor Mary Porteous	
Legal Adviser	Jane Williams	Mills & Reeve
Observers	None	

Declarations of interest:

- members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- executive summary
- PGD application form
- redacted peer review
- Genetic Alliance opinion written in collaboration with the Ichthyosis Support Group
- a redacted public comment from a Professor of Molecular Dermatology about this condition

1. Consideration of application

- 1.1. 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.
- 1.2. The committee noted that the condition being applied for is not on the approved PGD condition list.
- 1.3. 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'.
- 1.4. The committee noted that the condition is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected.
- 1.5. The committee noted that the condition is a rare skin disorder where an individual's skin becomes severely thickened and can have a yellow-brown or grey spiky cobblestone-like appearance. This can spread over wide areas of an individual's body.
- 1.6. The committee noted further that the condition worsens as the disease progresses and skin can crack to cause painful fissures which bleed and can become infected leading to malodour. In extreme cases it can lead to gangrene and loss of digits. The condition can have profound psychological effects.
- 1.7. The committee noted that the condition demonstrates a very high penetrance and symptoms are likely to present from early childhood.
- 1.8. The committee noted that there is no curative treatment for the condition, but that treatment for the lifelong management of symptoms was intensive and burdensome.
- 1.9. The committee noted that the application is consistent with the Peer Review.
- 1.10. The committee welcomed the advice of its specialist advisor, Professor Mary Porteous, who confirmed that the condition is as described in the papers.

2. Decision

- 2.1. The committee considered that the condition is serious due to the severity of symptoms and the need for a life-long treatment regime to seek to manage the symptoms.
- 2.2. 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.
- 2.3. The committee agreed to authorise the testing of embryos for Ichthyosis Hystrix of Curth-Macklin, OMIM #146590.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

A handwritten signature in black ink, appearing to read "DWA" followed by a stylized flourish.

Name

David Archard

Date

10/12/2015