Statutory Approvals Committee – minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Spermatogenic Failure, Y-linked, 2 (SPGFY2), OMIM #415000

Thursday, 17 December 2020

HFEA, 2nd Floor, 2 Redman Place, London E20 1JQ via Teams Meeting

Committee members	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Specialist Adviser	Dr. Alison Male	
Legal Adviser	Tom Rider	Fieldfisher - LLP

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:

- 9th 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
- Letter of support from the Person Responsible for centre 0044
- Supporting statement from a patient couple
- Genetic Alliance statement

1. Consideration of application

1.1. The committee welcomed the advice of its specialist adviser, Dr. Alison Male, who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the PGD application for Spermatogenic Failure, Y-linked, 2 (SPGFY2), OMIM #415000, is consistent with the peer review.

1.3. The committee noted that the condition being applied for is not on the list of approved PGD conditions.

1.4. The committee noted that the Genetic Alliance statement provided a perspective on the impact of the condition on patients, their families and carers.

1.5. 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.

1.6. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(c) of Schedule 2 of the Act, i.e. 'where there is a particular risk that any resulting child will have or develop – (i) a gender-related serious physical or mental disability, (ii) a gender-related serious illness, or (iii) any other gender-related serious medical condition'.

1.7. The committee noted Spermatogenic Failure, Y-linked, 2 (SPGFY2), OMIM #415000 is inherited in a Y chromosome-linked manner which means that all male children will inherit this condition, if the father has a relevant mutation. All female embryos are unaffected.

1.8. The committee noted penetrance for the condition is 100%.

1.9. Those affected by Spermatogenic Failure, Y-linked, 2 (SPGFY2), OMIM #415000 may be unable to produce sperm to achieve a pregnancy (19% of cases) and are thus completely infertile. The greater proportion exhibit low or very low sperm counts, significantly reducing their fertility. Where sperm are produced, ICSI/IVF may allow the men to become biological parents.

1.10. There is no cure for the condition although men with oligospermia may be helped with assisted reproductive technologies.

1.11. The committee noted the executive's request to consider Spermatogenic Failure, Y-linked, 2 (SPGFY2), OMIM #415000, for inclusion on the list of conditions approved for PGD (to undertake sex-selection to exclude male embryos). The committee agreed to consider the application on this basis.

2. Decision

2.1. In making its decision on whether to authorise this condition, the committee took into account the material provided within the application. This included information from the applicant, peer reviewer and an intended patient couple. The committee deliberated on the statutory requirements which it is required to assess when considering applications to undertake testing to establish the sex of an embryo. These are whether there is a particular risk that any resulting child will have or develop – (i) a gender-related serious physical or mental disability, (ii) a gender-related serious illness, or (iii) any other gender-related serious medical condition.

2.2 The committee had regard to the factors set out in its explanatory note when assessing seriousness. They include the age of onset of the condition, its symptoms, the variability of symptoms, whether the condition is treatable, and how invasive this is likely to be.

2.3. In coming to its conclusion, the committee noted that although present from birth, and as the condition causes male infertility of varying degrees, the age of onset where the condition is likely to be problematic is from adolescence and early adulthood, when a man is considering his reproductive options. The committee acknowledged that male infertility could have a psychological impact on the quality of life of those affected but agreed that the condition could not be considered to be fatal or life limiting. Treatment although invasive and potentially

emotionally challenging, is available in many cases by assisted conception, and sperm donation could also potentially be an option for those who wish to start a family. Fertility counselling is available to help ameliorate the emotional difficulties that could be associated with this condition.

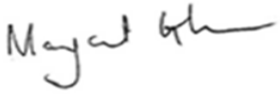
2.4. The committee confirmed that, on the basis of the information presented, it was satisfied that there is a particular risk that an embryo may have the abnormality in question, but it was not satisfied that there is a significant risk that a person with such an abnormality will, given the condition's worst symptoms, have or develop a gender-related serious physical or mental disability, a gender-related serious illness, or any other gender-related serious medical condition.

2.5. Therefore, after very careful consideration, the committee decided that the condition Spermatogenic Failure, Y-linked, 2 (SPGFY2), OMIM #415000 is **not** authorised for general testing and will not be added to the approved HFEA PGD list of conditions.

3. Chairs signature

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

Signature



Name
Margaret Gilmore

Date
14 January 2021