Genetic Alliance UK
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Consultation response

Mitochondrial Replacement Regulation
Human Fertilisation and Embryology Authority
Response by Genetic Alliance UK, 6th July 2015

Introduction

1. Genetic Alliance UK is the national charity working to improve the lives of patients and families affected by all types of genetic conditions. We are an alliance of over 180 patient organisations. Our aim is to ensure that high quality services, information and support are provided to all who need them. We actively support research and innovation across the field of genetic medicine.

Response to consultation questions

Question 2.4: Please provide details of any other relevant measures, evidence or criteria that could be used to determine the presence of a 'particular' risk.

2. If the woman seeking treatment has mitochondria with mitochondrial DNA mutations that are associated with the condition for which a licence is being applied, then we believe the 'particular risk' criterion has been satisfied.

Question 2.6: Please provide details of any other relevant information that could support an application for a particular patient.

3. The legal basis for these decision making criteria follows the same basis as that governing preimplantation genetic diagnosis (PGD) and uses equivalent wording. It therefore follows that there should be alignment between the two processes where similar or identical issues are being considered. Indeed, PGD has been used to avoid the birth of children affected by conditions caused by mutations in mitochondrial DNA (by selecting embryos with a sufficiently reduced mutation load as to satisfactorily reduce the risk of the resulting child from being affected by the condition concerned). E.g. Kearns Sayre Syndrome (KSS)/ Pearsons Marrow-Pancreas (PMPS) (OMIM #530000 & 557000).

4. The combined set of tests: 'particular risk', 'significant risk, and 'seriousness', have already been applied to conditions caused by mutations in mitochondrial DNA, as part of the HFEA's implementation of similarly constructed regulations with identical criteria governing individual access to PGD. It follows that the tests applied to satisfy the same criteria in regulating PGD should be equivalent to those applied in regulating mitochondrial replacement, and should deliver equivalent outcomes.

5. Where a condition has already been licensed for PGD, and is therefore on the list of licensed conditions, the assessment of seriousness should not be reapplied in decisions regarding access to mitochondrial replacement. In these cases the question should be whether there has been any material changes to the expected experience of a family having a child with this condition since it was licensed for PGD. If not, then the decision from the licensing of PGD should stand. If there has been a change, then a re-evaluation should occur. It would clarify and rationalise the decision

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making process to separate the assessment of significant risk and the assessment of seriousness more overtly. I.e. the assessment as to whether an embryo created by fertilising an egg from the applicant woman has a significant risk of having the condition for which a licence is being applied, should be separated from the assessment as to whether the condition for which a licence is being applied is considered serious.

6. The question of significant risk depends upon circumstances individual to the woman applying for treatment, and to deliver case by case regulation, the Licensing Committee will have to consider the circumstances of each individual woman applying. This is not the case for the question of seriousness. Though conditions caused by mutations in mitochondrial DNA are, like most genetic conditions, highly variable, their seriousness depends on the mutation in the genetic code. We propose therefore, that once a condition has been judged serious by the licensing committee, all future applications for mitochondrial replacement should not reapply the question of seriousness. (As in the process for PGD, if after a suitable period of time has elapsed, there has been any material changes to the expected experience of a family having a child with this condition, then it should be re-evaluated.)

7. We propose a list-based approach to the governance of the seriousness question in mitochondrial replacement. Genetic Alliance UK plays a role in the licensing of conditions for PGD. We provide a statement indicating the likely experiences of a family having a child with the condition under consideration, and indicate some of the considerations a couple requesting PGD might make. We have had feedback from both HFEA staff and licence committee members that this patient voice in the decision-making process is highly valuable. A separation of the judgement of seriousness and the judgement of particular risk would allow this approach to be extended to cover mitochondrial replacement, and would provide the licence committee with the same additional evidence that we provide for PGD decisions.