



British Fertility Society

response to the

Human Fertilisation and Embryology Authority

consultation

Medical Frontiers: debating mitochondria replacement

December 2012

This document represents the British Fertility Society (BFS) response to the Human Fertilisation and Embryology Authority (HFEA) consultation on 'Mitochondria Replacement'.

The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

Therefore the issue of possible future treatments for patients at risk of transmitting mitochondrial disorders, which will involve IVF procedures, is of interest to BFS members.

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Permissibility of new techniques

Q1: Having read the information on this website about the two mitochondria replacement techniques – maternal spindle transfer and pro-nuclear transfer, what are your views on offering (one or both of) these techniques to people at risk of passing on mitochondrial disease to their child? You may wish to address the two techniques separately.

It is the view of the British Fertility Society (BFS) that both techniques are very complicated and technically challenging. A number of excellent studies have been reported in a variety of mammalian species. However, further research needs to be performed before either technique is introduced into clinical practice. This should include studies to improve our knowledge of the biology of human mitochondria, and to provide further information concerning the safety of the two procedures. The BFS supports the proposals listed in section 5.4 & 5.5 of the report “Scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception” (http://www.hfea.gov.uk/docs/2011-04-18_Mitochondria_review_-_final_report.PDF). Therefore, the BFS has no objections to using these techniques, provided the procedures have been shown by robust scientific and clinical studies to be safe, effective and are capable of producing healthy offspring.

Changing the germ line

Q2: Do you think there are social and ethical implications to changing the germ line in the way the techniques do? If so, what are they?

Any offspring would clearly be the genetic offspring of the couple whose sperm and eggs generated the pronuclei (but containing the mitochondria of the donor) and therefore the BFS does not consider there are significant social and ethical implications.

Implications for identity

Q3: Considering the possible impact of mitochondria replacement on a person’s sense of identity, do you think there are social and ethical implications? If so, what are they?

There is currently no evidence to suggest that mitochondria donation will affect a person's sense of identity, nor can we envisage any reason that it should do so. We consider it essential that this is made absolutely clear to all parties involved to avoid all possibility of confusion, and to allay any anxiety concerning this point. It is the view of the BFS that there are no social or ethical implications for identity.

The status of the mitochondria donor

Q4 (a) In your view how does the donation of mitochondria compare to existing types of donation? Please specify what you think this means for the status of a mitochondria donor.

It is important that the proposed techniques are recognised as being absolutely distinct from, and in no way similar to, egg donation. The BFS strongly asserts that any suggestion that the child resulting from the proposed technique has 'three parents' must be avoided; this distorts the facts and appeals to sensational mis-interpretation. The only similarity to egg donation is in the inconvenience and discomfort to the donor in having ovarian stimulation and egg collection.

Q4 (b): Thinking about your response to 4(a), what information about the mitochondria donor do you think a child should have? (Choose one response only)

As far as the BFS is aware, the proposed techniques will not have any effect on the genotype or phenotype of the resulting child and so the information available about the mitochondria donor should be in keeping with what is the same for recipients of organ donation.

Regulation of mitochondria replacement

Q5: If the law changed to allow mitochondria replacement to take place in a specialist clinic regulated by the HFEA, how should decisions be made on who can access this treatment? (Choose one response only)

The BFS is of the opinion that the regulator should decide which mitochondrial diseases are serious enough to require mitochondria replacement in line with current approvals for Pre-implantation Genetic Diagnosis, and permit clinics and patients to decide when it is appropriate to treat for these disorders in individual cases.

Should the law be changed?

Q6: In Question 1, we asked for your views on the mitochondria replacement techniques MST and PNT. Please could you now tell us if you think the law should be changed to allow (one or both of) these techniques to be made available to people who are at risk of passing on mitochondrial disease to their child?

Yes, the BFS is of the view that the law should be changed to allow mitochondrial donation should the relevant experiments outlined in our answer to question 1 provide reassuring data. The BFS supports the need for regulation and the maintenance of an appropriate register and the HFEA (or its successor body) would be the obvious candidate for this. The BFS wish to emphasise the necessity for introducing such modifications to the Register in order to accommodate recording all such treatment, including details of the egg donors involved. There needs to be consideration of what information is kept but this form of donation should be considered in the same way as is organ donation, and not in the same context as gamete donation.

Further considerations

Q7: Are there any other considerations you think decision makers should take into account when deciding whether or not to permit mitochondria

replacement?

It is the view of the BFS that the criteria for the evaluation of research findings used to decide whether or not the technique(s) may be safely introduced into clinical practice must be defined in advance. This should include: (i) who will make the decisions; and (ii) on what grounds. Decisions should also be made in advance regarding: (i) how any possible sequelae in offspring will be examined; (ii) what arrangements will be in place to monitor for these; and (iii), for how long follow-up should be conducted.