This response was submitted to the call for evidence by the Nuffield Council on Bioethics on *Emerging techniques to prevent inherited mitochondrial disorders: ethical issues* between January 2012 and February 2012. The views expressed are solely those of the respondent(s) and not those of the Council.

British Fertility Society

response to the

Nuffield Council on Bioethics

Call for Evidence

Emerging techniques to prevent inherited mitochondrial disorders: ethical issues

January 2012

This document represents the British Fertility Society (BFS) response to the Nuffield Council on Bioethics, Emerging techniques to prevent inherited mitochondrial disorders : ethical issues

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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The BFS welcomes and applauds the possibility of developing advances in treatments that may lead to the alleviation of the suffering associated with inherited mitochondrial diseases. Equally, the BFS recognises that interested professionals and professional bodies have a responsibility to ensure that the lay public are fully informed, especially concerning techniques such as those proposed for such treatments. Thus, it is essential that discussion of this topic should be proportionate, and all efforts should be made to discourage sensational interpretation, particularly on the part of the tabloid media. In particular, the BFS wishes to emphasise that the priority is to establish whether or not the techniques under discussion are feasible and safe, and whether they should be introduced into routine clinical practice.

Bearing these points in mind, the responses of the BFS to the questions raised specifically in the Nuffield Consultation Document are as follows:

1. **Is it acceptable to select mitochondrial genes that will be inherited by future generations?**

   Yes

2. **What ethical distinctions can we make on treatments that would transfer pronuclei between embryos and seek to modify the DNA of an embryo?**

   This question is ambiguous and far-reaching, so it is not easy to provide a succinct answer. However,

   (i) If it is intended to refer to **pronuclear transfer**, its wording is misleading, since pronuclear transfer *per se* does not seek to **modify** the DNA of an embryo; it merely transfers the embryo's genetic material (which could include 'contaminating' mitochondrial DNA) into a recipient "vehicle" (the recipient oocyte) whose cytoplasm contains non-defective mitochondria. 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 ethical considerations are minimal. Far more important, and what should be the focus of this discussion, are the safety considerations of developing and performing such a procedure in clinical practice in humans.

   (ii) If the question is **really** intended to address opinions concerning altering the genomic DNA of an embryo, this undoubtedly raises major ethical issues; however, this would seem to be outside the scope of the present consultation.

3. **Is it reasonable to perform such experimental techniques as treatment?**

Yes, but only after sufficient animal studies have been undertaken to demonstrate that the technique is safe to produce healthy offspring.

4. What might these techniques signify for the relationship of the resulting child to the three adults with whom it shares a genetic connection?

Although there are concerns regarding how best to approach the fact that the cells of three adults will have contributed to the generation of a child, it is suggested that the process should be viewed in the same way as organ donation – as far as we are aware, the proposed techniques will not have any effect on the genotype or phenotype of the resulting child. It is important that the proposed techniques are recognised as being absolutely distinct from, and in no way similar to, egg donation. 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.

5. How might mitochondrial DNA be associated with a person's identity?

There is currently no evidence to suggest any link between the two; we consider it essential that this is made absolutely clear to avoid all possibility of confusion, and to allay any anxiety concerning this point.

6. **Could the relationships created between the people involved in these new techniques - particularly between the mitochondrial donor and a person born with their donated mitochondria - be seen as similar to those involved in**:

   a. organ or tissue transplantation? **Yes**
   b. gamete donation? **No**
   c. a donation of other bodily material? **Yes**

   Or, should these relationships been seen as unique?

   No

7. **Only daughters born as a result of these techniques would be able to pass their mtDNA on to subsequent generations. Would it be reasonable to permit prospective parents using these technologies to also use pre-implantation sex selection (preferring male embryos), if they requested it in order to limit the risks of transmitting any adverse side effects of the techniques to future generations?**

   For couples who are at risk of transmitting X-linked disorders to their children,

preimplantation genetic diagnosis (PGD) of the sex of the embryo, and selection of female embryos, is an accepted option. Thus, there is a precedent for a medically-indicated sex selection. This distinction from sex selection for social reasons must be made clear. In the case of mitochondria disorders, the risk of the donor mitochondria causing an adverse side effect in future generations is unknown and couples should have thorough counseling. Whether PGD for sex selection is offered to the patients needs to be carefully considered.

8. **If mitochondrial donation were to be approved for medical treatment in the UK, what government or regulatory policies, and/or professional guidelines would be needed to promote ethically sound practices?**

   Such treatment would fall within the remit of the HFEA (or its successor body), since they would involve the use of gametes and embryos *in vitro*.

9. **If mitochondrial donation were *not* to be approved for translation from research into medical treatment in the UK, what ethical concerns, if any, would follow?**

   Reproductive tourism, and consequent possible unregulated/under-regulated treatment available overseas, with the concern over possible exploitation of affected/at risk couples.

10. **Is it desirable for a record of the donation to be kept and managed by the relevant authorities, and if so, what should be recorded and to whom should this information be made available?**

    Yes, it is desirable. Again, the HFEA (or its successor body) would be the obvious candidate for a central registry of treatments, including details of the donor, particularly as, even if it is found to be safe and feasible, the demand is unlikely to require that it is made available outside a small number of specialist centres. There needs to be consideration of what information is kept but this donation should be considered as organ donation and not in the same context as gamete donation.