

HFEA consultation - regulating mitochondrial donation: seeking expert views



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BACKGROUND

In 2012, the Nuffield Council on Bioethics conducted a review of the ethical issues of novel techniques for the prevention of mitochondrial disorders. The conclusions have fed into debates surrounding the acceptability of the techniques. The report also makes recommendations regarding regulation of the techniques, including about counselling and long-term follow up.

The report is available online: www.nuffieldbioethics.org/mitochondria

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SPECIFIC COMMENTS

- **We set out the information that should be provided to fertility patients before consent to treatment is obtained. Before patients give their consent to treatment involving mitochondria donation, what information should clinics provide?**

At present those seeking licensed assisted reproduction treatments in the UK are offered, under the HFE Act, “proper” information and a “suitable opportunity to receive proper counselling about the implications” of the treatment. If introduced, the provision of cell reconstruction treatments should follow this model.

However, we note that in practice the quality of counselling for existing specialist procedures such as PGD can vary. Given the complex nature of mitochondrial inheritance and the issues of novelty around reconstructing eggs or embryos, we suggest that while the initial discussions about the procedure could be within a routine setting, there should be a further opportunity offered for prospective parents to speak to an expert in a specialist unit experienced in dealing with mitochondrial disorders. This specialist would have received appropriate training and have up-to-date information available in order to discuss patients’ options with them. The same level of specialist involvement is also required in the existing provision of PND around mitochondrial disorders and should be offered to inform and support patients as far as possible in the decisions that they make.

- **Many experts recommend that families using mitochondrial donation techniques should be encouraged to take part in long-term follow-up studies to monitor any possible effects on children born and future generations. We propose that clinics must submit their process for following-up children to us. Do you think this approach is appropriate? What do you think this process should cover?**

PNT and MST are innovative treatments. We believe that in the first instance that PNT and MST (or any comparable future treatment) should only be offered as part of a research trial in specialist centres.

Ideally, families who use cell reconstruction techniques should commit to allowing very long-term follow-up of their children and families over generations in order to further knowledge about the outcomes of these techniques.

This aim is to be strongly endorsed. However, this expectation may prove difficult to fulfil on the part of both families and the research community over several decades, and previous experience has shown only patchy success in this aim in regards to other newly-introduced assisted reproductive techniques. The voluntary nature of the research relationship can make it difficult to anticipate what level of short or long-term follow up data may be feasibly gathered from families.

To create the best conditions to enable long term follow up studies, we recommend the maintenance of a centrally-funded register of any such procedures performed in the UK, accessible to researchers (for suitably approved research) over several decades.

Assurances will need to be obtained from the Department of Health that funding can be made available in the long term for maintaining a national treatment register. This could require Government to make a commitment that would endure over several decades.