Mitochondrial Donation

A consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child

Response Form

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Question 1: Regulation 2 defines the removal or insertion of nuclear DNA involved in mitochondrial donation. Do you agree with this definition?
We have no reason to disagree.
Question 2: Regulations 4 (eggs) and 7 (embryos) only allow mitochondrial donation where all the nuclear DNA is transferred from an egg or embryo to another egg or embryo from which all the nuclear DNA has been removed. Do you agree with this description and restriction?
Yes.
Question 3: Regulations 5 (eggs) and 7 (embryos) require that, in order to agree that mitochondrial donation can go ahead, the HFEA must decide if there is both a particular risk that the egg or embryo of the patient has a mitochondrial abnormality and a significant risk that a person with the particular mitochondrial abnormality will have or develop a serious physical or mental disability, a serious illness or other serious medical condition. Do you agree that the HFEA should have this role?
The Nuffield Council on Bioethics report '*Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review*' makes a recommendation that in the first instance mitochondrial techniques for treatment purposes should be carried out only in the context of a research trial in centres specialising in mitochondrial disorders.

We believe that for the HFEA to have a central determination on each individual case seems unnecessarily burdensome in terms of procedure. We don't believe that it should be the HFEA's role to assess the risk or seriousness of the condition - this should be the role of the clinician(s) with the patient. The role of the Authority should be to ensure the clinical judgement is properly made, not to assess the clinical aspects of it according to the above conditions.

Question 4: Do you agree with the principle that centres should not be permitted to undertake mitochondrial donation without first obtaining authorisation to do so from the HFEA?

Yes, we agree that these treatments should only be carried out in premises licensed by the HFEA for that purpose.

Question 5: Do you agree that people donating eggs and embryos for the purposes of mitochondrial donation should *not* have the same status as those donating eggs and embryos for use in fertility treatment but rather regarded more like organ or tissue donors?

The Nuffield Council agrees with the view that a donor of mitochondria should **not** be given the same status in all aspects of regulation as a reproductive egg or embryo donor. We suggest that the differences would include:

- Mitochondrial donors should not be mandatorily required to be identifiable to the adults born from their donation
- We see no reason for the regulator to establish sibling registries of the kind that would contain the details of mitochondrial donors or the resulting people and are intended to enable those born using the mitochondria of the same donor to contact each other
- We do not see the need for a regulatory limit to be placed on the number of families to whom a mitochondrial donor could donate, which should be a matter for discussion between the woman and her doctor
- However, other aspects of the current regulation and safeguards for egg donors should be applied equally to mitochondrial donors, including the number of times that they receive ovarian stimulation drugs for this purpose and in respect of financial compensation

Question 6: Regulation 10 provides that the HFEA should tell a person aged 16, on request, if they were born following mitochondrial donation. Do you agree with this?

We don't take a view on whether people should be told on request about their having been born as a result of mitochondrial donation. Indeed, whilst we agree that a central register is needed, mainly for the purpose of follow-up and research, we would not say that this should necessarily be maintained by the HFEA (as an adjunct to its gamete donor register - indeed, this might make it seem more akin to gamete donation that we would have anticipated).

Question 7: Regulation 10 also provides that the information that the HFEA should provide in response to such a request should not identify the mitochondrial donor and be limited to screening tests carried out on the donor and about her family medical history, and any other non-identifying information that the donor has provided with the intention that it is made

available in these circumstances. Do you agree with this approach?
We agree that identity of the donor should not be disclosed, but it seems sensible that a certain amount of non-identifying information, including details of screening tests carried out, should be made available to those who might ask. As above, we would not say that this information should necessarily be maintained by the HFEA but could simply be a requirement placed on those centres providing the treatment. We further suggest that should mitochondrial donation techniques be permitted for treatment use in future, a voluntary system for contact between mitochondrial donors, set up and mediated by an appropriate central body, would offer the maximum flexibility to donors and the resulting people if they wished to become identifiable to each other or to make contact.
Question 8: Regulation 13 provides that the HFEA should tell a mitochondrial donor, on request, when a child has been born from their donation, how many and their sex. Do you agree with this approach?
We do not take a view on this particular question.
Question 9: Do you have comments on any other aspect of the draft regulations?
The Council's report sets out important conditions that it believes must be met should these treatments be offered to affected families. Firstly, we believe it is of paramount importance that families considering this treatment are given appropriate information and counselling. The advice should be given by a specialist who has completely up to date information and talk through all of the options, procedures and expected outcomes with the families involved. Secondly, as stated above, it is our view that these treatments should only be offered initially in specialist research centres as clinical trials. Centres should have clear longitudinal follow up plans and we suggest that consent to follow up should be included as a mandatory part of parental consent to participating in the trial. Whilst these are not on the face of the regulations, we would expect a clear signal to be given that licences issued would include these type of provisions as conditions of licence.