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

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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?

Yes

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?

Yes, although it is preferable to speak of physical or mental 'impairment' rather than 'disability' as the former has a purely biological basis while the latter has additional social implications.

It is also unclear what criteria will be used to determine the severity or 'seriousness' of a potential impairment or illness.

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

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?

Mitochondrial donation is identical neither to gamete or organ donation but falls into a separate category. While there is scientific consensus that mitochondria are unlikely to play a role in the transmission of hereditary characteristics this consensus falls short of certainty; the precise nature of the relationship between mtDNA and nDNA is not yet fully understood. Even if mtDNA does not have an impact on hereditary characteristics it still represents germ-line modification and will have an effect on subsequent generations in a way that organ donation does not. We believe that mitochondrial donation (and consequently mitochondrial donors) ought to be treated as a third form of donation, rather than approximated to either of the existing forms of donation. If future research indicates that mtDNA does affect hereditary characteristics then it ought to be viewed in the same manner as gamete donation.

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?

Yes, although mitochondrial replacement ought only to take place after the recipient has undergone counselling during which the advisability of telling a child about his or her genetic history from an early age ought to be discussed.

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?

Mitochondrial replacement affects the genetic constitution of resulting children and, as a consequence, is likely to affect their sense of personal identity to some extent. They ought to have access to medical and personal information with regard to donors.

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?

Yes

Question 9: Do you have comments on any other aspect of the draft regulations?

While supportive, in principle, of both MST and PNT, we believe that further research is necessary into the relationship between mtDNA and nDNA. Concerns have been raised, for example, with regard to potential mismatches between the mitochondrial and nuclear genome, with varying responses noted from scientists.

Concern has also been voiced with regard to heteroplasmy arising from donor mtDNA and the difficulties associated with eradicating this possibility.

PNT involves the creation and destruction of un-fused fertilised ova. While ethically a case can be made for viewing these as 'pre-embryos', legally they are classified as embryos. PNT in its current form involves deliberately creating embryos (in the legal sense), specifically for them to be destroyed; a departure from the policy of only using 'spare' embryos for research.

We believe that more research into the safety and efficacy of mitochondrial replacement therapy is necessary before regulations are introduced permitting the technique. It is estimated that only around 10 children per year might benefit from current techniques while 1 in 200 children are born with some form of mitochondrial disorder. Further research, resulting in assured safety and efficacy is likely to be more beneficial in the long-term than premature application of uncertain techniques. The introduction of regulations ought to await the results of such research.

Note: The HFEA subsequently approved the outcome of further research into the safety and efficacy of mitochondrial donation.

Brendan McCarthy 3rd November 2017