

2<sup>nd</sup> June 2014

Dear Consultations or Co-ordinator

I have submitted my response to the Department of Health consultation document "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". I would now like to offer some comments on the document itself.

This document refers to an important topic which has drawn a great deal of media interest and speculation and raises very strong and opposing opinions. In this context, this document needed to be very clear, simple and forward looking. It is important that this document attracted a large number of responses to make this a viable and useful exercise. But as a public document it also needed to provide a clear and succinct account as to why this document has come into being, why now, and why it is important.

My main concerns about this document are:

- a. The style of writing and the language used means it is overcomplicated and on occasion lacking the nuance required of a public document.
- b. Most of this document is dedicated to providing a 'background section', which sums up previous arguments around mitochondria disease (page 8 -15) and appears to be biased in the way it presented arguments
- c. Not enough detail is given in relation to the questions that are asked (and to which the public are expected to respond).

Overall, we have a document that tries to 'solve' previous arguments but does not make it easy to respond to the questions asked. As a result, this document does not move this debate forward and I fear it will not provide enough 'evidence' from the general public as to how mitochondrial donation should be regulated in future.

Below I provide just some examples of why I felt I needed to make a comment on the document.

**a. Style of writing**

Some of the discussion could be supported by scientific evidence rather than hearsay, for example:

P9 "It is generally agreed by scientists that it is genes in our nuclear DNA, together with environmental factors, rather than mitochondrial DNA, that shape our personal characteristics and traits".

The question of identity has been much debated and raises strong opposing opinions. It is therefore important that these kinds of statements are managed appropriately. There is no excuse (and no need) for such generalisations. If there is no alternative scientific evidence to support this statement, then attention could have been drawn to Nuffield Council on Bioethics report which addressed this question.

Another example is use of the word 'treatment', which then required further explanation.

p 40 "the intended effects of the proposal are: a. To enable safe and effective treatment of mitochondrial disease"

p10 (1.12) “The techniques would not treat or cure a person who already has a mitochondrial disorder”.

These are reproductive technologies that can prevent the transmission of mitochondrial disease from mother to child rather than ‘treatment’. However, whether or not IVF technologies count as ‘treatment’ is not the issue, but inclusion of a term such as this has the potential to confuse the issue and detract from the important questions.

#### **b. Extensive and confusing ‘background’ section**

The debates about the significance and utility of mitochondria DNA are still ongoing. It is possibly because of this that this document appeared to want to ‘solve’ or remove any ambiguity. Many of the arguments were not based on empirical evidence, were badly worded and appeared to reflect biased opinion. For example, the limited genetic contribution of mitochondrial DNA, its limited function and how it does not impact on the child’s identity are referred to at length on at least four different occasions. [Also compare with the paragraph on page 20 2.22 which refers to a similar topic but in a much more succinct and effective way]

For example, on page 9

1.24 The dominant DNA (the nuclear DNA) in any child born from these new techniques would be that of the mother and the man providing the sperm (usually the father). Although it would be the case that DNA from three people (the mother, the man providing the sperm and the egg donor ) would be present in the child, only a tiny percentage of the child’s DNA would come from the egg donor. Most importantly, the residual DNA from the donor would only be mitochondrial DNA so would not affect the resulting child’s personal characteristics and traits. This is because mitochondrial DNA only contains genes that are essential for normal mitochondrial function; personal characteristics and traits are derived from the nuclear material.

I have highlighted this paragraph because it contains two examples where the writing was clumsy and could be open to question (and therefore distracting from the real issue at hand which is the draft regulations):

- calling nuclear DNA ‘dominant’ and mitochondrial DNA ‘residual’ is not helpful. I wonder if this is the authors own way of differentiating between them, rather than based on ideas in common use or scientific evidence.
- the document states ‘the man providing the sperm (usually the father)’ – in the context of a technique which challenges our ideas of genetic parenthood, the phrase ‘usually the father’ is odd. Surely the man providing the sperm is always the (genetic) ‘father’. However, if the author wanted to explore ideas about genetic father compared with ‘social’ father, then this would be valuable, but possibly in another paragraph, and related to legislation or current practice (for example in contexts of sperm donation, surrogacy or adoption).

**c. Asking questions for future regulation**

The most important part of this document is from page 15 to 24, under the heading 'The Regulations'. This section contains the questions that are asked and information that might be relevant to inform a response to the question. This section refers to other documents such as the HFEA and Nuffield Council on Bioethics report and current regulations. This is a well written section (for example, I have previously drawn your attention to the style of writing in the paragraph on page 20, 2.22)

The questions asked in the document are useful, but some could be written in much more simpler terms. More evidence could be supplied in relation to each specific question which could help readers form an opinion.

I would like to draw your attention to the extent of the information associated with question 8 (page 22):

Information available to mitochondrial donors

2.32 The Government considers that mitochondrial donors should also be able to access non-identifying information on live births resulting from their donation. Regulation 13 will enable donors to request information on the number of children born plus the sex and year of birth of each child.

Question 8: Regulations 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?

This is a really important question. To help the reader form a response to this question, it would have been useful to provide further evidence for comparison, to help them think about the kinds of things that might be relevant. For example, in responding to this question I would have liked to have known what the current policies are for accessing information in cases of adoption or egg and sperm donation.

In conclusion, page 16 states "2.4 This consultation is therefore not about whether mitochondrial donation to prevent the transmission of serious mitochondrial disease should be *allowed*, but concerns the detail of the regulations that would put into effect the Government's intention to allow it".

I applaud this statement.. However, this document focuses too much on persuading the reader that the techniques *should be allowed*. This is such a shame, and detracts from the real focus of the consultation which is the draft regulations.

Having provided these comments, I hope this document does attract the responses required. It is critically important that if these techniques are allowed, then we have the mechanisms in place to support patients and families, the children born from the techniques, and the scientists or clinicians involved in the process.

Please don't hesitate to contact me if you require further information.

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