



The Church of Scotland

Church and Society Council

Official Response

SUBJECT: Mitochondrial Donation
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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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Organisation represented (if appropriate):

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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?

Your Comments:

We disagree with this definition, and would argue that what is being proposed is not in fact

mitochondrial donation, but is rather nuclear transfer. What will happen in practice will be that the nucleus will be transferred to another egg or embryo. This second egg or embryo will contribute much more than simply the mitochondria to the final structure, but would also contribute all the other cell structures apart from the donated nucleus.

We would argue that this is an unnecessarily risky route on which to embark. Only a few years ago, the Human Fertilisation and Embryology Act 2008 placed limits on the gestation of human embryos which had been manipulated, such that no manipulated embryo would be allowed to develop beyond 14 days. Allowing these technologies to enter routine clinical use would mean that such limits would in effect be removed.

It should also be noted that during the debate on the HFEA Act 2008 it was argued strongly that it was necessary to allow for the creation of human- animal hybrid embryos, for the generation of stem cells. These have proven to be technically impractical and essentially a waste of time and effort- quite apart from any ethical considerations. There have also been serious ethical and scientific concerns raised about these techniques (see for example "Mitochondrial Replacement, Evolution, and the Clinic" (Reinhardt et al Science 341, 1345 (2013))).

We fear that the techniques described here would be a similarly futile waste of energy and resources. We would consider that the general public would be more familiar with terms such as the nucleus and chromosomes than with mitochondria. Characterising the techniques proposed as "mitochondrial donation" seems unnecessarily confusing.

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?

Your Comments:

Given our primary reservations described above with regard to the definitions, adoption of or development of the techniques, we would be in favour of the restrictions implied in these regulations, as it would necessitate a further change in the law before any other similar techniques be proposed.

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?

Your Comments:

We believe that insufficient attention has been given to the likely health risks associated with these techniques. Already some studies indicate that children conceived through IVF are more likely to suffer from birth defects (see, for example, <http://www.uclahealth.org/body.cfm?id=561&action=detail&ref=2039>). Given the greater trauma inflicted on the egg or embryo in carrying out the techniques described here, it is probable that unacceptably high rates of birth defects would result. In addition, it is possible that the shear forces involved in the manipulation of the pro- nuclei or maternal spindle complex may result in physical damage to the chromosomes (e.g. chromosome breakage), with potentially disastrous consequences for any resultant child.

These techniques have been used in mammals such as mice, and in a smaller number of trials involving primates. However, the concerns about the potential health risks associated with these techniques in humans meant that the HFEA proposed that an extensive series of tests be conducted

prior to proceeding with PNT and MST. Rather than awaiting the publication of the tests and their findings, however, the Government has proceeded to publish draft regulations. We consider that the Government should, at the very least, wait for the conclusion of those tests before proceeding to draft legislation, far less put it out for public consultation.

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?

Your Comments:

We do not consider that any clinics within the UK should be undertaking these techniques.

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?

Your Comments:

The argument made in the discussion document about the status of the persons donating eggs and embryos for MST or PNT is based around a reductionist one, which takes the view that only the chromosomes themselves make any contribution to inheritance. The fact is that, the DNA which makes up chromosomes is of itself an inert chemical- unless chromosomes are supported by the proteins, etc, which make up the many other parts of the egg, they are unable to develop in order to generate a new individual.

Thus, the contribution made to the development of a new human being using these techniques by the donors of the eggs and embryos is vital, and is of a different order of magnitude to organ or tissue donation. MST/ PNT bring about the creation of a new life, while tissue and organ donation maintain a life already in existence.

For these reasons we would disagree with the proposal put forward in the document, and would argue that some legal status should be granted to the donors of the eggs and embryos.

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?

Your Comments:

We would agree that any person born following these techniques should have the right to know their heritage on reaching legal maturity; in this case, we should consider 16 to be an appropriate age.

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?

Your Comments:

We disagree with this approach, and feel rather that any children born following these techniques should be able to know as much as possible about their heritage. As such, we feel that they should be able to identify all persons involved in their conception, including the egg or embryo 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?

Your Comments:

We would agree that it is important that all individuals who have been involved in the creation of a new human being should be informed; thus, we agree with this approach.

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

Your Comments:

Members of our Council have professional experience working with children with severe physical disabilities. We are therefore very aware of the effects on the children and their families caused by their long term ill health, their low quality of life, their debilitating suffering and the devastation of a premature death. We are also aware of some of conditions which are the result of severe mitochondrial disease, and no one can fully understand the pain experienced by a parent who knows that this was caused by a condition handed down to their child.

We would wish to emphasise the rarity of mitochondrial disorders, and thus the rarity of couples who would even be eligible to consider this approach. Out of thousands of people born with the prospect of a severe disability, this proposed medical intervention would help only approximately ten people each year. Not all couples who are carriers would want to go along this path. We are concerned not just about the ethical and legal issues, but also the huge financial cost, all without guarantee of success.

As has already been said, we have concerns not just with the “direction of travel” with this research, but also the speed at which the Government seems intent on moving down this road. Not only are no other countries considering developing this kind of technology (indeed, many have expressly prohibited it), but the UK Government has failed to comply with the recommendation of the HFEA that more extensive investigations be undertaken before proceeding any further.

We would urge the Government to consider very carefully before bringing forward any legislation in this regard.