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HFEA publishes report on third scientific review into the safety and efficacy of mitochondrial replacement techniques

- UK’s dedicated ART regulator asked by Department of Health to give scientific opinion as part of broader consultation into permitting mitochondrial replacement under licence
- ‘Panel of Expert’ scientists reconvened to explore developments since second review
- Wide range of expert evidence and opinion sought from around the world

The Human Fertilisation and Embryology Authority (HFEA) has today published its report on the third review into the safety and efficacy of techniques for mitochondrial replacement [MR] [1], recommending that they be considered ‘not unsafe’ for use on a ‘specific and defined group of patients’.

In February 2014, the Government launched a consultation on draft regulations for the use of MR techniques - Maternal Spindle Transfer (MST) and Pronuclear Transfer (PNT) - to prevent mothers passing on serious mitochondrial diseases. Such treatments have not been carried out anywhere in the world and are currently illegal in the UK.

As part of the consultation, the Department of Health requested that the HFEA reconvene its Expert Panel to examine the safety and effectiveness of these techniques. This was the third review, with similar undertakings being carried out by panels in 2011 and 2013 [2]. The review was commissioned by the Government to contribute towards a decision on whether such techniques should be made legal [3].

The Panel was comprised of experts with broad-ranging scientific and clinical expertise [4], who considered the evidence contained in 17 different submissions [5] sent from scientists in the UK and abroad over the course of three Panel sessions.

Findings and recommendations:
The HFEA has produced a report outlining the Panel’s findings and recommendations to Government. It states that:

- The panel is of the view that the techniques of MST and PNT are potentially useful for a specific and defined group of patients: those wishing to have their own genetically-related child, but whose offspring are at risk of severe or lethal genetic disease, due to mutations in the mitochondrial DNA [“mtDNA”] which the mother carries.
- At each stage of the review process the panel reached a view that the evidence it has seen does not suggest that these techniques are unsafe.
- Research in this area has progressed well since the previous two reviews.
- However, there are still experiments – some critical, some desirable - that need to be completed before clinical treatment should be offered.

The full list of findings and recommendations can be found in the report [6].

Sally Cheshire, Chair of the HFEA, praised the open-minded process undertaken by the Panel, concluding that it is now for Government to decide the next step.

‘This scientific review is our third in three years and I am grateful to our panel of experts for the rigour of their work. The review process has assembled an evidence base on the safety and efficacy of these two mitochondrial replacement techniques which stands comparison with anything published in the UK or abroad.

‘The science is complex, but the aim is simple: to enable mothers to not pass on to their children a range of serious, and sometimes fatal, inherited conditions. In all of our discussions we should not lose sight of this.

‘Now it is a question for others. If the Government decides to seek to change the law they will need the approval of both Houses of Parliament, and it is only right that they consider all the ramifications, social as well as medical, before they make up their minds. There is a long way to go yet.’

Panel Chair, Dr Andy Greenfield said:
‘This review has been a demanding process for all involved. Perhaps the greatest challenge was the breadth of data that needed to be considered. The Panel has examined, discussed and re-examined data from disparate fields of science, including biochemistry, evolutionary biology, the genetics and developmental biology of model organisms and, of course, clinical genetics and embryology. We believe that our recommendations are firmly based on the data that we examined.’

Panel member, Professor Peter Braude said:
‘As a clinician I am aware that inherited mitochondrial disorders are horrible diseases that can devastate families. In the absence of any effective treatment, mitochondrial replacement therapies such as pronuclear transfer and maternal spindle transfer offer great hope to families afflicted by mitochondrial disorders.

‘Implementation of any new medical treatment is never wholly without risk, and genetic alteration of disease is an important step for society that should not be taken lightly. The panel has worked single-mindedly over a period of more than three years, to try and secure the best available scientific evidence in order that an informed decision can be made by the Department of Health as to whether the specific provisions made in the 2008 should be taken forward by Parliament. It is a shining example of evidenced-based regulation.’

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