

# HFEA statement regarding the Klaus Reinhardt et al Science paper 'Mitochondrial replacement, evolution, and the clinic'

**19 September 2013**

The panel of experts convened by the HFEA to examine the safety and efficacy of mitochondria replacement carefully considered the interaction between nuclear and mitochondrial DNA and concluded that the evidence did not show cause for concern.

Following a call for evidence, the panel considered studies and statements submitted by researchers and had discussions with experts in the field. The *Drosophila* studies cited by the author were not specifically analysed, although this issue was one of the key considerations in assessing the safety and efficacy of mitochondria replacement. As the report stated, the panel's conclusion was based on the fact that 'Fifty per cent of nuclear genes are paternally inherited and are consequently 'alien' to the mitochondrial DNA; backcrossing can replace the nuclear DNA entirely in a few generations. Furthermore, mitochondrial disease has not been noted to be more frequent amongst mixed-race children.'

The panel also considered the findings of studies on macaque monkey created through maternal spindle transfer (MST). In contrast to Reinhardt et al's summary, two different sub-species of macaques were used in the three-year follow-up study on MST-derived macaque offspring (Tachibana et al, 2013). These subspecies have distinct mitochondrial haplotypes, yet the resulting male monkeys were healthy and had normal mitochondrial function.

There are still hurdles to overcome before these techniques could be used clinically and it won't be a suitable treatment option for everyone at risk of having a child with a mitochondrial disease. As in every area of medicine, moving from research into clinical practice always involves a degree of uncertainty. Experts should be satisfied that the results of further safety checks are reassuring and long term follow-up studies are crucial. Even then patients will need to carefully weigh up the risk and benefits for them.

Ends

## Notes to Editors

The HFEA is the independent regulator for IVF treatment and embryo research. Our role is to protect patients and the public interest, to drive improvement in the treatment and research sectors and to provide information to the public and policymakers about treatment and research.

The HFEA was set up in August 1991 as part of the Human Fertilisation and Embryology Act 1990. The HFEA's principal tasks are to license and monitor clinics that carry out in vitro fertilisation (IVF), artificial insemination (AI) and human embryo research. The HFEA also regulates the storage of gametes (eggs and sperm) and embryos.

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