

NEWS

Draft UK regulations for mitochondrial donation are published

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The UK government is consulting on draft regulations for techniques to prevent the transmission of serious mitochondrial disease from a mother to her child.¹

An estimated one in 200 children born each year in the United Kingdom has some form of mitochondrial DNA disorder. These can range from mild and asymptomatic disorders to serious disorders including some types of muscular dystrophy, Leber hereditary optic neuropathy, and Leigh syndrome.

In 2009 the Human Fertilisation and Embryology Act was amended to allow mitochondrial donation, but a number of organisations opposed it. The technique is controversial because it combines nuclear DNA from both parents with a tiny amount of mitochondrial DNA from a donor. Some of the concerns raised were that the technique was similar to cloning or that the child would effectively have three parents. The government at that time responded by saying that the power would only be used once the techniques involved were considered to be effective and safe for use.

Last year a consultation by the Human Fertilisation and Embryology Authority (HFEA) showed general support for mitochondrial donation treatment, provided it was subject to strict regulatory controls.^{2 3} In June 2012 the Nuffield Council on Bioethics also concluded that it would be ethical for families affected by mitochondrial disease to use these techniques.^{4 5}

Two treatment techniques have been developed to prevent the transmission of serious mitochondrial disease: maternal spindle transfer and pro-nuclear transfer. In December 2012 an HFEA expert panel concluded that there was no evidence to indicate that either technique was unsafe but said that there was not enough research to recommend one technique over another. The government has asked the HFEA to reconvene the expert panel to give an updated assessment of the safety and efficacy of these techniques before the final regulations are submitted to parliament.

The draft regulations set out which eggs and embryos will be permitted for use in mitochondrial donation treatment. They describe the process that the eggs or embryos must have undergone and the circumstances in which the process may be

applied. The regulations also state that the HFEA must approve clinics before they can provide mitochondrial donation treatment. The consultation will run for 12 weeks until 21 May 2014.

The chief medical officer, Sally Davies, said, "Allowing mitochondrial donation would give women who carry severe mitochondrial disease the opportunity to have children without passing on devastating genetic disorders. It would also keep the UK at the forefront of scientific development in this area."

Peter Braude, emeritus professor of obstetrics and gynaecology at King's College London, commented, "It is true that genetic alteration of disease risk is an important step for society and should not be taken lightly. However, the proposed changes to the regulations ensure that it will be limited to informed couples, who understand from sad personal experience the significant effects of their disease and are best placed to balance the risks of the technology with the possibility of having children without mitochondrial disease."

Medical charities welcomed the move but urged the government to move quickly to pass the regulations. Robert Meadowcroft, chief executive of the Muscular Dystrophy Campaign, said, "It will soon be two years since the initial consultation with the public was announced and three since the review began. There have been lengthy waits at every stage, and we now call on the government to ensure that regulations are passed before the next general election, so that the technique can be moved towards clinical trials as soon as possible."

- 1 Department of Health. Open consultation: serious mitochondrial disease: new techniques to prevent transmission. Feb 2014. www.gov.uk/government/consultations/serious-mitochondrial-disease-new-techniques-to-prevent-transmission.
- 2 Mayor S. Chief medical officer advises government to allow mitochondrial replacement to prevent disease. *BMJ* 2013;346:f4211.
- 3 Human Fertilisation and Embryology Authority. Mitochondria public consultation 2012. www.hfea.gov.uk/6896.html.
- 4 Hawkes N. Intervention to prevent transmission of mitochondrial disorders should be allowed, subject to safeguards, report says. *BMJ* 2012;344:e4089.
- 5 Nuffield Council on Bioethics. Report on mitochondrial DNA disorders. Jun 2012. www.nuffieldbioethics.org/mitochondrial-dna-disorders.

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