Government gives the go ahead for mitochondrial donation during IVF

Ingrid Torjesen

London

The UK government will push ahead with plans to allow mitochondrial donation during in vitro fertilisation (IVF) where the child will be at risk of inheriting a serious mitochondrial disorder. The decision came after a public consultation and a safety and efficacy assessment, and the next step will be to lay the regulations permitting the procedure before parliament.

Around 1 in 6500 children born in the United Kingdom has a serious mitochondrial disorder, which can include some types of muscular dystrophy, Leber hereditary optic neuropathy, and Leigh syndrome.

Mitochondrial DNA is inherited solely through the maternal line. The technique of mitochondrial transfer is controversial because it combines nuclear DNA from both parents with a tiny amount of mitochondrial DNA in a donor egg to create what has been dubbed a “three parent baby.” As a result, the baby will not carry its mother’s mitochondria that have the DNA for the mitochondrial condition.

The government’s three month consultation on the proposed regulations drew 1857 responses from research bodies, patient bodies, professional organisations, faith organisations, parliamentarians, and many others. Four in five respondents simply expressed a view for or against the principle of mitochondrial donation rather than on the regulations, the Department of Health said. But where comments were made about the details of the regulations, respondents were generally positive about the proposed provisions.

Alongside the consultation the department asked the Human Fertilisation and Embryology Authority to reconvene an expert panel to further review the efficacy and safety of two mitochondrial donation techniques—maternal spindle transfer and pronuclear transfer. Reporting last month, the review found that both techniques were potentially useful for a specific and defined group of patients and that the evidence did not show that they were unsafe.

Under the proposed regulations the authority would consider each application on a case by case basis and would have to be satisfied of a particular risk of mitochondrial abnormality and a significant risk that the person with the abnormality would develop a serious illness or condition. Also, the authority would release only non-identifying information about the mitochondrial donor to people born after mitochondrial donation, once they reached age 16.

Before the regulations are put before parliament the Department of Health will review them, to take account of issues raised during the consultation process and to clarify consent requirements around the use and storage of eggs and embryos used in these mitochondrial donation techniques. It will also hold discussions with the Human Fertilisation and Embryology Authority about an appropriate approval process for the techniques, as recommended by the expert panel.

In a ministerial statement Jane Ellison, public health minister, said, “The government will consider the timing of the regulations in the light of these actions.” The Department of Health has promised an update on the timing of the regulations in the autumn, and scientists and charities have urged the department to press ahead quickly with no further stalling.

The Human Fertilisation and Embryology Act was amended in 2009 to allow mitochondrial donation, but a number of organisations opposed this; however, last year the results of a public consultation by the Human Fertilisation and Embryology Authority showed general support for it.

Jeremy Farrar, director of the Wellcome Trust, said, “As the government’s latest consultation has again shown, there is broad public support for making mitochondrial replacement therapy available to patients. There is now no excuse for the government not to table regulations for debate as soon as parliament returns this autumn, so that the HFEA [Human Fertilisation and Embryology Authority] can license clinics to treat affected families without delay once it is satisfied that any risks are acceptable.”

Doug Turnbull, professor of neurology at Newcastle University, said, “We would welcome a firm timetable for this to be tabled for debate in parliament and become a legal treatment. We have patients waiting who could greatly benefit from this new IVF technique.”

Robert Meadowcroft, chief executive of the Muscular Dystrophy Campaign, said, “A three year consultation and review process has shown that the majority of people in the UK are broadly supportive of mitochondrial donation IVF.”

He added, “It is now up to the government to ensure that these regulations are considered and approved by parliament before the next general election in May 2015, or risk losing the progress that has been made towards taking this pioneering technique forward. We need to see a firm commitment to debating this issue in parliament before the end of the year.”


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4 Torjesen I. UK moves a step closer to being first country in world to allow “three parent babies.” BMJ 2013;346:f1899.

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