Case Study: Medical Frontiers: Debating Mitochondrial Replacement

In March 2012, the Secretaries of State for Health and Business, Innovation and Skills, asked the Human Fertilisation and Embryology Authority (HFEA) to seek public views on two emerging IVF-based techniques to prevent the transmission of mitochondrial disease. Supported by Sciencewise, the HFEA commissioned a public dialogue to gain insight into public views on the ethical, social and regulatory considerations of these techniques with a view to informing any future policy change. The public dialogue was one element in a mixed methods approach, which also included a survey, open public meetings and an online consultation, and patient focus groups. The findings informed HFEA's advice to Government. This case study explores the impact of the public dialogue on policy developments.

1. Background

Mitochondrial replacement techniques (MRT) can prevent mitochondrial diseases being passed from a parent's DNA to their children. However, the Human Fertilisation and Embryology Act (1990) classified clinical use of eggs and embryos that have had their nuclear or mitochondrial DNA altered as illegal.

The two techniques looked at in the dialogue involve removing the nuclear DNA from an egg or embryo with unhealthy mitochondria and transferring it into a donor egg or embryo with healthy mitochondria. If allowed in treatment, the techniques would, for the first time, use modified embryos to make a child with DNA from its own parents and from a donor, with these changes being passed down the maternal line to the next generation. At the time, the researchers estimated that these techniques could become treatments within two years. *"As the UK scientists involved pioneered their world-leading techniques, so we had to develop new ways of discovering people's views about it. It was clear from the outset that such an innovative and potentially controversial technique would need to be discussed by members of the public in as much depth as possible."*[1]

Figure 1. Image from Google Images. Free to use.

2. Impact

The Sciencewise dialogue has already had significant impacts on policy development. The findings directly informed HFEA's advice to Government on 20th March 2013. This concluded that the dialogue showed broad support for mitochondria replacement being made available to families at risk of passing on a serious mitochondrial disease. The advice to Government identified safeguards to reflect the three conditions identified in the public dialogue.

[1] Quote given by HFEA representative in 2018

On 25th June 2013, in a debate in the House of Commons, then Parliamentary Under-Secretary of State for Health (Anna Soubry), noted that the dialogue was carried out by the HFEA "*in collaboration with Sciencewise, which has a key role in helping the public to understand complex scientific issues*". She reported that the HFEA had advised the Government that "*there was broad support for mitochondrial replacement being made available to families at risk of passing on a serious mitochondrial disease*".

On 28th June 2013, Dame Sally Davies, the Chief Medical Officer, announced the Department of Health's (DH) decision that "*innovative IVF-based techniques could be made available to patients to help prevent serious mitochondrial disease in the UK*". Her announcement referred to the public dialogue and its conclusion of support, "*subject to strict safeguards and careful regulation*". Draft regulations for MRT were published by the DH in February 2014, and passed in the House of Commons and the House of Lords in February 2015. The regulations include safeguards raised by the public dialogue.

Figure 2. Image provided by Involve.

After the development of a licensing framework and further testing of the therapy, HFEA granted the first UK licence for mitochondrial replacement therapy in March 2017.

HFEA said that the public dialogue had "*helped enormously to formulate the policy advice [HFEA] gave Government*" and provided "*a serious backbone to that assessment" by acting as a "direct route for public dialogue to feed into decisions of Parliament*". Stakeholders noted that the project provided the most extensive form of public opinion evidence collection in their professional experience.

This project has also won international recognition. Dr Peter Mills, Assistant Director of the Nuffield Council for Bioethics, spoke about the HFEA Sciencewise dialogue in a session titled 'Mechanisms of Deliberation and Oversight', as part of 'Editorial Aspirations: Human Integrity at the Frontiers of Biology', a conference held at Harvard University.

3. Vital Statistics

Commissioning body	Human Fertilisation and Embryology Authority
Duration of process	13 months: March 2012 – March 2013
Number of participants	1,070 (979 in public representative survey and approximately 90 involved in deliberative public workshops) in Cardiff, London and Newcastle
Total stakeholders involved	1,935 (seven in patient focus group, 92 across two open consultation meetings and 1,836 responded to an open consultation questionnaire)
Cost of project	£220,000 total, Sciencewise co-funding = £72,000
Dialogue contractor	OPM Group
Evaluation contractor	Dr Richard Watermeyer, Cardiff University School of Social Sciences, and Gene Rowe Evaluations