Tracing the impacts of public dialogue projects supported by Sciencewise:

Mitochondrial replacement

March 2016

Mitochondrial Replacement

Key facts

Date
March 2012 - March 2013 (13 months)

Costs
- Total cost of project: £220,000
- Sciencewise funding: £72,000

Commissioned by
Human Fertilisation and Embryology Authority (HFEA)

Delivery
OPM with Dialogue by Design and Forster

Evaluation
Richard Watermeyer, Cardiff University School of Social Sciences, with Gene Rowe Evaluations

Sciencewise Dialogue and Engagement Specialist (DES)
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Introduction

In 2012 - 2013, a major public and stakeholder consultation was undertaken by the HFEA to review the ethical, social and regulatory issues involved in the clinical use of techniques for mitochondrial replacement. These techniques had previously only allowed for research. The consultation was designed to contribute to the HFEA advice to Government on potential changes to existing legislation.

The dialogue project in summary

Mitochondrial replacement was illegal for treatment purposes in the UK. The Human Fertilisation and Embryology Act (1990), as amended in 2008, governs research and treatment involving human embryos and related clinical practices in the UK. The Act only permits eggs and embryos that have not had their nuclear or mitochondrial DNA altered to be used for treatment. Permitting mitochondrial replacement in treatment required a change in the law by Parliament, through secondary legislation to introduce regulations. A six-month inquiry by the Nuffield Council on Bioethics into the ethical issues raised by the new techniques was launched in January 2012 and reported in June 2012.

Also in January 2012, the Secretary of State for Health, and the Secretary of State for Business, Innovation and Skills, asked the HFEA to seek public views on emerging IVF-based techniques to prevent the transmission of mitochondrial disease (explicitly proposing that the consultation was carried out with support from Sciencewise). The aim of the dialogue and consultation was to identify:

- The process of deliberation people use to form views on mitochondrial replacement
- The differences between informed and uninformed public views on these techniques
- Interested stakeholders' arguments for and against the use of the techniques
- Analysis of the ethical and regulatory issues involved.

July and August 2012. The deliberative workshop events with the public took place. The project overall also included stakeholder engagement throughout (including in a formal oversight group), opinion polling, open public meetings, a focus group, internal technical discussions, and an open written online consultation. A total of 3,005 public and stakeholder participants was involved: 1,070 public participants - 90 in deliberative workshops with recruited public participants, plus 979 in poll survey; plus 1,935 stakeholders - 7 in focus group, 92 in open meetings and 1,836 responses to the open consultation questionnaire. Sciencewise provided advice and support to the whole project, working closely with the Oversight Group.

The results of the specific 'dialogue' element of the project were that the participants broadly agreed support for the techniques, with caveats and conditions (as spelt out in the dialogue report). The deliberative public workshops also broadly took the view that certain requirements needed to be in place before support could be given to the use of the techniques:

- A more comprehensive scientific assessment of safety and efficacy must be done.
- There needs to be more information about how individuals will be able to access the techniques, with an emphasis on the importance of fair, equitable and affordable access.
- There needs to be more information about mitochondrial disease provided to the public, along with information on testing and diagnosis.

January 2013. The HFEA reconvened the core panel of experts who had reported previously on the safety and efficacy of the methods to avoid mitochondrial disease (whose previous work had been completed in 2011), to provide an updated

view of the science to support the assessment of the efficacy and safety of the two medical techniques being considered (MST and PNT). **More scientific assessment of safety and efficacy were among the key requirements resulting from the dialogue.** The results of this update exercise were also considered by the Authority in March 2013 (see below).

Impacts on policy

The dialogue findings fed directly into HFEA advice to Government considerations of whether to change the law to allow clinical practice of mitochondrial replacement. The stages in the influence and impacts on policy have been:

- **20 March 2013. Reflection of dialogue results in HFEA papers leading to HFEA decisions on advice to government**. A detailed report of the results of the deliberative public workshops (the actual 'dialogue' element') was produced by the contractors (OPM) in February 2013. The HFEA produced a paper for the Authority meeting on 20 March 2013 at which they decided on the advice that would go forward to government on the issue. These papers are all published on the HFEA website, and the Authority meeting was open to the public.

  The main HFEA paper for the Authority explained the deliberative workshop process and summarised the results, and the full report of the results of the deliberative workshop were circulated to the Authority and published as Annex ii (Annex i was a summary of the evidence from across all strands of the consultation). The HFEA agreed its advice to Government at its meeting on 20 March 2013, concluding that the results of the consultation showed broad support for mitochondrial replacement being made available to families at risk of passing on a serious mitochondrial disease. The HFEA advice specifically identified a series of safeguards which reflected the three conditions identified in the results from the public dialogue, and drew extensively on all the results from the consultation.

- **28 March 2013**. The finalised public dialogue and scientific update reports were formally sent to Government.

- **25 June 2013**. A debate in the House of Commons during which the Parliamentary Under-Secretary of State for Health (Anna Soubry) described the consultation on mitochondrial replacement as being "*In collaboration with Sciencewise, which has a key role in helping the public to understand complex scientific issues, the HFEA took many different approaches to ensure that it gathered public views on the issue*", and the HFEA report included "*the outcome of its public dialogue*". 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*" and that it also advised that "*if treatment were to be authorised by Parliament, it should be under certain conditions such as its being available only in licensed clinics*" (Hansard 25 June 2013; Column 64 - 65WH[1]).

- **28 June 2013**. The Chief Medical Officer (Dame Sally Davies) announced[2] that the Government (Department of Health) had decided that "*Innovative IVF-based techniques could be made available to patients to help prevent serious mitochondrial disease in the UK*". The announcement included specific reference to the public consultation and its conclusion of support, "*subject to strict safeguards and careful regulation*".

- **1 July 2013**. Anna Soubry made a further statement in Parliament that the Government "*largely accept the advice contained in the HFEA's report of 28 March. We therefore propose moving forward towards laying regulations ...to allow mitochondrial replacement techniques to prevent the transmission of serious mitochondrial disease, subject to strict safeguards ... We therefore intend to publish draft regulations for consultation in autumn 2013 with the intention that, subject to the views received, these would be laid before Parliament next year.*" As well as enabling women "*who carry mitochondrial disease the choice to have genetically related children without risk of serious and life-threatening conditions. It would also keep the UK in the forefront in scientific development in this area*". (Hansard 1 July 2013; Column 34WS - 35WS).

- **27 February 2014**. Draft regulations for mitochondrial donation published by Department of Health. Further public consultation launched, open for three months.

- **12 March 2014**. House of Commons adjournment debate on mitochondrial replacement (Hansard 12 March 2014; Column 164WH). The contributions to the debate made significant references to the public consultation / dialogue. The Parliamentary Under-Secretary of State for Health (Jane Ellison) referred (Column 173WH) to "*the comprehensive public dialogue and set of consultations in order to understand the public's views on and understanding of this issue. The HFEA consultation was held between July and December 2012. It looked at the social and ethical issues raised by mitochondrial replacement, as well as addressing a range of practical regulatory issues. Sciencewise, which plays a key role in helping the public to understand complex scientific issues, commended that public dialogue and the HFEA as an exemplar in its approach to gathering public views on a complex issue.*"

  Jane Ellison continued "*The HFEA gave a full set of advice to the Government in March 2013 based on the findings of the public dialogue and including further advice from the expert panel that it had reconvened. That concluded that although there continues to be nothing to indicate that the techniques are unsafe, further research on some specific*

[1] http://www.publications.parliament.uk/pa/cm201314/cmhansrd/cm130625/halltext/130625h0002.htm
[2] DH and HFEA Press Release, 28 June 2013. Innovative genetic treatment to prevent mitochondrial disease

aspects should be undertaken. Overall, the advice from the HFEA, informed by the balance of views from the public and stakeholders, was that the new treatment techniques should be allowed so long as they are safe and carefully regulated."

- **June 2014**. HFEA releases third scientific review of safety and efficacy (one of the conditions identified from the deliberative workshops for public consent to the clinical use of mitochondrial replacement).

- **22 July 2014**. Department of Health publishes Government response[3] to the public consultation on draft regulations. 1,850 responses received in total. This referred directly to the dialogue several times including twice in the initial background section. Other references were: that "*The Government is of the view that if the HFEA's register does show that the applicant was born as a result of the use of mitochondrial donation, the applicant should be able to access non identifying information about their donor. This reflects the HFEA's public dialogue and consultation and feedback from the Nuffield Council on Bioethics 2012 report, Novel techniques for the prevention of mitochondrial DNA disorders, as well as being informed by the responses to this consultation*." (page 30).

  Also "*The Government recognises that allowing the use of mitochondrial donation techniques in treatment in the UK provokes strong opinions on both sides of the debate. The Government did not pose the question of whether it was appropriate to allow mitochondrial donation in the consultation because this specific point had been the subject of a public dialogue/ consultation exercise carried out by the HFEA in 2012/13 and did not consider it would be appropriate to cover the issue again in this consultation exercise, as the Government had decided on and announced its policy position.*" (page 41).

- **1 September 2014**. House of Commons backbench debate on mitochondrial donation, called by Fiona Bruce MP, to note the HFEA's most recent scientific review. The debate made extensive reference to the public consultation / dialogue. David Willetts MP said "*This is a scientific advance that does not affect human identity, that is the opposite of eugenics, that enables people to escape a potential new cruelty if we do not act on this knowledge, and that is not a slippery slope. This is not just my view. We conducted a structured dialogue to consult members of the public on what they thought. When they understand that this is not to do with hereditary characteristics being affected by an arrogant intervention to create a designer baby, they support these interventions. If they support them, then so should we, in all parts of the House*." (Hansard 1 September 2014; Column 98)

  Jane Ellison (see above) said: "*This is undoubtedly a really difficult area in which to gauge public opinion, because it is complex and technical and a lot of people know nothing about it ... That means that the exercise of engaging the public needs to be carried out in a thoughtful and comprehensive way. That was exactly what the Government did—we tested the public acceptability of introducing these techniques through a comprehensive dialogue process commissioned by the HFEA and led by external experts. It included events such as workshops and focus groups, and it showed that when the process of mitochondrial donation was fully explained to them, the majority of people supported its use provided that it was carefully regulated. The Department of Health's consultation was on the draft regulations, and those who commented on them broadly supported them. I urge people to be mindful of the way to go about testing public opinion on the matter. We have to ensure that it is done on the basis of facts*." (Column 120-121)

- **19 September 2014**. Evaluation of separate opinion survey published[4]. The Wellcome Trust commissioned an evaluation of the survey by ComRes in early 2014 called CARE 3 - Parent Embryo Survey. The evaluation (conducted by the same evaluators that did the independent evaluation of the HFEA consultation) concluded "*Indeed, our evaluation of the HFEA's public consultation on the issue makes explicit that dialogical methods of public deliberation and consultation are far more robust and effective at extracting credible and meaningful public input than non-dialogical kinds on such complex issues*." (page 8)

- **22nd October 2014**. Parliamentary Select Committee on Science and Technology. Evidence hearing to examine the science and proposed regulation of mitochondrial donation.

- **17 December 2014**. Government published regulations on allowing mitochondrial donation.

- **3 February 2015**. MPs debate amendment to the Human Fertilisation and Embryology Act making mitochondrial donation legal. Jane Ellison (see above) introduced the regulations by explaining the process to date including reference to the public consultation / dialogue including: "*Over the last five years, there has been extensive engagement and consultation with the public on this issue, including an ethical assessment by the Nuffield Council on Bioethics in 2012; a public dialogue and consultation exercise carried out by the Human Fertilisation and Embryology Authority in 2012-13; and a public consultation on draft regulations carried out by the Department of Health in 2014*." (Hansard 3 February 2015; Column 160). The vote was 382 in favour of the regulations; 128 opposed. There was extensive media coverage of the issues around this debate leading up to the debate and subsequently (see separate analysis in monthly Impacts and accolades summary, January 2015).

[3] Department of Health. *Mitochondrial Donation. Government response to the consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child*. Public Health Directorate, Health Science and Bioethics Division. July 2014.

[4] *Evaluation of the ComRes CARE 3 – Parent Embryo Survey. Final Report*. Dr Richard Watermeyer and Dr Gene Rowe. 19 September 2014. PIER Logistics and Gene Rowe Evaluations.

- **24 February 2015**. House of Lords debate to approve the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015. Lord Howe, Parliamentary Under-Secretary of State, Department of Health, introduced the debate and included specific mention of the extent and high quality of the public consultation / dialogue (Hansard 24 February 2015; Column 1569): "*My Lords, the purpose of the regulations is to enable women to have their own genetic children, free of terrible disease caused by disorders in their mitochondrial DNA. The regulations do so by allowing healthy mitochondria from a donor to replace the unhealthy mitochondria in a woman's egg or embryo … Over the last five years, there has been extensive engagement and consultation with the public on this issue, including, first, an ethical assessment by the Nuffield Council on Bioethics in 2012; secondly, a highly commended, respected and wide-ranging public dialogue and consultation exercise carried out by the HFEA in 2012-13; and, thirdly, a public consultation on draft regulations carried out by the Department of Health in 2014 … This process was commended in a recent letter to the Guardian from eminent scientists and Nobel Prize winners from the UK and across the world. The letter included this sentence: 'the UK has run an exemplary and internationally admired process for considering benefits, risks, ethical issues and public consent, which must properly precede a change in the law'*."

  In later challenges to the motion to approve the regulations, and an amendment, Lord Howe went on to say (Column 1621): *"The Government are therefore satisfied that there is sufficient scientific evidence to justify Parliament being asked to consider regulations to enable the use of two mitochondrial donation techniques in clinical practice. As I have said, it will be for clinicians in consultation with families to decide which technique would be best in each case. It is worth noting that the HFEA's public dialogue showed a considerable level of public acceptability for both techniques.*

  My noble friend also referred to the ComRes poll and suggested that we had somehow unfairly dismissed it. The ComRes poll was commissioned by the CARE organisation—Christian Action Research and Education—which I understand opposes the introduction of mitochondrial donation. An evaluation of the survey was conducted by Pier Logistics and Gene Rowe Evaluations. The evaluators considered the survey to be a deeply flawed piece of work. They criticised the intentional use of what they described as, 'sensationalist, inflammatory and misleading language to characterize the debate'. There was also considered to be: 'An unreasonable degree of selectivity within respondents' informational options and the intimation of an exercise focused on the generation of self-ordained results'. The evaluation summary commented that the survey was, 'a good example of poor public consultation'."

  During the debate, specific regulations drafted as a result of the consultation were identified by Lord Howe: "*Regulations 16 and 17 set out special provisions for consent, which were identified through the public consultation process.*"

  Other points at which the consultation was referred to during the debate include the following:

  Viscount Ridley (Column 1586): "*Is it safe? We have heard that the safety and efficacy of both techniques have been established as far as is possible by exhaustive study, independent scrutiny and public consultation.*"

  Lord Walton (Column 1596): "*I have to say that I now firmly believe that the work has been done: all the research has been done, the consultations have been widespread. The Nuffield Council on Bioethics, along with the expert committees, has issued a series of completely positive reports. All the organisations in the medical profession, starting with the BMA, the royal colleges, the Medical Research Council and the Association of Medical Research Charities, are universally in favour of accepting the regulations at this stage, because they believe that the consultation, along with the research, has probably been the widest, most comprehensive and most detailed that has happened in the case of any medical procedure in history.*"

  Baroness Warwick (Column 1608) said: "*The Nuffield Council on Bioethics found that, given the benefits to individuals if shown to be sufficiently safe, the techniques are ethical for families to use. The public, during consultation, concurred.*"

  In his closing remarks, Lord Howe also referred to the 'in depth consultation' (Column 1622): "*I outlined the rolling programme of work that has gone into assessing the safety and efficacy of these techniques, as well as their ethical and public acceptability. That process has, I believe, been admired and commended across the world. So much progress has been made in the lifetime of this Parliament that in the Government's view it is right that Parliament should now have the opportunity to vote on whether to allow the families who wish to use these techniques to have children free of the devastating consequences, which we have heard about from noble Lords, within a robust regulatory framework. The request to the Department of Health to develop these regulations was made at the start of this Parliament in 2010. The subsequent in-depth consultation and assessment has taken place through the lifetime of this Parliament. It seems highly appropriate that we complete the task by approving the regulations today.*"

  At the end of the debate, the motion was agreed.

- **29 October 2015**. The regulations to permit mitochondrial replacement came into force and the HFEA made plans to license and regulate mitochondrial donation. The development of these plans followed a further online survey and one-day workshop in London on 23 June 2015, to gain expert views. A two-stage licensing process was proposed – any clinic proposing to carry out either of the two techniques would need to apply to the HFEA for a license for the techniques and then seek authorisation to undertake the treatment in the case of a particular patient. Clinics would also be required to submit information to the HFEA about the mitochondrial donor, the patients being treated and sperm provider, and the treatment cycles. (http://www.hfea.gov.uk/6896.html)

By 29/30 October, the HFEA had created consent forms, guidance for clinics, application forms for clinics to be licensed to use the techniques and to apply to use the techniques for specific patients, and communicated to centres that these were in place.

- **As at February 2016**. The only remaining step that needed to happen before clinics could apply for licenses were completion and publication of further research on safety and efficacy, followed by another scientific review and a final assessment of some safety tests that were recommended earlier. The HFEA confirmed the importance of the dialogue throughout the process: *"the main outcome being that the public views have been reflected all the way along from developing draft proposals… to signing off of the regulations and developing the licensing process."*

Impacts on HFEA and others

- **November / December 2013**. Sciencewise follow up interviews with HFEA and key stakeholders identified the following comments (numbers identify specific interviewee):
  - The dialogue "*Helped enormously to formulate the policy advice we gave Government. Provided a serious backbone to that assessment. Government about to consult on draft regulations. Minded to change the law*" (HFEA)
  - "*Directly fed into law potentially being changed ... Direct route for public dialogue to feed into decisions of parliament*" (HFEA)
  - The experience of the public dialogue "*Reinforced our broad position [that] ... with the right issue this is definitely the way to do things" (8). It enabled the HFEA to "try out techniques that we might use again in future ... Enabled us to evaluate using those techniques and am sure we'll use them again in the future*" (HFEA)
  - "*Dialogue is good for complex topics ... Gets beyond headline responses or ill-informed gut reactions" (HFEA). It is "essential for any ground breaking change in the law. Any policy to do with human reproduction potentially affects lots of people - important that they have the opportunity to express their views" (HFEA). This was a "unique technique - controversial and ground breaking - needs solid basis of public being informed and consulted. This was achieved*" (HFEA)
  - Using a variety of methods to engage with the public "*Made decision making easier ... More secure because [our Board] felt they had a proper handle on what the public felt rather than relying on one method that might be open to criticism*" (HFEA)
- **April 2014**. Independent evaluation of the public dialogue and consultation published by HFEA and Sciencewise[5]. Although undertaken from the start of the project, and continuing for only a short time after it finished, the evaluation report took a long time to finalise (hence the late publication date). This evaluation concluded that there were significant positive impacts from the dialogue, including:
  - The project was seen to be *"a unique event in public consultation when experienced as the interface between a highly innovative, 'state-of-the-art' science and its emotional and ethical interpretation and public construction*." (evaluation report p95)
  - Stakeholders saw "*The value of the consultation as a means of reassuring politicians for whom the scientific and ethical complexity of the techniques represents too great a risk in the policy context*." (p101).
  - The dialogue "*produced a credible corpus of evidence facilitating and ... enhancing and enriching, the capacity of government to make an informed decision based on public intervention / input regarding the regulation of techniques to avoid mitochondrial disease in clinical treatment.*" (p5)
  - The dialogue "*provided a set of views that will be relied upon for years to come ... becoming a reference point and basis for educational and policy announcements based on evidence, and a model for regulation in other national contexts ... Great insight was attained into how a quality consultation should be arranged, with the consultation providing an 'off-the-peg' model of public engagement" (p102).* The project provided *"Increased credibility for the HFEA*" (p102)
  - "*Government must realise that continued and long-term investment in dialogue / consultation of this sort is essential in the generation of the most robust evidence-informed policy*." (p101)
  - Stakeholders suggested that the dialogue would result in benefits for the UK in this field of research and practice: "*Scientists will identify the UK as leading the way – setting a precedent difficult for other countries to ignore or oppose*." (p101)
  - The HFEA undertook an internal lessons learned exercise, building from the formal wash-up meeting convened by Sciencewise, to explore and embed learning from the experience (p92).

[5] *Evaluation of the project: Mitochondria Replacement Consultation*, by Dr Richard Watermeyer and Dr Gene Rowe. Cardiff University and Gene Rowe Evaluations. http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Mitochondria-evaluation-FINAL-2013.pdf

- The dialogue provided the HFEA with "*a rich source of learning in best practice in public engagement; in effective working with a range of external and contracted parties in fulfilling the objectives and aspiration of public consultation in emergent and controversial science; and an overall template for use in future work*." (p101)

- **As at February 2016**. Follow up interviews with the HFEA found the dialogue project had achieved longer lasting organisational impacts and benefits including: "*Contributed to people having confidence that the HFEA is the appropriate body to regulate these novel techniques and to do so at kind of arm's length from government and involve the appropriate experts. Generally been a good reference point when the purpose of the HFEA has been debated."*

  The HFEA was likely to use public dialogue again: "*If there was a relevant issue that related to something that had social and ethical implications and we knew that there would be large public interest then we would consider running some more public dialogue … It definitely needs to be part of the process … for large changes in policy that have social and ethical implications."*

  The HFEA also said *"The main point is that good evidence (which public dialogue brings) much reduces the risk of opponents challenging the policy development process, and so can avoid signficant downstream legal costs"*.

- **Also as at February 2016**. The Department of Health confirmed that the process on mitochondrial replacement "*had influenced our Minister in terms of being able to present a robust process of policy consideration and development, taking into account public views*."

  The Department of Health also pointed to some cost savings by doing a comprehensive process at the start of the decision making: "*Arguably by undertaking a comprehensive dialogue, an open process … at the beginning of the process … we didn't need to undertake another consultation about the public acceptability of the techniques after that. It was a one stop shop. So arguably there were some savings for us*."

  The Department especially valued the strengths of the particular dialogue methods used: *"Because we were applying previously used principles around public dialogue with a clear set of rules and commissioned from independent experts but coming back through the HFEA which itself is an independent body. It gave us a lot of confidence to utilise that data .. We had a much more systematic and scientific approach in terms of asking non-leading questions to people and fully explaining the background to people that gave us a very solid base to go forward and answer any accusations that the public didn't understand or weren't properly informed about it. It also gave Ministers confidence that there was broad public support if they agreed to this going forward.*"

  The Department also said: "*It's given us a highly credible foundation to undertake further evidence gathering work to build a strong case to change the law and then supported the technical steps that we've needed to undertake to actually change the law and make the case to parliamentarians that the law should be changed and has broad public support."*

References and citations

- Andrew Mandelbaum, Senior Program Officer at the National Democratic Institute in the US, used the project as an example of good practice in a session on how to conduct public consultations in legislative processes at the World Bank Institute workshop in Marseille on 10-11 June 2013 (report from Edward Andersson, Deputy Director Involve).

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24 February 2016