



# Medical frontiers: Debating mitochondria replacement

## Annex II: Deliberative public workshops

Report to HFEA

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## Executive summary

The Office for Public Management (OPM), in partnership with Forster and Dialogue by Design, was commissioned by the Human Fertilisation and Embryology Authority (HFEA) to conduct a multi-method research and engagement project looking at the possible social and ethical issues relating to two techniques for the avoidance of mitochondrial disease: pronuclear transfer (PNT)<sup>1</sup> and maternal spindle Transfer (MST)<sup>2</sup>.

As part of this research and engagement, OPM ran three deliberative public workshops each consisting of two series. The workshops aimed to explore the in-depth attitudes of a group of randomly selected members of the public and to understand the journey that participants go on as they become increasingly engaged with and knowledgeable about the issues.

Series one workshops were held in Newcastle, Cardiff and London in July 2012. These workshops focused on helping participants to understand the potential treatment techniques – pronuclear transfer (PNT) and maternal spindle transfer (MST). For series two, the groups were reconvened in the same locations in July and August 2012. The reconvened workshops focused on the potential social and ethical issues relating to the techniques.

At each workshop in both series, participants worked in three groups of 8-10. Each group comprised of people with a range of different demographic characteristics.

In terms of key findings, participants' views remained broadly in favour of the two new techniques over the course of the two days. The principal reason given for this was largely because the techniques give parents the opportunity to have healthy children who are genetically their own, which is not possible using current techniques. In order to form considered opinions, participants used a range of comparisons and analogies, for example with adoption, organ donation and sperm donation, in their discussions.

Participants' views were also shaped by information on the amount and role of mitochondrial DNA in a person's genetic makeup that was described by scientists in the video. The importance that participants placed on individual and personal choice for patients also shaped their views on the techniques. There were some participants who had some concerns about the techniques, due to doubts about the robustness of the scientific evidence presented on day one.

### 1. Understanding the science – series one

Series one workshops were designed to help participants to develop their understanding of the science in a step-by-step process. First, they learned about and reviewed basic concepts such as organisms, cells and DNA. They were then introduced to the more complex topics of mitochondrial disease and the new techniques. Learning was supported by a short biology quiz and an animated briefing video. An expert on the science was on hand to answer any

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<sup>1</sup> Pronuclear transfer involves transferring the pronuclei from an embryo with unhealthy mitochondria and placing them into a donor embryo which contains healthy mitochondria and has had its pronuclei removed. A pronucleus is a small round structure containing nuclear DNA seen within an embryo following fertilisation. A normal embryo should contain two pronuclei, one from the egg (maternal pronucleus) and one from the sperm (paternal pronucleus).

<sup>2</sup> The maternal spindle is a structure within the egg containing the mother's nuclear DNA. Maternal spindle transfer involves transferring the spindle from the intended mother's egg, with unhealthy mitochondria, and placing it into a donor egg with healthy mitochondria.

questions that participants had (see Appendix C for a list of the experts who staffed the workshops and the supporting materials).

Participants' initial discussions about mitochondria and mitochondrial disease raised a range of questions and concerns, particularly about the pathology of the disease, its transmission, prevalence and diagnosis. Concerns about the potential severity of mitochondrial disease led to questions by some participants about why the public had not heard about the disease before. Facilitator observation and participant feedback over the course of the day indicated that input from the scientists was very valuable: they were engaging, spoke in lay terms about complex topics and helped participants grasp the building blocks needed to support the later social and ethical discussions. Additionally, participants also found the handouts and the bespoke video useful too. These gave them clear and accessible information that was easy to follow.

## 2. Emerging views on mitochondria replacement techniques – series one

Overall, participants were fairly positive about the new techniques at this stage of the dialogue. The majority of participants were in favour of the new techniques because they felt these guaranteed parents a healthy child that was *genetically their own*, which is something they felt was important to a great many parents. They spent some time discussing the differences between the two new techniques. A small number of participants were against the use of PNT on the grounds that it involved manipulating and disposing of embryos. More often, participants felt that the use of embryos – and thus also use of PNT – might be an issue for 'other people'. These 'others' were often named as 'religious groups', who it was felt would be the most likely to object.

Participants raised questions and concerns about what, if any, risks were associated with the techniques, and what research had been done to date about success rates and long term safety. They were also keen to learn about the regulatory assurances for these techniques. These questions were either answered by the science expert or a representative from the HFEA present at the workshop, or if the questions related to social and ethical issues, they were noted and discussed at the second workshop.

At all three locations, participants asked about the cost of implementing these new techniques. They questioned whether investing in techniques to eradicate mitochondrial disease is appropriate when health funding is severely constrained. The argument was made largely on the basis of the low prevalence of the disease compared to diseases such as cancer. A majority did think that the techniques could save the healthcare system a great deal of money over the long term, since it would not have to treat people with mitochondrial disease in the future. Discussions about costs often led to conversations about the importance of affordable and fair access to these new treatments should they be approved.

Participants recognised that some people might feel that these techniques are akin to 'playing god' and could result in a 'slippery slope' to 'designer babies' and 'aborting disabled people'. However, most participants focused instead on the potential for these techniques to eradicate disease and give parents the opportunity to have a healthy child. Indeed, from the outset of series one, it was clear that most participants were more interested in these techniques as a means to address disease than from the perspective of reproductive ethics.

A number of factors shaped participant's emerging views on, and levels of support for the new techniques. The most influential were comparisons with available techniques and where the choices should lie. In discussion of pre-implantation genetic diagnosis (PGD) and prenatal diagnosis (PND), participants made a lot of negative comments about PND in

particular. They felt that the new techniques could offer a better alternative because they avoid the disease altogether, rather than PGD and PND which test to see whether mitochondrial disease is present in embryos or foetuses. In general, these comparisons with existing techniques resulted in broad support for the new techniques.

A second influential factor was the **importance of allowing choice. Participants placed great weight on personal and individual choice** and did not think it was appropriate to restrict access to these new techniques to individuals and families just because some people, who they tended to identify as 'religious groups', might be opposed.

### 3. Views on specific ethical and social issues – series two

The second series focused on the ethical and social issues associated with the two new techniques. Discussion was supported by a number of tools, including bespoke scenarios, a video, and brief presentations from bioethicists, followed by a question and answer session.

At the start of the day participants identified the issues they felt it was important to cover. This was followed by some focussed discussion on two specific ethical and social issues:

- DNA from three people and what that might mean for the child and/or donor
- The techniques as germline therapy

To stimulate discussion participants were provided with short scenarios that illustrated these issues. Following initial discussions about the scenarios they also watched videos and heard from ethics experts, both of which presented a range of opinions on the issues involved. In order to track changes in attitudes, participants were asked to complete an ethics questionnaire, which included questions relating to these two issues, at the start and end of the day. In the sections below we will outline participants' views on these two issues, the factors that shaped and changed their views, and the impact these discussions had on their support for the new techniques.

#### 3.1 Attitudes towards DNA from three people and identity

Participants across the three locations had a range of reactions to the first scenario to which they were introduced. This presented the story of Susie, a little girl born as a result of the mitochondrial techniques who wondered about her mitochondrial donor. One area where participants generally agreed was that Susie had the 'right to know' about how she was conceived.

When considering the fact that a child born from the new techniques would have nuclear DNA from both parents and mitochondrial DNA from a donor, hereafter described as **DNA from three people**, there was more variability in participants' views and about how this may impact on identity. Discussions over the course of the day suggested that most participants rejected the 'three parent' label because they felt that the contribution of mitochondrial DNA to a child's personal characteristics was negligible. However, there were also a few participants who felt that the fact that the donation of healthy mitochondria enabled the child to exist was very important and should give the donor some sort of parental status. At the end of the day, participants were more likely to not be concerned by the 'DNA from three people' issue. Analysis of the ethics questionnaires revealed that 57% of participants reported that they were 'not very' or 'not at all' concerned at the end of the day, compared with half (51%) at the start of the day.

There was also variability in participant's views on **whether a child born from these techniques should be able to access information about the donor**. Discussions

indicated that those participants who supported the anonymity of the mitochondrial donor felt quite strongly that the rights of the donor should be protected, and that donors should be given the choice as to whether they want their identity to be revealed to the child. On the other hand, there were also participants who felt that children should have the opportunity to know the identity of the donor, if they wanted. At the end of the day, a larger number of participants favoured the anonymity of the donor. Analysis of the ethics questionnaires revealed that more than four out of ten participants (45%) either strongly disagreed or tended to disagree that any child born after these techniques should have the right to know about the individual who donated the mitochondria, compared with 31% at the start of the day. However, the number of participants favouring the child's right to know about the donor did not change very much – from 33% at the start of the day, to 31% at the end of the day – which indicates that these participants tended to remain steadfast in their views.

A number of factors contributed to helping participants form and change their views about these issues. All discussion groups at each of the three locations used a range of **comparisons and analogies**, for example with adoption, organ donation and sperm donation, in their discussions. Many were influenced by presentations from the experts in which they made comparisons between mitochondrial donation and blood transfusion or bone marrow donation. Participant's views on this issue were also shaped by information on the **amount and role of mitochondrial DNA** in a person's genetic makeup that was described by scientists in the video. Many participants picked up on a comment by an expert in a video about the small number of mitochondrial genes compared to nuclear genes. These comparisons, analogies and information about mitochondrial DNA meant that by the end of the workshop participants were more likely to not be concerned about the issue of DNA from three people. Some participants' views on the issue were also shaped by the **importance they placed on the rights of the child** born from these techniques and this meant that these participants tended to remain steadfast in their attitudes towards children being able to find out about their donors.

### 3.2 Attitudes towards germline therapy

The second scenario focused on Martin and Jane, parents of a child with mitochondrial disease who disagree about whether to use these new techniques to conceive another child, and therefore alter the germline of future generations. Discussions indicated that initially, a majority of participants supported Jane, who wants to have another child via the techniques and several participants felt that Martin was being 'unreasonable'. A number of participants agreed that Martin would change his mind with a better understanding of the science, and many also felt that generally it was important to give parents more information to enable them to make the right decision.

Participants also discussed the extent to which uncertainty about the impact of these techniques on future generations should factor into whether these techniques should be licensed. At this stage participants tended to feel that despite the information and evidence presented on the known risks and uncertainty they were 'worth it' if it meant that the parents could have a healthy child. The risks involved were therefore acknowledged by participants, but did not raise very much concern about the techniques representing germline therapy. Some participants also felt that there is always uncertainty when it comes to new treatments.

Analysis of the ethics questionnaires revealed that in the course of the day, attitudes towards germline therapy remained stable, with 64% not at all or not very concerned about germline therapy at the beginning of the day and 62% at the end. Participants' views on the germline therapy issue were largely shaped by **the importance they placed on individual and**

**personal choice for parents.** Findings from the ethics questionnaire also highlighted the importance that participants placed on individual choice throughout the day. Participants were most likely to feel that couples themselves should make the decision about treatment (in consultation with their doctor), without the involvement of an expert regulator. This continued to be the case, and in fact increased slightly (from 35% to 40%), by the end of the day.

#### 4. Other information and evidence that shaped support for techniques – series two

After discussion about the two specific ethical issues, participants were given the opportunity to watch a further video which presented a range of opinions on the potential social and ethical issues relating to safety, risks, regulation and monitoring. A number of discussion groups picked up on a reference in the video by a scientist to a study on fish about the potential for factors present in cytoplasm (which may or may not involve mitochondria), to influence the number of vertebrae that are formed. For a few participants in each of these groups the mention of this study raised doubts about the robustness of the scientific evidence presented on day one<sup>3</sup>. They felt that this was new information which had not been made available during the first day of the dialogue and questioned whether they had been given all the relevant scientific information. This strong response was felt by a few participants, while many others either did not pick up on the comment, or felt that it was part of the inevitable uncertainty in science and did not cause them concern. What is clear is that for some participants their **trust in the safety of these techniques is relatively fragile, and easily disrupted by new information.**

A few participants also picked up on concerns by a scientist in the video that if the techniques are not licensed in the UK they will become available in other nations with less stringent regulation regimes. These participants tended to agree that it was **important for these techniques to be introduced in a regulated environment.** Participants felt that regulation would ensure the fairness and affordability of the techniques and that they are only used for the purposes of reducing the incidence of disease.

#### 5. Changes in views over the series two workshops

In series two workshops, participants recorded their responses to the following question:

*'If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?'*

Responses were marked on a scale of 1 to 10, with 1 indicating 'reject' and 10 indicating 'support' in their response to the question.

They did this on three occasions throughout the day. The purpose of this was to provide us with a broad indication of whether and how new information, evidence or discussion impacted on their views of the treatments. On the final occasion, we asked participants to

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<sup>3</sup> The reference to this study was dropped from later versions of the video used in the consultation as it was not felt to be relevant because of the lack of transferability of the implications of it to humans and the fact it related to science rather than ethics



explain why their response was on a particular place on the scale. Overall, participants' views did not change greatly throughout the course of the series two workshops, remaining broadly in favour of the techniques. The principal reason for this was largely because the techniques give parents the opportunity to have healthy children who are genetically their own, which is not possible using current techniques.

## 6. Messages for Secretaries of State

Some groups used the last session to express their support for the introduction of the techniques, alongside their conditions. The fundamental reason given for supporting the techniques is that the state should not preclude individuals from having this choice available to them. In other words, participants felt that the choice about whether or not these techniques were appropriate to use was one to be made by parents in discussion with health professionals. Many participants identified a number of requirements associated with their support for the techniques (1, below). Others were more cautious and their support was contingent upon other things happening before they felt a decision could be made. While there was a breadth of the discussions over the two days, the final points across the three locations were relatively similar.

### 1. Support for the techniques with caveats and conditions:

- Individuals need to be provided with all the relevant information they require to make an informed choice. This includes information on the potential and long-term risks, any uncertainties, and the pros and cons of the two different techniques or any alternative treatments
- The techniques must be introduced in a regulated environment
- Parents who choose to access these techniques should be offered counselling
- Donors' identity should be protected
  - Although different views remain about whether some information should be available to the child
- Fair access to these techniques is essential and they should be available on the NHS, to all who might benefit from them, free of charge
- The techniques are to be used to produce a healthy child and for no other purposes

### 2. Requirements before support can be given:

- A more comprehensive scientific assessment of safety and efficacy must be completed; some participants expected human trials a stage prior to wider licensing
- 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

# 1. Introduction

## 1.1 Background and context

Mitochondria are present in almost all human cells. They are often referred to as the cell's 'batteries' as they generate the majority of a cell's energy supply. For any cell to work properly, the mitochondria need to be healthy. Unhealthy mitochondria can cause genetic disorders known as mitochondrial disease.

There are many different conditions that are linked to mitochondrial disease. They can range from mild to severe or life threatening, and can have devastating effects on the families that carry them. Currently there is no known cure and treatment options are limited. For many patients with mitochondrial disease preventing the transmission of the disease to their children is a key concern.

Mitochondrial disease can be caused by faults in the genes within a cell's nucleus that are required for mitochondrial function or by faults within the small amount of DNA that exists within the mitochondria themselves. It is the latter form of mitochondrial disease that could be avoided using two new medical techniques, termed pro-nuclear transfer (PNT)<sup>1</sup> and maternal spindle transfer (MST)<sup>2</sup> which UK researchers are working on.

These techniques are at the cutting edge, both of science and ethics and are currently only permitted in research. They involve removing the nuclear DNA from an egg or embryo with unhealthy mitochondria, and transferring it into an enucleated donor egg or embryo with healthy mitochondria.

The Human Fertilisation and Embryology Act (1990) (as amended) ('the Act') governs research and treatment involving human embryos and related clinical practices in the UK. The Act currently prevents the clinical use of these techniques (or any other technique that involves genetic modification of gametes and embryos to treat patients). However, in 2008 the Act was amended, introducing new powers which enable the Secretary of State for Health to permit techniques which prevent the transmission of serious mitochondrial disease. The Secretary of State for Health and the Secretary of State for Business, Innovation and Skills asked the Human Fertilisation and Embryology Authority (HFEA) to seek public views on these emerging techniques. On considering advice from the HFEA the Government will decide whether to propose regulations legalising one or both of the procedures for treatment.

The HFEA, together with the Sciencewise Expert Resource Centre<sup>4</sup>, therefore commissioned OPM (in partnership with Forster and Dialogue by Design) to conduct a multi-method research and engagement project looking at the possible social and ethical issues and arguments relating to the techniques. The project consisted of five strands:

1. Deliberative public workshops
2. Public representative survey
3. Patient focus group
4. Open consultation meetings
5. Open consultation questionnaire

This research provides the evidence base that will inform the HFEA's advice to the Secretary of State.

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<sup>4</sup> The Sciencewise Expert Resource Centre (Sciencewise-ERC) is the UK's national centre for public dialogue in policy making involving science and technology issues

The **deliberative public workshops** aimed to explore the in-depth attitudes of a group of randomly selected members of the public and to understand the journey that participants go on as they become increasingly engaged with and knowledgeable about the issues.

This report presents the detailed findings from these workshops.

## 1.2 Methodology

Three deliberative public workshops were held in Newcastle, Cardiff and London in July 2012. The groups were reconvened for a further three workshops in July and August 2012. Participants were randomly selected members of the public recruited to represent a broad spectrum of age, gender, socio-economic status and family circumstances (see Appendix A for the demographic profile of participants).

Thirty people were recruited to each workshop. At each workshop participants were representatively distributed into three groups, giving a total of nine discussion groups at each of the two days. The overall numbers involved at each workshop and the size of the table groups meant that each session could elicit a suitable breadth and depth of contributions.

Each group discussion was facilitated by an independent and experienced facilitator. One facilitator also led the plenary discussions (the workshop programmes can be found in Appendix B).

Participants received a thank you payment for attending the workshops, which is standard practice in deliberative workshops with members of the public. They were given to help compensate participants for their time and to encourage them to attend both the first and second workshops.

The first workshops in each location focused on the scientific building blocks that would help people discuss the social and ethical issues relating to the techniques. This involved running a short biology quiz and providing written information sheets, a specially made video and a presentation by a scientist working directly on the techniques concerned (see Appendix C for workshop materials and links to the videos).

The overall purpose of the second meeting was to engage participants in the potential social and ethical issues that relate to the new techniques, building on the science covered in the first meeting. At the start of the second day, the dialogue participants were asked to record on a scale of 1 to 10, with 1 indicating 'reject' and 10 indicating 'support' in their response to the following key question:

*'If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?'*

Participants were then asked to revisit the statement at two further points in the day, to determine the extent to which new information, evidence and discussions had an impact on their support for the treatments. The data captured were analysed and the average/mean score for each discussion group (9 discussion groups), for each location (3 locations) and the overall average/mean score was calculated. We provide an overview of these mean scores, and how they varied over the course of the day in the body of the report.

Participants were asked to explore and discuss two potential ethical and social issues over the course of the day. In order to track changes in attitudes, participants were asked to complete an ethics questionnaire, which included questions relating to these two issues, at

the start and end of the day. An analysis of these findings is presented in the body of the report.

Discussion was supported by scenarios describing different perspectives on the ethical questions to which the techniques give rise, presentations by bioethicists, a video of a patient talking about the experience of having mitochondrial disease, and a second video showing scientists, bioethicists and social commentators expressing a range of different views.

## 2. Understanding the science – series one

### 2.1 Overview of journey

The three series one workshops in Newcastle, Cardiff and London were designed to provide participants with the scientific knowledge and understanding that would help them to develop informed opinions towards the social and ethical issues relating to the new techniques. We felt it was important not to assume participants' levels of understanding and to provide them with a straightforward way of either refreshing existing knowledge or of learning something new.

Each series one workshop started with a biology quiz where participants worked in small groups and gathered information on basic concepts such as cells, DNA and mitochondria from handouts and posters. Next, we showed a video which provided more detailed information on the concepts explored in the discovery exercise and also familiarised participants with mitochondrial disease. A scientist was also on hand to answer any questions (see Appendix C for a list of the expert at the workshops and the supporting materials).

Levels of knowledge about mitochondria and mitochondrial disease were very low across participants, with the exception of a few individuals who had done some research prior to the workshop. More participants were aware of some of the broader issues relating to genetics and assisted reproduction and had some knowledge of the basic biology, though levels of knowledge varied across participants.

Initial discussions about the science resulted in a range of questions and concerns. Most notably, all groups had questions about the pathology of mitochondrial disease, its transmission, prevalence and diagnosis. A number of participants also had concerns about families and, in particular, women who may not know they carry the disease before they start a family of their own. Participants raised concerns about the potential severity of mitochondrial disease which led to questions by some about why the public had not heard about the disease before and what was being done to treat and eradicate the disease.

Participants reported having thoroughly enjoyed the learning process and that the subject matter had been "*interesting*" and "*fascinating*".

### 2.2 Factors that facilitated learning

Facilitator observation and feedback from participants over the course of the day highlighted that a number of factors relating to the design of the workshops contributed to participants' ability to grasp the scientific concepts introduced on the first day. For example, the participation of an **engaging scientist** who went from table to table and facilitated question and answered questions was extremely valuable. The scientist was approachable and enthusiastic and most importantly, able to explain complex scientific concepts and answer questions using layperson's terms. He/she assumed that participants had no previous knowledge of the science and therefore started with the basic concepts, which gave participants the time and space they needed to slowly build up their understanding.

Participants also felt that the handouts provided worked well because they provided them with **clear and accessible information** that was easy to follow. The use of diagrams and the specially made video in particular was felt to be helpful by many participants. The **sequencing of learning sessions** also proved helpful. At the first session they learnt about

and reviewed basic concepts such as organisms, cells and DNA before being introduced to the more complex topics of mitochondrial disease and the new techniques.

In addition to the above factors relating to the design of the first workshops, the fact that the **subject matter was new** to and not part of participants' every day life, also meant that they were interested and focused on learning over the course of the day.

## 3. Emerging views on mitochondria replacement techniques – series one

### 3.1 Support for and concerns about mitochondria replacement techniques

After the initial discovery stage, participants were introduced to mitochondrial disease and the new techniques for avoiding the disease. Materials used to support this included written hand-outs and a video and discussion with the science expert. As well as learning about the new techniques participants also learned about the current options currently available to couples who want to avoid transmitting the disease to their children. These are: adoption, using a donor egg, pre-implantation genetic diagnosis, and prenatal diagnosis.

Overall, most participants were fairly positive about the new techniques at this stage of the dialogue. The majority were in favour of the new techniques because they felt that, unlike the current options available, the new techniques guaranteed that parents would be **able to have a healthy child** and avoid passing on mitochondrial disease completely. Some participants also felt that the techniques meant that the disease would also no longer be passed down the germline to future generations. Many participants reported that they understood how difficult it can be to have a severely disabled child and felt positively about the potential for these techniques to result in healthy children.

Another reason participants felt positively about the new techniques was because they felt that they allowed parents to **have a child that was genetically their own**. These participants placed a great deal of emphasis on the 'right of parents' to be able to pass on their own genes to their children.

Participants spent some time discussing the **differences between the two techniques**. In a few groups, the discussion covered the difference between the two techniques and the use of embryos in one (PNT) in contrast with the use of eggs in the other (MST). A small number of participants were against the use of PNT on the grounds that it involved manipulating and disposing of embryos and that this was inappropriate from a moral and ethical perspective. The more predominant view amongst participants was that objections about the use of embryos and hence PNT were more likely to come from 'other people', with these others often being identified as 'religious groups'. Participants argued that objections from a small group of people should not stand in the way of medical progress or prevent access to these techniques for those who need them.

Two out of the three discussion groups at the workshop in London felt that PNT was the better option. This was on the basis of information from the science expert, who said that the pronucleus was larger and therefore easier to see and access than the spindle. Other reasons cited for favouring PNT over MST was that the former involves working with an already fertilised egg, while the latter does not guarantee that the egg would fertilise. On the whole, participants felt that what was most important was to test which technique had the highest success rates and was the safest.

Once participants felt confident about their understanding of the new techniques they felt able to raise some questions. These included questions about the **risks associated with the techniques**, for the mother, child and future generations; information relating to long term-safety; the nature of **research** carried out to date and whether animal trials had been successful. Some participants had questions about the **regulatory environment** for

reproductive techniques and reported having little knowledge of regulatory bodies. These questions were either answered by the science expert or a representative from the HFEA present at the workshop, or if the questions related to social and ethical issues, they were noted and discussed at the second workshop.

A number of participants continued to raise questions about the **pathology, prevalence and diagnostic testing** of mitochondrial diseases. They wanted reassurance that the proper diagnostic testing and records would be in place to ensure that all women that carried the disease were aware of its presence in their germline before they started a family.

### 3.2 Views on ethical and social issues

In addition to their questions on the science itself, participants in this first series of workshops also raised and discussed spontaneously a number of ethical and social issues.

In all three locations and in most discussion groups, participants asked about the **cost of developing and funding** the new techniques. Mindful of current constraints on healthcare funding, they questioned whether it was right to invest in techniques to eradicate mitochondrial disease when the prevalence of the disease was much lower than the prevalence of other diseases, such as cancer.

On the whole, participants tended to feel that the investment was 'worth it' for a range of reasons. The majority felt that the techniques had the potential to save the healthcare system money that it would otherwise have to spend on treating and supporting people who developed mitochondrial disease in the future. Some participants wanted evidence that this would be the case and that the benefits of the treatments would outweigh the cost. Others felt that although the prevalence of the disease was lower than that of other diseases, its severity meant that investment was warranted. Some participants felt that investment is warranted because scientists are closer to developing effective preventative techniques than they are for other diseases. They noted too that other diseases - such as cancer - already receive a lot of funding. A few participants supported the investment because of the potential for learning from the treatments. They felt that scientists and doctors might learn about how to prevent other diseases. Lastly, some argued that it is important for the UK to be leading research and development of these new techniques.

Discussion about costs and funding often led to conversations about **access** to these new treatments, should they be approved. Affordability and fairness are important to participants, who stressed that it is important to ensure that the techniques are available on the NHS and not accessible to private patients only.

Participants discussed the 'slippery slope' argument and the potential for these techniques to open the way to '**designer babies**' selected on the basis of personal characteristics. Participants in one group felt that this argument would be raised by those who don't understand the science, implying that they, having understood the science, did not feel that the 'slippery slope' argument was valid. Overall, participants supported techniques used for health reasons – such as the two techniques under discussion – but not those selecting for personal characteristics. This led some to report that their views on the acceptability of the techniques would change if mitochondrial DNA was found to have an impact on personal characteristics.

In all three locations, participants discussed the issue of '**playing God**.' They felt that some people could see the new techniques as a step towards 'aborting disabled people'. They discussed the 'boundaries' of genetic testing and whether it was fair for people to make



judgments about what constitutes a good quality of life. A minority of participants felt unable to support these – or any techniques involving genetic testing – because of their concerns about these issues. However, most participants focused instead on the potential for these techniques to eradicate disease and give parents the opportunity to have a healthy child. Indeed, from the outset of series one, it was clear that most participants were more interested in these techniques as a means to address disease than from the perspective of reproductive ethics.

### 3.3 Factors that shaped emerging views

A number of factors shaped participants emerging views on and level of support for the new mitochondrial techniques.

First, all discussion groups across the three locations found it helpful to make **comparisons with the current available techniques** in trying to weigh the pros and cons of the new techniques. As mentioned earlier, many participants noted, almost immediately, that the new techniques were preferable to the existing option of pre-implantation genetic diagnosis (PGD) because they guaranteed that the child would not have mitochondrial disease. They also noted that unlike adoption and the use of donor eggs, the new techniques would allow parents to have a child that is genetically related to both parents. Some participants described using a donor egg as ‘having someone else’s baby’ which they recognised may not be what parents want.

Participants drew on the experience of friends or family to relate how adoption, although valuable from a moral and social perspective, can be a long and arduous process. Another factor raised in the discussion of adoption was that it can be easier to adopt toddlers than babies, which can be seen as a disadvantage. Some participants felt that the new techniques would mean there would be less take up of adoption and therefore an increase in the number of children waiting to be adopted. One participant, who had been adopted, felt that much of the discussion was misguided and argued that she was as much her parent’s own child as any genetically related offspring would be, and very far from being ‘someone else’s baby’.

PGD and prenatal diagnosis (PND) were discussed in most small groups: PND in particular was viewed very negatively. Several participants felt that the potential for PND to result in terminations made it contentious and for a small number of participants it was unacceptable because they opposed termination of pregnancies altogether. For others the impact on the parents was a primary consideration, with a positive test result giving parents a potentially traumatic decision to make. Many of those who felt negatively about PND thought the new techniques could offer a better alternative because they avoid the disease altogether, rather than testing to see whether the embryo or fetus is affected. In general, these comparisons with existing techniques resulted in broad support for the new techniques.

The scope for **personal and individual choice** played an important role in determining participants’ emerging views on the new mitochondrial techniques. For example, participants did not tend to think it was appropriate to restrict access to these new techniques because some people, who they identified ‘religious groups’, might oppose them on moral and ethical grounds. As discussed earlier, participants acknowledged arguments about ‘playing God’ and the ‘slippery slope’ but felt strongly that parents should have the opportunity to choose for themselves. Participants did however welcome the debate and acknowledge the importance of different groups expressing their views on genetic treatments.

Finally, participants’ emerging views were a function of the fact that at this stage in the dialogue they had been provided with **incomplete information**. The purpose of the series

one workshop was to focus on the science underpinning the new techniques. Further information relating to social and ethical issues was not provided until the second series. In this absence of information participants therefore had a number of concerns which were broadly in line with the social and ethical issues to be discussed during the second series. These included questions about regulation, costs and access to the new techniques, progress in animal trials and the known risks associated with the new techniques. Some participants therefore had reservations about the techniques because they had not yet had a chance to hear about and reflect on such issues. Nevertheless, at the end of the first series many participants felt positively towards the new techniques.

The series one workshops ended with participants being encouraged by facilitators to reflect on the issues discussed and talk about them with families and friends.

## 4. Initial support for new techniques – series two

The series two workshops were held in the same locations as series one – Newcastle, Cardiff and London – and brought together the same participants. The focus was on the social and ethical issues relating to the two techniques to which they had been introduced to in series one.

Before the discussions began, participants were asked to complete a brief questionnaire that included questions about their views on some of the issues to be discussed. This exercise was repeated at the end of the day.

At the start of the dialogue between participants, we asked them to record their response to the following question:

*‘If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?’*

Responses were on a scale of 1 to 10, with 1 indicating ‘reject’ and 10 indicating ‘support.’

This exercise was repeated at two further points in the day. The purpose of this was to provide us with a broad indication of whether and how new information, evidence or discussion impacted on their views of the treatments. The overall mean score, across discussion groups and locations, at the start of the day was 8.2 which indicates that the participants started the day with fairly high support for the new techniques. This is not surprising since the first day had been primarily about understanding the science underpinning these techniques and participants had only just started to discuss the social and ethical issues associated with the techniques.

The table below provides an overview of how mean scores varied across locations and discussion groups.

**Table 1: Mean scores across locations at the start of the day**

	Group 1	Group 2	Group 3	Mean at location
<b>Cardiff</b>	7.5	8.3	8.4	<b>8.0</b>
<b>London</b>	5.9	9.7	7.5	<b>7.7</b>
<b>Newcastle</b>	8.4	9.4	9.1	<b>9.0</b>

*Base sample (first scoring): Cardiff = 28, London = 26, Newcastle = 28*

For one group the mean score was low (group 1 in London); this group expressed greater concerns about justifying investment in these techniques compared to investment in eradicating diseases with higher prevalence. Across the three locations, some groups also had individuals who felt more strongly about the risk of parents ‘playing God’ or the risk of these techniques leading to others which allow the selection of personal characteristics. Additionally, lower mean scores were also shaped by participants’ desire for more information about the regulation of and risks associated with these techniques.

On the other hand, higher mean scores were generally shaped by participants’ feeling that the new techniques were positive because they gave parents the opportunity to have healthy

children that were also genetically their own, something that they recognised none of the existing techniques to avoid mitochondrial disease were able to guarantee.

## 5. Views on specific ethical and social issues – series two

Series two workshops began with an overview of some of the potential social and ethical issues associated with the new techniques. Following this, participants focused on two specific ethical and social issues:<sup>5</sup>

- DNA from three people and what that might mean for the child and/or donor
- The techniques as germline therapy

To stimulate discussion participants were provided with short scenarios that illustrated these issues. Following initial discussions about the scenarios they watched videos and heard from ethicists or bioethicists. These stimuli mapped out some of the main dimensions of the debates that surround these techniques. In the sections below we outline participants' views on these two issues, the factors that shaped and changed their views, and the impact these discussions had on their support for or rejection of the new techniques.

### 5.1 Attitudes towards DNA from three people and identity

#### 5.1.1 Overview of attitudes and concerns

Participants across the three locations had a range of responses to the first scenario, which presented the story of Susie, a little girl born as a result of the mitochondrial techniques who wondered about her mitochondrial donor. Participants tended to agree **that Susie should know how she was conceived** and identified a number of reasons why this was important. Some took a fairly straightforward 'rights' perspective whilst other argued more pragmatically that medically relevant genetic information would be important to Susie and her healthcare providers. Some participants felt that giving children this type of information would be essential because long-term monitoring of individuals born of these techniques would be necessary. Participants expressed these views prior to watching the video and hearing from the ethicists and continued to hold them after discussion of the points raised in these materials.

There was more **variability in participants' views on the child having DNA from three people and how this might impact on identity**. Discussions over the course of the day suggested that most participants rejected the 'three parent' label because they felt that the contribution of mitochondrial DNA to a child's personal characteristics was negligible. Some participants argued that the relationship between the donor and the child was more like that of a grandparent; genetic but not directly so. However, a few participants felt that the donation of healthy mitochondria had enabled the child to exist and this should give the donor some sort of parental status.

Some participants discussed whether the mitochondrial DNA would have an impact on the identity of the child. Most participants felt it would not, particularly if the nature of their conception was properly and expertly explained to the child. Many argued that a 'search for identity' was something that all young people experienced. Several participants took a

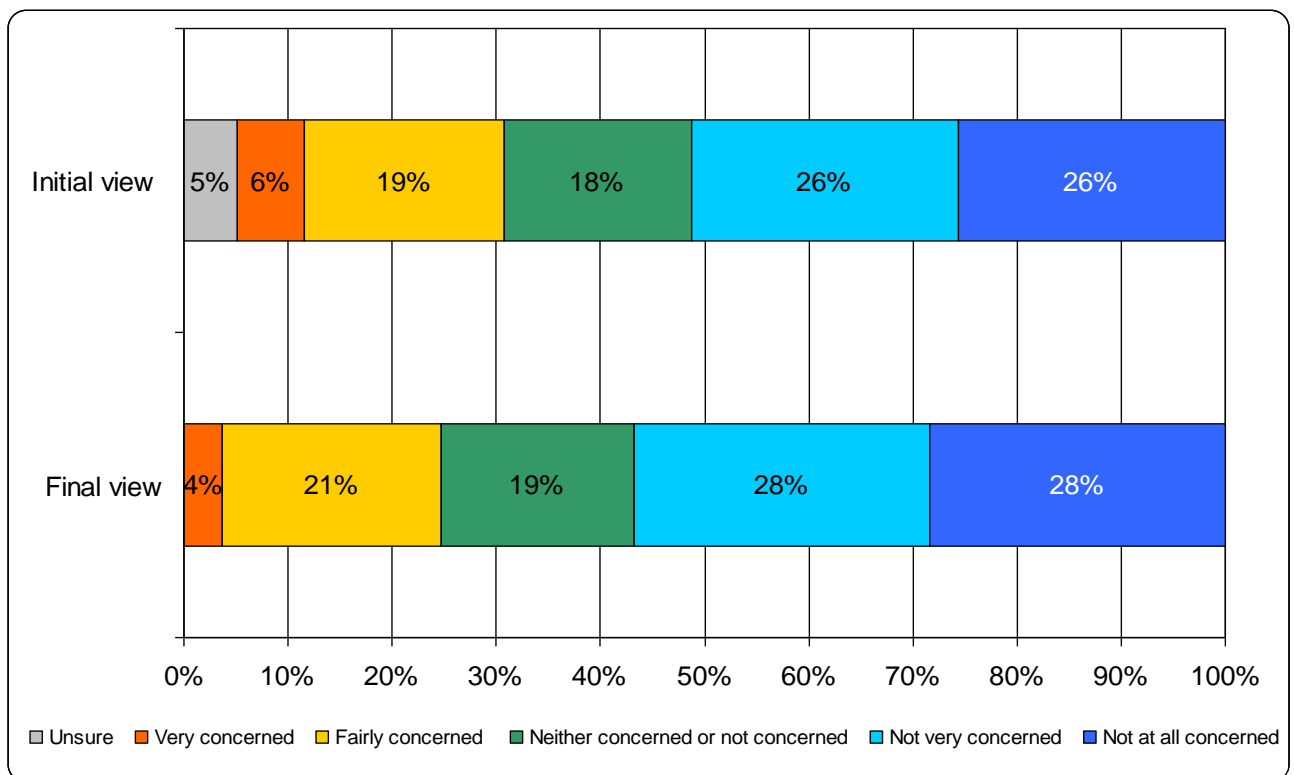
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<sup>5</sup> Participants were asked to consider the following key ethical issues which were identified during stakeholder workshops and interviews earlier in the project.

slightly different perspective, discussing the emotional impact on the child and drawing parallels with adopted children who are keen to find their biological parents as they seek to establish their identity.

The findings from the ethics questionnaires distributed at the start and close of series two workshops show that views on the ‘DNA from three people’ question remained relatively stable throughout the discussion. At the end of day, the questionnaire shows that a majority of participants (56%) were more likely to be ‘not very’ or ‘not at all’ concerned about an egg or embryo resulting from the mitochondrial techniques containing genetic information from a third person. This is a small increase on the proportion holding this view at the start of the day (51%). With respect to those who had begun the day being ‘very’ or ‘fairly’ concerned about this (26%) approximately the same proportion (25%) held similar views at the end of the day (25%).

**Figure 1: Any resulting egg or embryo from the mitochondrial techniques will contain a small amount of genetic information in its mitochondria from a third person (the donor). What is your reaction to this?**



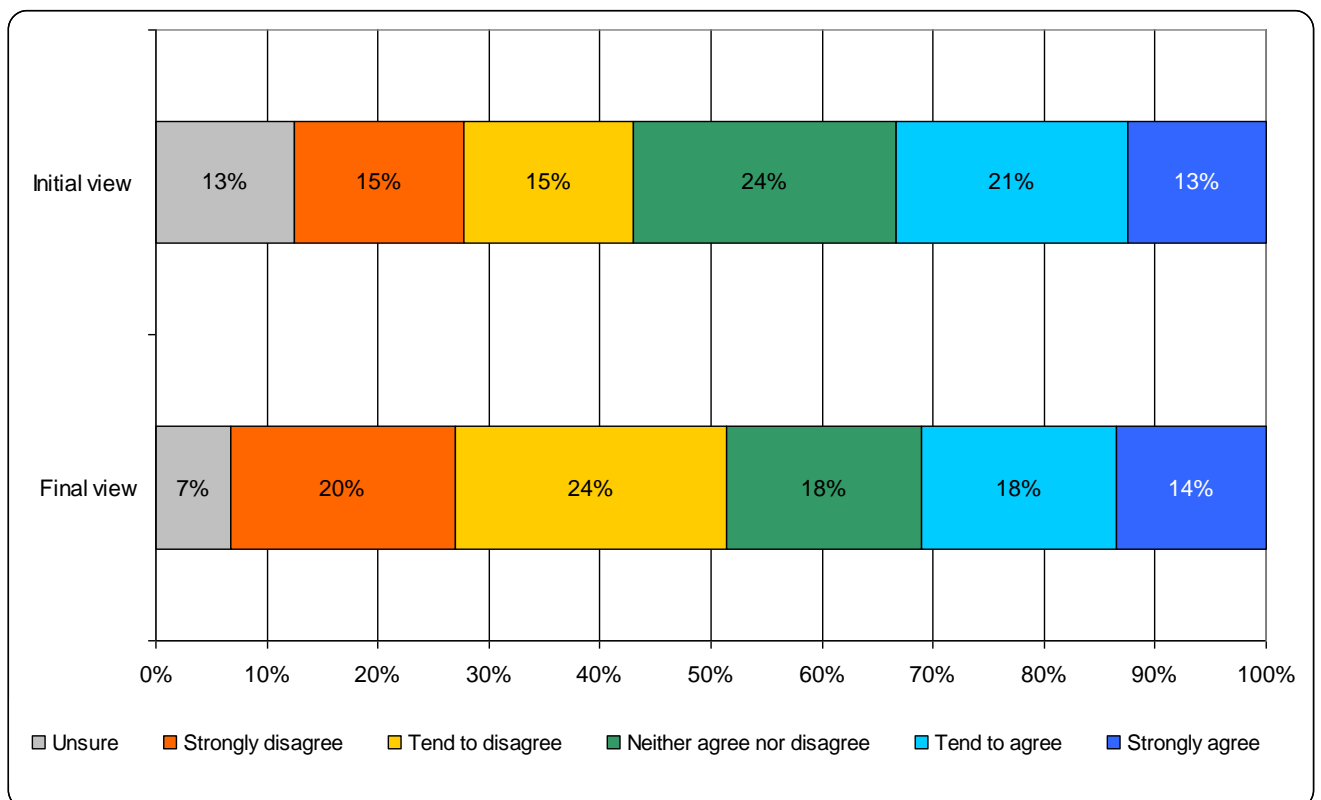
Base sample is number of participants completing ethics questionnaire at the start and end of the day: Initial = 78, Final = 81

Participants’ views on **whether a child born from these techniques should be able to access information about the donor** were varied. In discussions, participants who supported anonymity for the mitochondria donor strongly argued that the donor’s rights should be protected: they felt that donors should be given the choice as to whether they want their identity to be revealed to the child. Some participants felt that not protecting the privacy of donors could potentially result in fewer people making donations. Others felt that anonymity was appropriate because the contribution of mitochondrial DNA was not significant enough, and that it was similar to an organ transplant where donors also have anonymity.

Some participants argued, in contrast, that children should have the right to know the identity of the donor, if they wanted. They felt that the majority of children would probably not want to know but that the opportunity should be open to those who did want this information. These participants felt that donors should be fully informed before donation and accept responsibility for the fact that a child may come searching for them at some point in the future. Participants in one group suggested a third way, where a ‘donor profile’ with descriptive but not identifying information about the donor be made available to the child if they chose.

Findings from the closing questionnaire suggest that a majority of participants favour anonymity for the donor, as illustrated in Figure 2 below. A total of 45% of participants<sup>6</sup> either strongly disagree or tend to disagree that any child born after these techniques should have the right to access the individual who donated the mitochondria, compared with 31%<sup>7</sup> at the start of the day. However, the number of participants favouring the child’s right to know about the donor did not change very much – from 33% at the start of the day to 31% at the end of the day – which indicates that these participants tended to remain steadfast in their views. Additionally, of the 5% who were initially ‘unsure’ and shifted their position, equal numbers ended the day either concerned or not concerned.

**Figure 2: Any child born after these techniques should have the right to access the individual who donated the mitochondria**



Base sample is number of participants completing ethics questionnaire at the start and end of the day:  
Initial = 72, Final = 74

<sup>6</sup> Has been rounded up

<sup>7</sup> Has been rounded up

### 5.1.2 Factors that shaped and changed views

A number of factors contributed to helping participants form and change their views about the use of DNA from three people and the implications of this for the child and donor. Throughout their discussions, participants used a range of **comparisons and analogies** to help them structure and convey their arguments and attitudes. For example, participants discussing whether or not children born from these techniques should have access to the identity of their donors tended to make comparisons with adoption. Comparisons with adoption also helped participants to visualise how the use of DNA from three people might impact on the identity of the child. As the discussion progressed, the value of the comparison with adoption waned as participants began to argue that the relationship between a parent giving up a child for adoption and that child, and the relationship between someone donating mitochondrial DNA and the child born with this mitochondrial DNA were two very different types of relationship. Instead, they moved towards an analogy with sperm or organ donation. These were seen as more appropriate and more helpful to discussions about the '3 parent' label and the rights of the donor and the child.

Many participants took into account the comparison made by experts, between mitochondrial donation and blood transfusion or bone marrow donation. This perhaps provides some explanation for the decrease in the proportion of participants concerned about the child having DNA from three people (Figure 1) between the start and the end of the day. However, a number of participants continued to feel that mitochondrial donation was more significant than a blood, organ or bone marrow donation and therefore continued to be concerned about the DNA from three people issue.

Participants' views on this issue were also shaped by **information on the amount and role of mitochondrial DNA** in a person's genetic makeup. In the video shown to participants, one expert mentioned the small number of mitochondrial genes compared to nuclear genes, while another stressed that while there are few mitochondrial genes they are clearly important. Participants in most discussion groups picked up on these statements, and most felt that the first statement confirmed their view that the 'three parent' label was unwarranted and even 'misleading'. A few participants felt that the small amount of mitochondrial genes from the donor meant that this would not be an issue in terms of the identity of the child.

For a few participants, their uncertainty about the appropriateness of particular analogies and comparisons – for example, with blood transfusions - was strengthened by the thought that whilst the quantity of DNA was small, the relationship between quantity and effect was neither direct nor straightforward. On the whole, however, participants' concern about the DNA from three people tended to reduce over the course of the day and, although this cannot be confirmed, the information in the video and that presented by the expert scientists might well have played some role in this reduction.

Some participants' views were also shaped by the **importance they placed on the right of the child** born from these techniques. This relates primarily to the child having the right to access information about the donor if they choose. However they also argued that a blanket approach was not appropriate and that access to information about a donor should 'depend on the child's need'. This meant that participants tended to remain steadfast in their attitudes towards the anonymity of the donor. As discussed earlier, the number of participants favouring the child's right to know about the donor did not change very much – from 33% at the start of the day to 31% at the end of the day.



## 5.2 Attitudes towards germline therapy

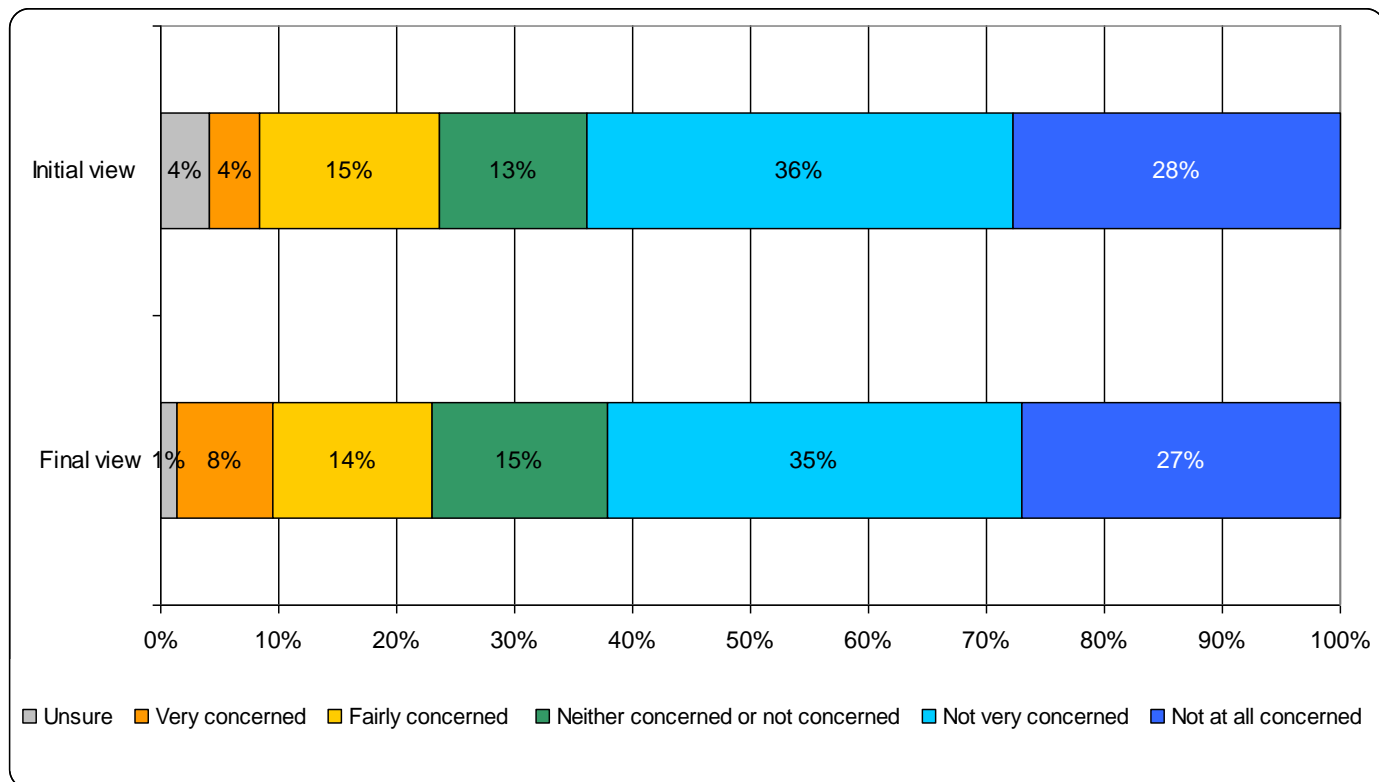
### 5.2.1 Overview of attitudes and concerns

The second scenario focused on Martin and Jane, parents of a child with mitochondrial disease who disagree about whether to use these new techniques to conceive another child, and thereby alter the germline of future generations. In initial discussion of this scenario, participants were more likely to support Jane, who wants to have another child and to use the techniques to avoid the possibility that this child will have mitochondrial disease. Several participants felt that Martin was being 'unreasonable'. They felt that Jane was right in wanting treatment to prevent the disease being transmitted to their next child and that she was acting in the child's best interest. After further discussion, however, some felt that Martin's concerns might be based on a lack of information and that he would change his mind with a better understanding of the science. Many felt that, in general, parents should have the information that will enable them to make the right decision. However, participants also acknowledged that decision making can be difficult and that needing to take difficult decisions can have a negative impact on a couple's relationship. They were also concerned about how siblings might feel and about the impact of ongoing monitoring of any child born from these techniques. Several groups felt that counselling should be available to parents in this situation. Most participants were not greatly concerned about the implications of these techniques for future generations, except for the possibility that mitochondrial disease could be eradicated and health outcomes for children born from these techniques thereby improved.

Participants discussed the extent to which uncertainty about the impact of these techniques on future generations should be a factor in whether or not they should be licensed. At this stage of discussion, participants tended to feel that the information and evidence with which they had been presented suggested that the known risks and uncertainty were 'worth it' if it meant that the parents could have a healthy child. That is, participants acknowledged that there were risks in germline therapies but were not greatly concerned by these. Some participants also felt that there is always uncertainty when it comes to new treatments.

These discussions meant that throughout the day, **attitudes towards germline therapy** remained stable, with 64% not at all or not very concerned about germline therapy at the beginning of the day and 62% at the end. This is illustrated in the chart below.

**Figure 3: The techniques to avoid mitochondrial disease would involve altering the make-up of an egg or embryo, specifically the mitochondria. The donated healthy mitochondria would replace the intended mother's faulty mitochondria and would then be passed down to the child and, in turn, to that child's children and beyond. This is called germline therapy, because the change goes down through the generations (the germline). Assuming that scientists could show that this is safe, how do you feel about this?<sup>8</sup>**



Base sample is number of participants completing ethics questionnaire at the start and end of the day:  
Initial = 72, Final = 74

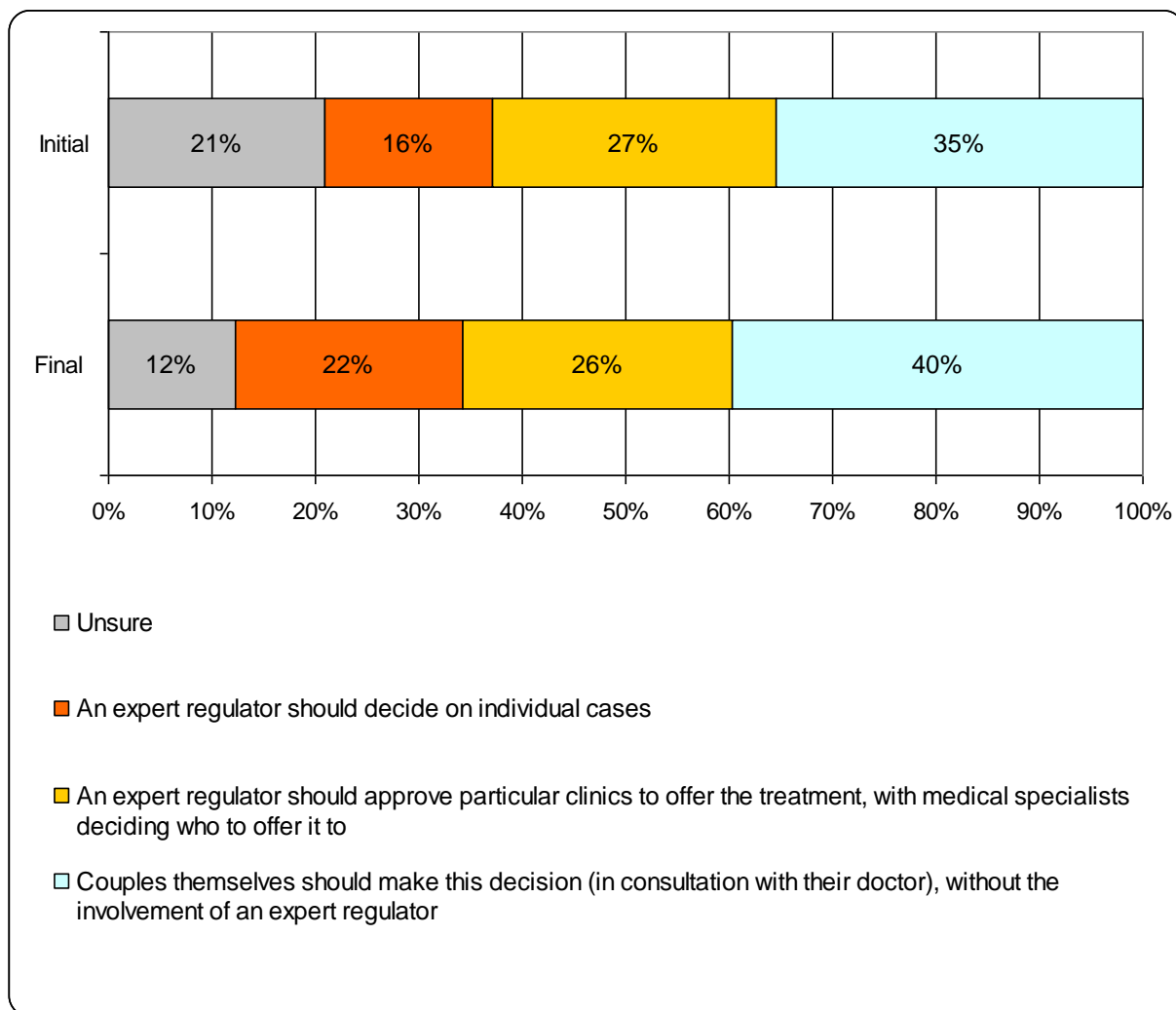
### 5.2.2 Factors that shaped and changed views

One main factor shaped participants' views on the germline therapy issue, which has been discussed previously and was a recurrent theme throughout this work: the importance of **individual and personal choice for parents**. Most participants stated that parents should be able to make the decision about using the techniques and altering the germline: that is, that the government should not prevent parents from having this choice by deciding against the techniques being available to those who might need them. They recognised the complexity of the issues and debate and that views would be varied and often strongly held. However, holding choice open to parents was seen as paramount. What the scenario illustrated was that making the choice would be difficult and that parents would need support in order to take the course that was right for them.

<sup>8</sup> It should be noted that prior to considering this question, participants were made aware that mitochondria are only inherited maternally; therefore the issue of inheritance to subsequent generations is only relevant if the offspring are female.

Findings from the ethical questionnaire reinforced the importance that participants placed on individual choice. They were most likely to feel that couples themselves should make the decision about treatment (in consultation with their doctor), without the involvement of an expert regulator (Figure 4, below). The proportion holding this view increased slightly throughout the day, from 35% at the start of the day to 40%, at the end.

**Figure 4: Currently, these techniques cannot be offered to couples as the law only allows the techniques to be carried out in research. However, Parliament may have an opportunity to change the law to allow these techniques to be offered to couples. If Parliament did change the law, who do you think should decide whether individual couples should have the treatment?**



*Base sample is number of participants completing ethics questionnaire at the start and end of the day: Initial = 62, Final = 73*

### 5.3 Impact on attitudes towards these techniques

The discussions about the two specific ethical issues – DNA from three people and germline therapy – did not appear to have a significant positive or negative impact on participants' support for the new techniques. After discussion of these issues, they recorded their second response to the question described at the start of this section:

'If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?'

Again, they used a scale of 1 to 10, with 1 indicating 'reject' and 10 indicating 'support'. At this stage of the day, the overall mean score across discussion groups and locations was 8.4, only slightly higher than at the start of the day when it was 8.2. The table below provides an overview of how mean scores changed from the start of the day across locations and groups.

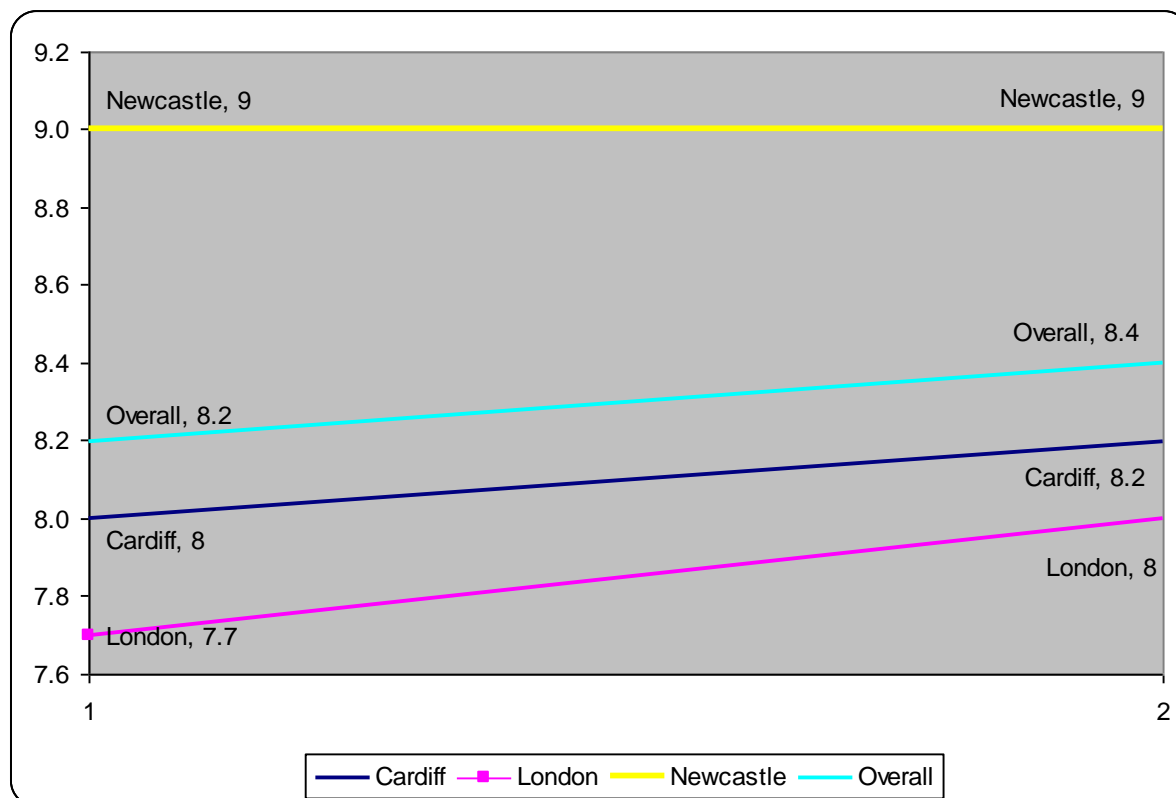
**Table 2: Change in mean scores across locations**

	Group 1	Group 2	Group 3	Mean at location
<b>Cardiff</b>	7.5 → 8.5	8.3 → 8.1	8.4 → 8.1	<b>8.0 → 8.2</b>
<b>London</b>	5.9 → 5.9	9.7 → 9.5	7.5 → 8.1	<b>7.7 → 7.8</b>
<b>Newcastle</b>	8.4 → 8.7	9.4 → 9.4	9.1 → 8.9	<b>9.0 → 9.0</b>

Base sample (second scoring): Cardiff = 29, London = 26, Newcastle = 28

Additionally, the chart below illustrates how the mean scores at each location and the overall mean score changed from the start of the day.

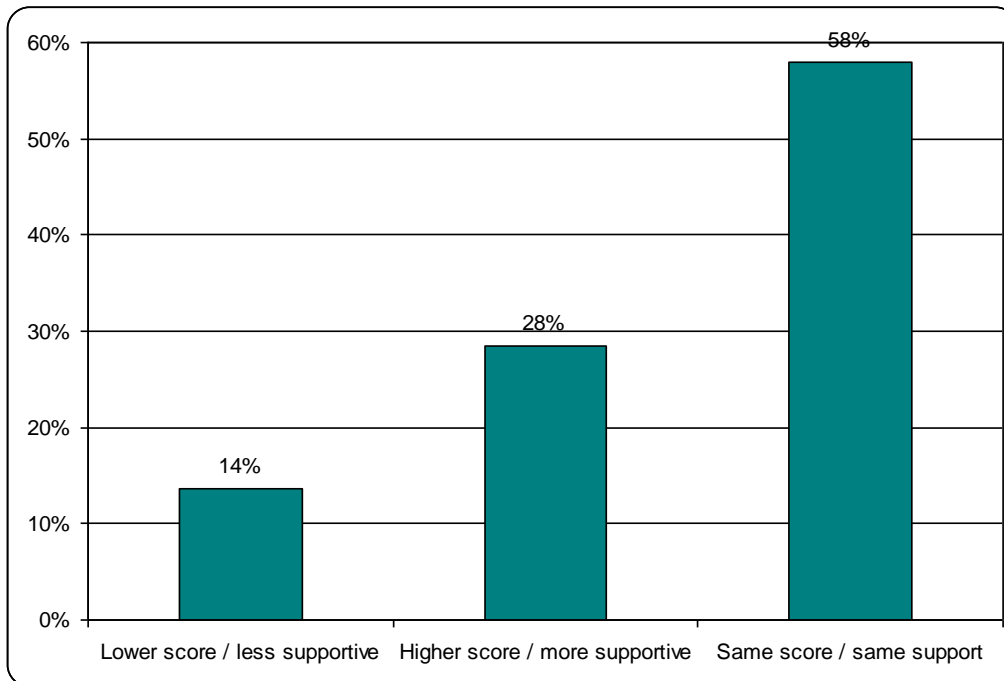
**Figure 5: Change in mean scores across locations**



As the chart above illustrates, the mean level of support at two locations increased very slightly and stayed the same at one location. These findings indicate that participants generally remained steadfast in their support for the new techniques regardless of discussions about the two ethical issues. At an individual level, almost sixty percent of

participants (58%) reported the same scores at the first and second scoring sessions, with a further 28% reporting a higher score at the second scoring session and only 14% reporting a lower score. This is illustrated in the chart below.

**Figure 6: Direction of change in individual scores / support for techniques – first and second scoring sessions**



*Base sample (first and second scoring): 81 participants*

As discussed in previous sections, the importance which participants placed on individual choice appears to have contributed to the continued support for the techniques throughout the dialogue workshops. Mostly, participants differentiated between techniques that aim to determine personal characteristics, which they did not support and those aimed at preventing disease, which they were more likely to support. Many found the argument focussed on quantity to be persuasive: they thought that the small quantity of mitochondrial DNA when compared with the quantity of nuclear DNA meant the ethical issues had less importance. Participants continued throughout the day to see the new techniques as a means to prevent disease and give parents the opportunity to have healthy children. While they recognised and discussed the ethical objections, these were outweighed by their ethical commitment to parental choice.

## 6. Other information and evidence that shaped support for techniques – series two

After discussion about the two specific ethical issues, participants watched a video presenting a range of opinions on some of the social and ethical issues relating to safety, risk, regulation and monitoring. This video generated further conversations and discussions which continued to shape the participants' views about the techniques.

In the sections below we discuss two further factors that shaped participants' views:

- Uncertainty about risks and science
- The importance of the techniques being introduced in a regulated environment, in order to ensure that the technology isn't misused

### 6.1 Uncertainty about risks and science

After watching the video discussing some of the social and ethical issues relating to safety and risk, participants raised questions about the certainty of the science. Some argued that more testing and trials should be done before the techniques were made available to the public. This view was prompted primarily by a reference made in the video to a study on fish about the potential for factors present in cytoplasm (which may or may not involve mitochondria), to influence the number of vertebrae that are formed. For a few participants in each of these groups the mention of this study raised doubts about the robustness of the scientific evidence presented on day one<sup>9</sup>. They felt that this was new information which had not been made available during series one and questioned whether they had been given all the relevant scientific information. This strong response was expressed by a few participants only: others either did not pick up on the comment, or felt that it was part of the inevitable uncertainty in science and did not cause them concern. What is clear is that for some participants their **trust in the safety of these techniques is relatively fragile, and easily disrupted by new information**. Some of these participants therefore suggested that it would be better if the techniques were trialled with a small group of people before being made available to the wider public.

Other participants focussed on some scientists' view that monitoring and follow-up is of prime importance, given that there is **uncertainty about the risks** associated with the techniques. Participants agreed that monitoring is an important part of breakthroughs in medicine. However, there was some concern that the demands of monitoring may be too much of a burden on some people and that they may therefore choose to withdraw. Some also questioned the feasibility of tracking and monitoring people born from this technique for the rest of their life, especially if they were opposed to such monitoring. Again, some participants suggested that trialling the techniques on a small group of people first would make monitoring and therefore risk assessment easier.

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<sup>9</sup> The reference to this study was dropped from later versions of the video used in the consultation as it was not felt to be relevant because of the lack of transferability of the implications of it to humans and the fact it related to science rather than ethics.

## 6.2 The importance of regulation

A few participants picked up on concerns by a scientist in the video that if the techniques are not licensed in the UK they will become available in other nations with less stringent regulation regimes. These participants tended to agree that it was **important for these techniques to be introduced in a regulated environment**. This was to ensure that the techniques are only used for the purposes of reducing the incidence of disease. It was also related to practical concerns regarding fairness and availability, with participants feeling that regulators had a role to play in ensuring that the techniques would be available to all people and not just those able to afford private treatment.

## 7. Final support for new techniques – series two

Towards the end of the series two workshops, participants were again asked to record their response to the following key question:

*'If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?'<sup>10</sup>*

On this last occasion the overall mean score across discussion groups and locations, was 7.8, showing that participants ended the day with fairly high support for the new techniques. However, this was lower than the mean score of 8.2 at the start of the day and the mean score of 8.4 in the middle of the day. The table below provides an overview of how mean scores varied across locations and discussion groups at the end of the day. As this illustrates, there is quite a difference between groups that have very high support for the techniques with mean scores close to or over 9 (e.g., group 2 in London or Newcastle), and those who appear to be more reserved in their support, with mean scores close to or lower than 5 (e.g., group 1 in Cardiff or London).

**Table 3: Mean score responses to question: 'If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?'**

	Group 1	Group 2	Group 3	Mean at location
<b>Cardiff</b>	4.8	8.8	6.5	<b>6.7</b>
<b>London</b>	5.8	9.4	8.1	<b>7.7</b>
<b>Newcastle</b>	8.6	9.8	8.9	<b>9.1</b>

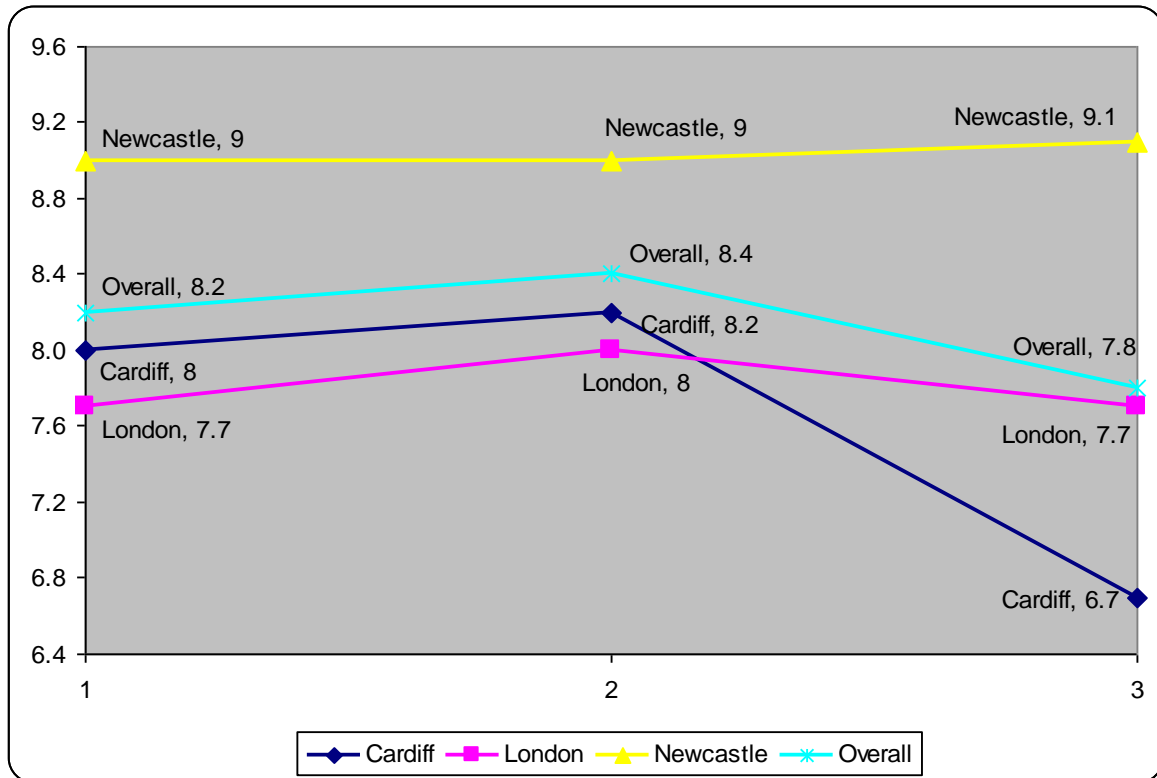
*Base sample (final scoring) = Cardiff = 28, London = 25, Newcastle = 28*

Additionally, the chart below highlights how the mean scores of each location and the overall mean score changed over the course of the day.

<sup>10</sup> As on previous occasions, responses were recorded on a scale of 1 to 10, with 1 indicating 'reject' and 10 indicating 'support'



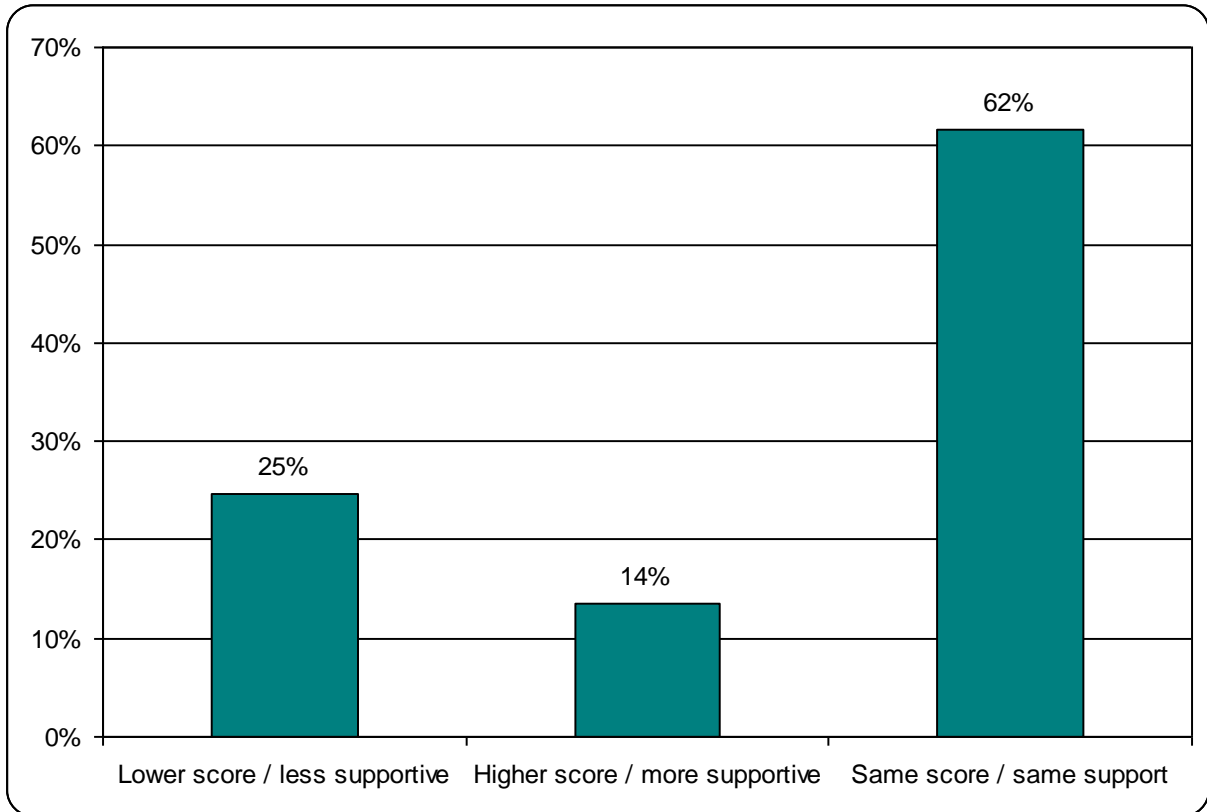
**Figure 7: Changes in mean scores, across location and overall, in response to the question: 'If the treatment can be shown to be safe, to what extent would you support or reject it being made available to families through HFEA licensed clinics?'**



In London, Cardiff and overall, there was a slight rise in the mean between the first and second scoring sessions. In the final scoring session the mean drops, and in Cardiff it does so quite dramatically. In Newcastle the mean score stays more or less constant over the course of the day. This drop in the overall mean score and two location mean scores suggests that issues around risk and uncertainty had an impact on views and, in particular, that participants were concerned about the study on the fish model (see section 6.1). These concerns had an impact on the extent to which participants felt able to support these techniques being available to anyone who might need them. This may have also have been a contributing factor in the quarter of the participants (25%) who changed their views in a negative direction, becoming less supportive of the techniques (see Figure 8 below). This illustrates that for some participants, trust in the safety of these techniques is relatively fragile, and easily disrupted by new (contradictory) information, even when it is introduced late on in the process.

Levels of support in some sub-groups within a location – for example, group 2 in Cardiff and in London and all groups in Newcastle either stayed the same or increased over the course of the day. Analysis of table discussions suggests that this is at least in part because participants remained focused on the potential health benefits offered by these techniques and on the importance of individual and personal choice. More than six out of ten participants (62%) reported the same score at the second and final scoring sessions. Fourteen percent (14%) of participants increased their level of support for the techniques. These findings are highlighted in the chart below:

**Figure 8: Direction of change in individual scores / support for techniques – second and third scoring sessions**



*Base sample (second and third scoring): 81 participants*

## 8. Messages for Secretaries of State – series two

In the final session of the series two workshops, participants summarised their views into short messages to convey to the Secretaries of State with responsibility for making a decision about the licensing of these techniques. Some groups used this opportunity to express their support for the introduction of the techniques, alongside their conditions. Others were more circumspect, outlining the things they wanted to happen before a decision could be taken. Across all three locations, the final points raised were similar and illustrate broad agreement amongst a majority of participants.

### 8.1. Support for the techniques, with caveats and conditions (see below):

- Individual choice is important and parents should be able to choose to use these techniques
- Individuals need to be provided with all the relevant information they need to make an informed choice. This includes information on the potential risks, any uncertainties and the pros and cons of the two different techniques
- The techniques must be introduced in a regulated environment
- Parents who choose to use these techniques should be offered counselling
- Donors' identity should be protected
  - Although different views remain about whether some information should be available to the child
- Fair access to these techniques is essential and they should be available on the NHS, to all who might benefit from them, free of charge
- The techniques are to be used to produce a healthy child and for no other purposes

### 8.2 Requirements before support can be given:

- A more comprehensive scientific assessment of safety and efficacy must be done, for example through human trials first
- 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

## Appendix A – Profile of participants

	Cardiff		London		Newcastle	
	N	% of total	N	% of total	N	% of total
<b>Gender</b>						
Male	13	43	13	43	15	50
Female	16	54	14	47	15	50
Not answered	1	4	3	10	0	0
<b>Ethnicity</b>						
White British / White Other	20	67	16	53	24	80
Mixed	2	7	0	0	0	0
Asian	4	13	6	20	4	13
Black	3	10	6	20	2	7
Not answered	1	3	2	7	0	0
<b>Age</b>						
18 - 24	6	20	4	13	6	20
25 - 34	4	13	5	17	6	20
35 - 44	9	30	5	17	5	17
45 – 54	5	17	7	23	6	20
55 – 64	3	10	5	17	4	13
65 +	3	10	2	7	3	10
Not answered	0	0	2	7	0	0

<b>Socio economic group<sup>11</sup></b>						
A	2	7	0	0	3	10
B	4	13	11	37	4	13
C1	7	23	9	30	10	33
C2/D/E	16	53	8	27	13	43
Not answered	1	3	2	7	0	0
<b>Follows science issues on television/radio/papers</b>						
Yes	15	50	14	47	14	47
No	14	47	14	47	16	53
Not answered	1	3	1	7	0	0
<b>No. of participants who attended both days<sup>12</sup></b>	29 out of 30		26 out of 30		28 out of 30	

<sup>11</sup> Social grade was decided by asking the potential participant to identify the job of head of the household and the response was coded to the appropriate NRS Social Grade (<http://www.nrs.co.uk/>) by the recruiter. The level of social grade is decided on different criteria depending on the type of job. For example it could be number of people responsible for, type of qualification needed, level of skill needed etc.

<sup>12</sup> All participants attended day 1.

## Appendix B – Workshop programmes

### Day 1

Time	Session
9.30 – 10.00	Arrival, registration, coffee and complete initial questionnaire
10.00 – 10.25	<b>PLENARY: Welcome, introductions and overview of the day</b> HFEA OPM
10.25 – 10.45	<b>Small group discussion: understanding initial views / knowledge</b>
<b>10.45 – 11.00</b> <b>Coffee break</b>	
11.00 – 11.30	<b>Bluff your way in biology</b> Small group discovery session
11.30– 12.15	<b>What is mitochondrial disease?</b> Video
11.45 – 12.15	<b>Mitochondrial disease and techniques for avoiding mitochondrial disease.</b> Table discussions
12.15 – 12.30	<b>Review of the morning</b> Plenary
<b>12.30 – 13.15</b> <b>Lunch</b>	
13.15 – 13.40	<b>Expert question and answer session</b> Plenary
13.40 – 14.10	<b>What is new about these techniques? How are they different from assisted reproduction techniques that are currently permitted?</b> Table discussions
14.10 – 14.30	<b>What have you discovered today and what more do you need to know?</b> <b>What will you tell your friends and family about today?</b> Working tea time – small table discussions
14.30 – 14.50	<b>Summing up the day and looking forward</b> <b>Quiz (chance to win a box of chocolates....)</b>
14.50 – 15.00	<b>PLENARY: Close and thanks</b> <b>Evaluation questionnaires and ‘thank you’ payments.</b>

**Day 2**

<b>Time</b>	<b>Session</b>
9.30 -10.00	<b>Arrival, registration, coffee</b> Participants complete ethics questionnaire and return to registration desk (or table facilitator, whichever is easiest).
10.00 – 10.10	<b>PLENARY: Welcome back</b> OPM & HFEA
10.10 – 11.00	<b>PLENARY: Recap of the issues</b> Video: patient experience
<b>Coffee break</b> <b>11.00 – 11.15</b>	
11.15 – 12.45	<b>Small table discussion</b> Identifying social and ethical issues Scenarios and deliberation on two specific issues: <ul style="list-style-type: none"> <li>• DNA from three people</li> <li>• Germ line therapy</li> </ul> Video and expert presentation Rapid table feedback
<b>Lunch break</b> <b>12.45 – 13.30</b>	
13.30 – 14.15	<b>PLENARY</b> Issues and discussion Video
14.15 – 14.35	<b>Small table discussion</b> Reviewing the issues What's most important? What messages do we want to give to the Secretaries of State?
14.50 – 14.55	<b>PLENARY: Final feedback, thanks and close</b> What we will do with your contributions. How to stay involved
14.55 – 15.00	<b>Evaluation and ethics questionnaires and 'thank you' payments</b> Leave us your contact details if you'd like to stay in touch with the project.

## Appendix C – List of experts and workshop materials

Location	Dates	Experts
Cardiff	Day 1 14 <sup>th</sup> July	Dr Lyndsey Butterworth, Research Associate, Institute for Ageing and Health, Newcastle University
	Day 2 28 <sup>th</sup> July	Dr Sheelagh McGuinness, Fellow, Birmingham Law School, University of Birmingham
London	Day 1 14 <sup>th</sup> July	Professor Mary Herbert, Professor of Reproductive Biology, North East England Stem Cell Institute (NESCI), Newcastle University
	Day 2 28 <sup>th</sup> July	Dr Iain Brassington, School of Law, Manchester University
Newcastle	Day 1 21 <sup>st</sup> July	Professor Doug Turnbull, Professor of Neurology, North East England Stem Cell Institute (NESCI), Newcastle University
	Day 2 4 <sup>th</sup> August	Professor Steve Wilkinson, Professor of Bioethics, Keele University

**1 - Information handouts** – A series of handouts were provided to participants. These covered the aims of the public dialogue; some of the basic science; information about mitochondrial disease; the research and regulation and a glossary of terms.

**2 - Bluff Your Way in Biology** – Each participant was asked to take part in a short quiz on the basic biology associated with mitochondria replacement, drawing on information posters that were placed around the room. Participants could work alone or in groups and were encouraged to share their learning on completing the quiz. The quiz handout sheet is set out below.



### **Bluff your way in biology – discovery session**

You have 20 minutes to use the resources in the room to collect information that will help you to answer three questions:

- What is a cell?
- What is DNA?
- What are mitochondria
- What do mitochondria do?

There are large posters on the wall and the same information is provided on handouts round the room. We have our expert on hand too, who will be happy to answer any questions you have.

You can tackle this in any way you like:

- Work as a team on all three questions
- Work in pairs or threes, each one gathering some information on one question and then come back together to discuss what you've found out
- Work individually and share learning afterwards.

There is a grid on which to record what you find out.

What is a cell?	
What is DNA?	
What are mitochondria?	
What do mitochondria do?	

**3. Briefing videos** – As part of the dialogue, two short and accessible briefing videos were produced using a vox pops and animations with a voiceover to introduce the key issues.

**Mitochondria Replacement – the science video**<sup>13</sup> – This video demonstrated what mitochondria are, and how the new techniques to prevent mitochondrial disease would work.

**Mitochondria Replacement – the ethics video**<sup>14</sup> – This video highlights some of the ethical considerations. This includes issues of identity and parentage; changing the germline; and the individual risks and benefits of the new techniques.

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<sup>13</sup> Available at: <http://vimeo.com/45389280>

<sup>14</sup> Available at: <http://closeupresearch.com/ethics.html>