



# Our Voice: *Mito* community priorities for the Australian mitochondrial donation pilot

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In March 2022, the Australian Senate voted in favour of the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 after a robust debate and conscience vote in both Houses of Parliament. The mitochondrial donation pilot stage is set to commence in 2023, with applications to the [Medical Research Future Fund \\$15 million opportunity](#) closing in September 2022.

In its role as the key consumer organisation for the mitochondrial disease (mito) community, Mito Foundation is well placed to influence the design and delivery of the pilot stage. To achieve the best outcome for the mito community, it is important that Mito Foundation has a rich understanding of what is most important to the mito community.

This project used interviews with sixteen mito community members to explore their expectations, concerns and questions about the pilot stage of mitochondrial donation in Australia. This builds on the knowledge gained through the advocacy campaign for the legislation change. From this knowledge, Mito Foundation has developed recommendations that can be used to inform the development of the pilot stage.

We are grateful for the generosity of the mito community members who gave their time to this project.

## Recommendations

These recommendations have been developed by considering how the mito community's priorities can be addressed. The audiences for these recommendations include:

- The successful applicant for the pilot stage; other interested stakeholders.
- The Australian Department of Health.
- The National Health and Medical Research Council and the Medical Research Future Fund, particularly the assessors of the Mitochondrial Donation Pilot Program Grant Opportunity.
- Mito Foundation.

Because the scope and approach of the pilot stage is not clear, recommendations are not directed to specific audiences. All audiences should consider the role(s) they can play in implementing these recommendations.

*Image: Maeve's Law is named after five-year-old Maeve who lives with Leigh syndrome*

## 1. Meet the information needs of the mito community

Before the pilot commences, provide as much information as possible to the mito community. To help people plan their families, priority should be given to information about eligibility and timeframe. Early information about egg (oocyte) donation options and legal framework should also be prioritised.

Throughout the pilot, ensure that information about the process is available to trial participants and potential participants. This should include who is eligible, likely timeframes for the pilot, process steps, and what couples can do to prepare.

All communications should acknowledge the rights of families impacted by mito to choose which, if any, reproductive technologies they use to build their families.

## 2. Explore eligibility criteria

Decisions about eligibility should be made based on both the physical and psychosocial impacts of mito on individuals and families. Consider the inclusion of forms of mito that are serious but not usually considered life-threatening (such as LHON). Ensure that decisions reflect the variations in how mito can affect different family members.

The expertise of those with lived experience of mito should be included in decisions about eligibility criteria.

## 3. Carefully design the model of care

The dual importance of ensuring that the scientific goals of the pilot are met while trial participants are well supported will need to be reflected in the way the pilot stage is delivered. An ideal model of care will need to address:

- Integration between the pilot stage researchers and the health care teams of the trial participants.
- The amount of travel for all parties and the role of telehealth in minimising this.
- How psychological support will be provided at all stages.

The model of care will need to consider the multiple ways that people with mitochondrial DNA (mtDNA) changes currently access health care. This should include people who do not already see a mito specialist service and may not have accessed clinical genetics services themselves.

The teams running the pilot stage should work with mito community members (such as through a co-design process) to develop the model of care.

## 4. Accelerate access for couples who are waiting; provide clear timeframes

For potential parents in the mito community, the schedule of the pilot will determine the way they seek to build their families. Options to bring forward access should be explored. For example, working concurrently on confirming eligibility, preparing couples, securing donated eggs, and establishing the mitochondrial donation technique in Australia.

Even if access cannot be accelerated, the pilot should provide potential participants with clear information on timeframes. This will allow potential parents to make informed choices about other options for building their families.

## 5. Work to reduce stigma in the general community

A strategy to maintain and grow the understanding of mitochondrial donation beyond the mito community should be developed. This could be informed by public awareness activities in other health conditions.

## 6. Learn from the United Kingdom's experiences

The Australian pilot stage should seek to learn from and build on the successes of the United Kingdom (UK) program. This should be a strong influence on all aspects of the pilot, including laboratory techniques, models of care, approaches to egg donation, and communicating with the mito community.

## Methods

The project used semi-structured interviews with people who either had a mito diagnosis themselves or have one or more family members with mito. All stages of the project were completed by Mito Foundation staff (CS, RD, SM and CB).

Participants were recruited by RD and CS from a pool of mito community members who had been involved in the advocacy campaign for legislative change, and a small number recruited through other Mito Foundation activities where they expressed interest in the pilot stage of mitochondrial donation. Consent was obtained from all participants.

Interview questions (see Appendix) were designed by CS and RD. Interviewees were asked about how they defined success of the pilot stage, what their expectations of the pilot stage were and what they are most concerned about.

Interviews were conducted by CS and RD and transcribed by RD and CB. Interviews were reviewed for themes by CS, RD and CB independently and then brought together to identify common and less common findings. This report was written by CB and CS and reviewed by RD and SM.

## Limitations

This project only included a small number of mito community members. On several themes, participants had different perspectives, and different levels of knowledge about mitochondrial donation.

Most participants had pre-existing links to the Mito Foundation and many had previous contact with the person who had interviewed them. This likely influenced their responses.

Future projects, including the consumer engagement activities of the mitochondrial donation pilot, can seek to overcome these limitations.

## Participants

15 interviews were conducted with 16 participants (one interview was with a married couple). The characteristics of the participants are shown in Table 1. Other characteristics are not reported to avoid identifying participants.

Table 1: Characteristics of participants

Gender	% (n)
Female	75.00 (12)
Male	25.00 (4)
Level of involvement in legislative campaign <sup>1</sup>	
High	44.75 (6)
Medium	37.50 (8)
Low	18.75 (2)
Personal link to mitochondrial donation <sup>2</sup>	
Unlikely to use	43.75 (7)
Potential parent	31.25 (5)
Potential grandparent	25.00 (4)

<sup>1</sup>Defined as: High - was involved extensively in multiple stages and activities in the campaign, Medium - was involved in 1 or 2 campaign activities and familiar with the campaign, Low - Only received communications, did not take an active role in the campaign.

<sup>2</sup>Defined as: Potential parent – is considering accessing mitochondrial donation as a way for them to have a child; Potential grandparent – has a child that may consider accessing mitochondrial donation; Unlikely to use – mitochondrial donation is unlikely to be used for their family, often due to mito being caused by changes to nuclear DNA rather than mtDNA.

# Results

These themes summarise the results of this project:

1. **Will this be ready in time for us?** The immediate need for clarity on timeframes of the pilot.
2. **Will we be included?** Questions on eligibility.
3. **Support us while we build our family.** The dual importance of both outcomes and experience.
4. **Help us understand and help us explain it to others.** The information needs of the mito community and others.

Together, these themes capture the participants' combined views on what a successful pilot stage will look like. The descriptions of these themes highlights the areas where participants agreed and those where they had diverse points of view. In many cases, differences were influenced by:

- Their personal connection to mito and whether they hoped to use mitochondrial donation in the future.
- Their knowledge of the genetics of mito, including the genetics of mito in their own family
- Their knowledge of mitochondrial donation
- Previous experiences with assisted reproductive technology including IVF.

## Theme 1: Will this be ready in time for us?

This theme captures priorities related to the mito community's immediate questions and concerns about when the pilot will commence. For some participants, having access to mitochondrial donation as quickly as possible was important.

### Key message

### My clock is ticking



**“I’m running out of time. I don’t have a lot of time left to get this up and running. I would like to have a clear indication of how long this is going to take and where I’m personally sitting on this for me to be ready and for this whole process to actually be implemented into the clinic.”**

Some participants have been advocating for legislation change for many years, and their hopes have changed through that time.

***“Way back then (when the campaign started) it was just a potential idea and I never thought it would happen in my reproductive lifetime.”***

Participants also talked about wanting to understand what they could do to get ready for taking part in the pilot.

For others participants, timely access was less important than getting the technique right. This was more common in potential grandparents and younger potential parents.

## Key message

### Don't rush this now



“Even if it was to take a little bit longer, make sure you’re doing it right the first time. If it’s going to take another 12 months to get it right, sort the kinks out before it’s released to everyone. It’s probably well worth it really, we have come this far.”

One of the common messages from these two groups was that clarity on timeframes was important. Those planning already to use mitochondrial donation as soon as possible, told us they understood that it may not work out for them.

*“I guess that’s the hardest thing is not knowing what is next so just knowing how it’s going to look and what’s involved is important to us.”*

## Theme 2: Will we be included?

Participants, particularly those who are potential parents and potential grandparents, told us they are concerned about whether the pilot will be accessible to them based on the type of mito their family had. One participant described their current feeling as being “in limbo” due to this uncertainty.

## Key message

### Equity of access



“There are types of mito that aren’t affected in the same ways that other types of mito are. It’s a vast spectrum and what I would hate to see is those people that we fought for relentlessly in this campaign then get left out because they’re not included in (the pilot) ... I feel like they should still have a voice.”

One participant was concerned that Australia’s eligibility would be modelled on the UK. They felt that the uncertainty of heteroplasmy could be handled more inclusively in Australia.

*“It needs to be more widely available than the UK trial was. ‘Severely affected’ should be changed to ‘seriously’. The threshold needs to be lower in Australia. I am really worried that (our family is) not going to be able to use it because of this definition. Even after we’ve fought for this.”*

Several participants had a family history of Leber's Hereditary Optic Neuropathy (LHON). These participants emphasized the severity of LHON and argued the case for its inclusion:

***"For society to have something that causes massive anxiety and costs to the community...all the support that's needed for blindness in the case of LHON and shock when it happens to families. In my case my brother lost his eyesight at the prime of his life and really I think it's caused him huge depression and difficulty with life."***

***"For me personally, this is where the bittersweet comes in because I don't want to take away from the joy from this, it's a momentous thing. But something that makes me nervous is the potential for LHON to possibly not be included, or at least not in the early stages...I completely understand that fatal conditions should get prioritization but I think I would try to emphasize that LHON is not mild as people might think as well and it's important it gets looked at too ... Knowing that you carry it can be that ticking time bomb. You may not present with symptoms but you could so there's that aspect of even if it isn't multi organ it affects in other ways like mental and social aspects."***

***"My brother's life, his direction changed completely, everything he knew was stripped away from him and there's talks of suicide and it's still ongoing. ... I dread the day that I have to tell my girls that they carry this gene mutation and what it means for them. If mitochondrial donation is available to them in the future it would be amazing as they would have the control to remove all of the anxiety & fear associated with carrying LHON in starting a family, freeing their children from possible blindness."***

One participant asked about eligibility unrelated to mito, such as for single parents or same sex couples.

### Theme 3: Support us while we build our family

This theme captures priorities related to the design of the pilot stage. It brings together the participants' answers to questions regarding what a successful pilot would look like.

#### Key message

#### The goal is a mito-free baby



***"The most important thing? That the research is performed correctly so that families aren't having a child that ends up with mitochondrial disease. (My partner) and I said we will never have a child as long as it's going to suffer with mitochondrial disease"***

There was consensus that the pilot stage cannot be considered successful unless the babies born are mito-free. Many potential parents told us they would not consider having a child without the promise that babies born through mitochondrial donation will be free of mito.

Many participants shared with us the personal hope they had for the pilot: the pilot was their chance to become a parent, or their chance to have a healthy grandchild. One potential grandparent told us about her daughter who had ruled out becoming a parent because of the risk of transmission of mito: ***"Now she has another option, so it means a heck of a lot. Now she potentially can re-adjust her thinking to being a mother of her own children."***

Two participants told us they expected that other IVF testing, unrelated to mito, would be available. One participant told us that they thought that both mitochondrial donation techniques (maternal spindle transfer and pro-nuclear transfer) should be available in case a couple had an ethical objection to one technique.

## Key message

### We understand it's a clinical trial



**“I think you expect that when you take part in a clinical trial. We expect for the first 5 to 10 years of the child’s life that we will be seeing these doctors again because we are part of a clinical trial. I personally believe and expect that when that stage comes there will be doctors involved and it’s no different really to looking after my health now.”**

Participants were asked about the issue of over-medicalisation of a pregnancy, childbirth and childhood. Most were not concerned about this, and explained they understood that they would be part of a research project. They told us they expected that babies would be checked up on and tested frequently.

Some participants shared their views of what level of testing and monitoring was appropriate.

***“A lot of us go to see paediatricians frequently in the first six months or year anyway, so (I expect follow-up of the child) won’t be that different from usual.”***

***“it’s so easy to get really excited about the science and how things are progressing and it’s so exciting but just to ground yourselves and not forget that these are human beings”***

***“I suppose you don’t want (the child) living knowing a medical team by a first name basis”***

One participant felt strongly that monitoring of the baby should be minimised and that the pilot should help families feel normal.

***“You just want to get out the other side and go ‘yes you’ve done it’ and live a normal life because everyone wants to be normal.”***

## Key message

# The science needs to be accompanied by medical and emotional support



**“I think the biggest message that I’d want to give (decision makers) is to make sure that they’re getting the science part and not sort of muddying the waters, but making sure that they’re also looking at the social aspect of it and the impact that is having on the families and the people and the people around them.”**

Almost all participants told us about the importance of emotional support. The participants who had previous experiences of IVF told us that they had found the process “gruelling” and that the emotional support they received would not meet their expectations for the support needed in the pilot of mitochondrial donation. One participant told us they knew that counselling was available when they were going through IVF, but that they believed it needed to be proactive and integrated in the pilot stage.

Beyond direct counselling and psychological support, several participants had expectations that this would be integrated throughout the process.

***“I hope it is warm, comfortable, not too invasive and have them feel like they’re part of a family with their medical team you know with their obstetrician and the nurse that nurses you through your pregnancy and great celebrations at the end.”***

***“While it is a very clinical process that we are talking about, so it’s having that holistic and human side to it as well and empathy of ‘this is going to be stressful’ and having support on that side as well.”***

***“It’s such a daunting process as it is. IVF itself as it is, and this is an added aspect of that which has some uncertainties.”***

Participants also told us that support for fathers and other family members was important.

Several participants’ told us they expected this support to start early in the process and continue after conception: ***“People with mito having children is a lot to go through so I hope the research process isn’t just ‘that’s done and dusted’ once the pregnancy occurs.”***

Two participants told us that the patient or family was more important than the science.

***“I don’t want it to be all about the technique and the lab. It’s got to be about clinical care. We’re dealing with people, with the health of the mother and dealing with the health of the child.”***

***“The health and wellbeing – physical and mental – is the most important part.”***

## Key message

### Healthcare for the mother is critical, including choice of prenatal care provider



**“I would be horrified by the idea that a pregnancy would be managed by the clinical trial team, it should be an obstetrician of my choice.”**

Participants told us they understood that pregnancies from mitochondrial donation would be high risk and require prenatal care from an obstetrician. However, many participants shared their expectation that their obstetrician of choice will accompany them throughout their pregnancy, and that their medical team will be integrated with the research team conducting the trial.

***“(The obstetrician will) not just inserted into the process at some random point, they’re actually with me from zero, day zero, when I’m ovulating to the point when I’m having that child. I would want them to walk with me through that journey because with an obstetrician it’s not just a medical journey, it’s a very emotional journey”***

For women symptomatic with mito, underlying health issues that might impact the pregnancy and vice versa need to be factored in. Some participants understood this and told us about the importance of getting the mother in the best shape for pregnancy and closely monitoring her in the context of her mito.

***“So these mums need to be monitored closely and cared for properly. There’s no point having the technique if the baby gets other complications during pregnancy. So I can’t stress that enough. That’s my one big fear.”***

***“There’s no point doing this if you’re going to have a mother who’s going to be very unwell during the pregnancy and crash afterwards and basically not be there for her child.”***

## Key message

### Work with my health care team



**“I’m aware I would need my endocrinologist on top of the diabetes aspect of things, and the cardiologist in terms of the heart condition. So they would need to be working closely with the research team and (my mito specialist) to make sure my health is as optimal as possible.”**

Participants in this project described a variety of ways that they currently access health care. This included people that see mito specialist services in their own state and interstate through telehealth. It also included people who do not see mito specialists as they have no symptoms of mito even though they carry a mtDNA change that has caused severe symptoms in their family member. One participant who is a potential parent explained they did not even see the same GP regularly.

One participant told us it was important that the pilot considers how they will reach those who do not identify as having mito as they have few or no symptoms. They may not be in regular contact with specialist medical services. She spoke about her hope for her daughter's future interaction with the pilot:

***“If she’s connected with somebody ... who’s warm and knowledgeable who helps build that pathway it’s going to be much easier because ... she doesn’t think of herself as a patient.”***

There may be a need to build trust between the trial participants and the research team and/or their clinical teams. One participant told us that given many people with mito have had long and traumatic diagnostic odysseys and other interactions with health services, additional care may be required.

## Key message

### Travel is not a barrier, but help us reduce its toll



**“We don’t mind about travel. We would love to have a baby and would be willing to do whatever it takes regardless of where it is. It would be nice for it to be in (home city) but it’s not the be all and end all for us.”**

Several participants identified the intersecting challenges of travel with also having mito and being pregnant. Participants assumed that travelling during pregnancy would be minimal and that local health professionals would play a key role in this stage, potentially with support from centralised expertise.

One participant identified the intersection of travel and emotional support, highlighting the difficulty of going through IVF away from family and friends. They felt that disruption to families should be minimised.

Financial costs of taking part in the trial were not mentioned in most interviews. In a small number, this was raised by participants, sharing their expectations that there would be no out of pocket costs for participants in the pilot.

***“The expenses related to the person having the procedure and the family it affects should also be supported by the government.”***

## Theme 4: Help us understand and help us explain it to others

This theme captures what the mito community told us about their information needs during the pilot stage.

### Key message

## Maintain the communication approach from the legislative change campaign



**“Just keep the communication up – which the foundation has already done amazingly. And keep the community involved as much as it possibly can be.”**

The information needs discussed in the interviews applied to several audiences:

- Couples who take part in the pilot
- The friends and families of couples who take part in the pilot, who will be a part of their journey
- The wider Australian mito community

Several participants who were advocates during the campaign for legislative change explained that the information the Mito Foundation had provided had helped them to explain mitochondrial donation to their friends and families. They shared hopes that this would continue so that they could explain what they were going through to their own communities.

### Key message

## Provide clear information about what is going to happen when I join the pilot



**“That the whole process is clearly set out so I don’t have to ask a billion questions because I’m nervous ... I’d want to understand what is involved at the beginning and what happens later.”**

Most participants were seeking information about how the process would work while they were in the trial.

***“I (want to) know exactly what’s going to happen from zero to one month, to two months and a bit of a trajectory of what’s going to happen rather than jumping into something.”***

Participants told us that having clear information about the process would help them to plan around their work and other commitments, particularly when they needed to travel. Several participants wanted to understand which parts of the process are part of IVF, and which are specific to mitochondrial donation.

### **Key message**

## **Tell us about risks and success rates; learn from the UK**



**“I’d be interested to know how it’s all going in the UK, with the progress of the children ... and what the stats are with all the mothers: how many have gone through the process and what percentage had the donation work and the pregnancy work.”**

Participants told us that they would want to know the success rates, and were expecting this information to be informed by the UK’s program. Participants understood that IVF itself, even for those without fertility challenges, did not have a 100% success rate.

A small number of participants asked about how their privacy would be protected.

### **Key message**

## **We would like to understand how egg donation will work**



**“... and I don’t know where the donor egg comes from.”**

Several participants brought up egg (oocyte) donation and had many questions about how this would work. Some participants assumed couples wanting to use mitochondrial donation would need to find their own donor, but they were unsure of what the criteria would be for this (such as upper age limits and health screening). Several participants had concerns about legal and privacy issues, including regarding the parenting rights of donors.

***“I would like the 3rd donor to be anonymous, unless it could be from an unaffected family member for instance. I wouldn’t really want contact.”***

One participant with a family member with mito caused by a change to their nuclear DNA told us they would like to know more about donating eggs towards to pilot.

## Key message

### Improve the understanding of mitochondrial donation to reduce stigma



**“Designer babies! (The public is) going to think we’re going to change the colour of their eyes which is so, so, so far from it. I think that’s what worries me a lot, is that kind of public backlash. But that still can be addressed even in the clinical trial stages.”**

Several participants told us it was important that the pilot stage works to improve understanding of mitochondrial donation in the wider community. They explained that the goal of this was to reduce stigma and they drew parallels to how public perceptions of IVF have changed since it first emerged.

***“I think it’s also important to demonstrate to anyone that has been previously against or questioning mitochondrial donation that it is safe and proving it can work.”***

One participant suggested a communication that explained the legislation in a simplified way could be useful. They suggested that this would be useful for people going through the trial to share with their friends and family.

## Key message

### How we talk about mito is important



**“How do we speak to children with mito and say that we want to avoid people having mito, but we still value people with mito?”**

Several interviews touched on this complex topic. One participant felt the campaign had focussed too much on childhood forms of mito, which are often caused by changes to nuclear DNA (and therefore mitochondrial donation was not relevant to them).

Other participants identified the challenge of making mitochondrial donation available while not implying judgement on families who have passed mtDNA changes onto their children.

Participants told us that the varied and complex emotions that the mito community has already felt throughout the campaign for legislative change will continue and these need to be considered.

## Appendix: List of survey questions

1. What does the success of the mitochondrial donation campaign mean to you?
2. The next phase for mitochondrial donation in Australia will see a clinical trial being run for families who want to use the technology. What do you believe is most important for this clinical trial to get right?
3. If you had a meeting with a key decision maker for the pilot stage of mitochondrial donation, what would you tell them?
4. Is there anything that is worrying you about the next stage of mitochondrial donation?
5. Imagine you or someone in your family is part of the clinical trial. Can you describe for me what that would ideally look like?
6. One of the issues the UK has is about not over-medicalising the process of building a family using mitochondrial donation. What do you think about this issue in Australia?
7. What do you think made the campaign a success?
8. Which parts of your involvement in the campaign did you enjoy?
9. Were there elements of your involvement that made you unsure or uncomfortable?
10. Do you think Mito Foundation could have done anything differently?
11. Is there anything else you want to tell us?

## Version control

**Version 1.0** – 29 June 2022 - first publication.

**Version 1.1** – 30- June 2022 – Revised title, updated wording of recommendations for clarity; changed label for classification of connection to mitochondrial donation to better explain this category; corrected errors in punctuation and formatting.

## Suggested citation

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