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# **The Science of Mitochondrial Donation and related matters**

**Supplementary Submission**

**by the**

**Australian Mitochondrial Disease Foundation**

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The Australian Mitochondrial Disease Foundation (AMDF) appreciates the opportunity to provide a supplementary submission to the Senate Community Affairs References Committee's Inquiry in *The Science of Mitochondrial Donation and Related Matters*. As indicated previously, the Foundation and the community that we support also thank Senators for their interest in this issue and their ongoing willingness to investigate it.

The purpose of this submission is to clarify some matters raised at the Committee's public hearing on 17 May in Sydney and to provide further information for Senators' consideration. Given that, since the hearing, a number of additional submissions have also become available, the AMDF is keen to address some of the matters raised therein. Some of the comments below are therefore simple clarifications whilst others address more substantive issues.

Before addressing these matters, which are grouped in alignment with the Committee's terms of reference, the AMDF would like to note that, whilst some submissions raise matters that require consideration, overall to date they demonstrate strong support for the introduction of mitochondrial donation into Australia coupled with the recognition that we need to proceed carefully.

### Issues covered in this supplementary submission

The science of mitochondrial donation and its ability to prevent transmission of mitochondrial disease

- Established science of mitochondrial donation
- "Not a cure"
- Severe mitochondrial disease

The safety and efficacy of these techniques, as well as ethical considerations

- Safety of the technique(s)
- Efficacy of the techniques
- Australian capability in relation to mitochondrial donation
- Ethical considerations

The status of these techniques elsewhere in the world and their relevance to Australian families

- Accessing mitochondrial donation overseas
- Counselling and follow up

The current impact of mitochondrial disease on Australian families and the healthcare sector

- UK Impact Assessment of mitochondrial donation
- Costs currently being borne by patients and the Australian healthcare system



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Consideration of changes to legal and ethical frameworks that would be required if mitochondrial donation was to be introduced in Australia

- Using the UK framework as a basis, including how this could be adapted to Australia
- The 'slippery slope'

The value and impact of introducing mitochondrial donation in Australia

- Enabling families and children to live normal lives

Other related matters

- Adoption, including feasibility, eligibility, birth parent influence and relevance as a comparison
- Building awareness and understanding of mitochondrial disease and donation, including AMDF activities, supporting the Citizens' Jury and the role of legislative change in raising awareness and acceptance.

## The Science of Mitochondrial Donation and its ability to prevent transmission of mitochondrial disease

### Established science of mitochondrial donation

The process in the UK firmly established the scientific evidence base for mitochondrial donation and its role in preventing transmission of mitochondrial donation between mother and child. As noted in various submissions, the scientific review in the UK was considered to be the most rigorous look at any scientific endeavour coming into humans.<sup>1</sup> It was also based on expert international advice and information.

Further, an open letter on this issue co-signed by 40 international experts in the field recognised the process that the UK went through, acknowledging it as internationally admired and covering off on the various benefits, risks, ethical and other issues necessary before adoption of such a change.

Since that letter was written in 2015, there have been no substantive advances in relation to mitochondrial donation. The science has thus been extensively reviewed, comments sought and received from the existing field of international experts and, on the basis of that, the UK Parliament enacted their legal changes.

Given this, additional scientific review in this area cannot currently elicit more information. In addition, given that there is no suggestion or evidence of those international experts changing their stance, further enquiry is unlikely to result in additional or alternate expert opinion. Replicating the thorough, expert and rigorous work already done is thus unnecessary and would serve to only prolong the process of decision making for families with mitochondrial disease.

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<sup>1</sup> The full quote of this, from Dr Jeremy Farrer, Director of the Wellcome Trust, is *"I don't think there's been any more rigorous look at any scientific endeavour coming into humans"*.



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### *“Not a cure”*

One of the matters that has been raised in some submissions to the Inquiry and at the hearing was the argument that mitochondrial donation is ‘not a cure’. The AMDF has not, and does not believe any other group has, ever presented mitochondrial donation as a ‘cure’ for mitochondrial disease.

Unfortunately at this time there is no cure and few treatments for mitochondrial disease which is one of the reasons its impacts on patients and families are so devastating and why the community is seeking the opportunity for Australia to adopt mitochondrial donation as an option for affected families.

That mitochondrial donation is not a cure does not undermine its therapeutic and other benefits however. Vaccines do not ‘cure’ diseases nor do lifestyle changes ‘cure’ other conditions: many are examples of preventive health interventions.

### *Severe mitochondrial disease*

As raised at the hearing, the UK regulations allow for mitochondrial donation to be undertaken where a license is issued to a couple at risk of passing on severe mitochondrial disease to their children. Whilst no specific definition has been outlined in the regulations, the determination of what is considered ‘serious’ is determined by the medical team referring the patient for mitochondrial donation; the external reviewer responsible for reviewing the case; and, ultimately, the panel at the Human Fertility and Embryology Authority (HFEA) who are ultimately responsible for issuing the license.

The HFEA panel originally recommended that mitochondrial donation should be adopted ‘where inheritance of the disease is likely to cause death or serious disease and where there are no acceptable alternatives’.

In practice, the AMDF has been advised by those working close to the process that the HFEA recommendation is the approach taken: ‘severe’ is generally considered to be a condition which would have an early onset in a child’s life; and significantly impact their day-to-day functioning and quality of life. It may but would not necessarily be life-limiting.

### *The process to assess the ‘severity’ of mitochondrial disease*

The HFEA submission (53a) notes that, to support an application for mitochondrial donation, two steps will need to occur. The first of these is that an assessment needs to be done regarding the ‘particular risk’ of an egg or embryo having mitochondrial abnormality due to mitochondrial DNA. This means that a woman would need to have a high, almost 100%, risk that her eggs will have mitochondrial abnormalities caused by mitochondrial DNA. The Committee heard from one such woman as part of the public hearings.

Step two involves the assessment of whether a ‘significant risk’ exists that a child with those abnormalities will have, or develop, a ‘serious’ mitochondrial disease. An assessment both of

‘significant risk’ and ‘seriousness’ needs to be made and, to support an application, a clinic will need to provide patient-specific information to support this assessment. This will include:

- the patient’s medical history
- the patient’s mutant mtDNA load
- the patient’s family medical history of the mtDNA mutation or disease
- scientific literature relevant to the mtDNA mutation or disease, and
- any additional information which the clinician may consider is relevant to the application.

Further information regarding information required can be located at pages 315-318 of submission 53a.

## The safety and efficacy of these techniques, as well as ethical considerations

### Safety of the technique(s)

The issue of safety has been long considered in relation to mitochondrial donation and the subject of significant international scientific review. The independent panel of experts convened by the HFEA to review the safety and efficacy of mitochondrial donation have considered this issue on four separate occasions and each time reached the conclusion that there is no evidence to suggest that the technique is unsafe.

This is reiterated in various submissions to the Inquiry, including submission 45 from the Wellcome Centre for Mitochondrial Research and submission 49 from Professor Mary Herbert of the Institute of Genetic Medicine in Newcastle-upon-Tyne, both of whom have been strongly involved in the UK review and regulatory environment.

Submission 45 also notes the preclinical evaluation published by the Centre in 2016. This study considered the incidence of gene expression levels and chromosomal damage between embryos that had undergone PNT and control embryos. No difference was found, reaffirming the safety of the technique.

Further, in terms of safety, it needs to be noted that no evidence exists of significant risks to children as a result of mitochondrial donation (submission 12 and others). Mitochondrial donation will impact only the recipient’s capacity to generate energy and will not impact an individual’s physical appearance, intelligence, behaviour or other personal characteristics.

### Efficacy of the techniques

Evidence sources regarding safety and efficacy include data originally derived from mouse models. These models, originally pioneered over thirty years ago, used pronuclear transfer (PNT) and resulted in healthy and normally-reproducing offspring. Extensive subsequent work continues to



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support the safety of the technique given [the birth of] normal offspring and its effectiveness in mitigating the risk of transmitting mitochondrial DNA mutations (submission 49).

Professor Herbert's submission also notes that the other technique legal in the UK – maternal spindle transfer (MST) – works effectively in Macaque monkeys but shows a higher incidence of abnormal fertilisation than PNT when used on human eggs. Professor Herbert does note however that, where the eggs have normal fertilisation, these appear to develop normally. Professor Herbert thus concludes that *“while ethically less contentious than PNT, in the sense that it does not involve destruction of an embryo, MST may be less efficient in producing viable embryos.”*

The issue of “carry over” of the mother's mitochondrial donation was discussed at length at the Inquiry and questions were asked regarding the impact of this. Submissions 23, 25, 31, 45 and 49 also mention it and submissions 23 and 49 note that a minority of embryonic stem cells taken from embryos post mitochondrial donation show some reversion towards the maternal haplogroup.

AMDF understands that the translation of data regarding embryonic stem cells to babies is unclear and, as indicated at the hearing and in submission 23, having mitochondrial DNA levels below 2% appears to be the appropriate level to avoid or minimise this risk.

Two other techniques were raised in relation to mitochondrial donation – germinal vesicle transfer (GVT) and polar body transfer – in submissions 31 and 48 respectively.

These techniques are not permitted by the UK regulations for mitochondrial donation which limit the techniques to pronuclear transfer and maternal spindle transfer. Advice received by the AMDF is that the potential for germinal vesicle transfer in mitochondrial donation was not considered by the UK's independent scientific panel due to limited evidence to support its use. Whilst it has been performed in mice, further studies are apparently needed to improve its efficiency before it would be considered for clinical application.

In relation to polar body transfer, additional work is also considered necessary to optimise procedures and assess safety and efficacy before consideration would be given to making it one of the legal techniques in the UK.

As such, international and scientific evidence suggests that the two techniques currently relevant to mitochondrial donation are pronuclear transfer and maternal spindle transfer. Given their safety profiles, the AMDF would support both pronuclear transfer and maternal spindle transfer being made available with parents being given information and counselling before determining which is most appropriate to their circumstances.

### Australian capability in relation to mitochondrial donation

Australia's capacity to perform mitochondrial donation was also raised at the hearings and it is important to note that Australia already has scientists undertaking the relevant techniques in animal models (submission 27). Further, Australia's expertise in mitochondrial genetics research is of relevance and we have the opportunity build on that and our capacity in IVF more generally to



become world leaders in this area. Submissions 2, 4, 12, 17, 19, 20, 21, 23, 24, 27, 29, 34 and 35 all indicate that Australia has the appropriate skills, engagement and capacity to deliver mitochondrial donation.

It should also be noted that the UK facility licensed to perform mitochondrial donation by the HFEA has indicated its willingness to work with Australian centres wishing to establish mitochondrial donation services (submission 12). This reflects the strong working relations that exist in this area and the international recognition Australia attracts in this area.

It is also worth noting that Australia possesses not only the scientific capacity to introduce mitochondrial donation but is also in the process of building a working knowledge of the UK regulatory system, including the procedures and practice around reviews and approvals. At least one Australian researcher sits on the relevant committee of the HFEA that reviews couples to determine whether mitochondrial donation is appropriate for them. This expertise would prove invaluable in introducing an Australian-based system.

### Ethical considerations

The majority of non-religious-based ethicists responding to the Senate Inquiry indicate support for the cautious introduction of mitochondrial donation. This potentially reflects evidence given at the Inquiry that the risk of the technique is less than the risk of mitochondrial disease but also reflects a number of other considerations including the capacity to have a genetically related child.

As summarised in submission 34 from the Biomedical Ethics Research Group at the Murdoch Children's Research Institute, the general view would appear to be that 'while safety concerns justify a cautious approach to the use of MRT, including conducting rigorous safety trials, extensive monitoring, and long-term follow up, they do not justify a legal prohibition on it'.<sup>2</sup> Safety monitoring should be built into the process of introducing mitochondrial donation into Australia as in the UK.

Further, submission 27 notes that 'while accepting that there are always risks with new technology, it would appear that the balance of risk versus benefit in this debilitating disease is now at a point where its uptake should occur'.

The AMDF is supportive of a number of issues raised by those expert in the field of ethics, including the need for the provision of effective information, counselling and followup both to families and their resultant children.

In our original submission, the AMDF also noted that there were some elements of the UK regulations that would need amendment to fit with Australian expectations and norms. The principal of these is the issue of donor anonymity that the AMDF does not think appropriate nor acceptable in the Australian context. Any children born from mitochondrial donation in Australia

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<sup>2</sup> Mitochondrial Replacement Therapy





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should have the right to identify their donor and, as in the UK, parents should also be encouraged to communicate to their children their origins and so forth.

Given that egg donation is voluntary in Australia, the AMDF does not acknowledge the relevance of those submissions that relied heavily on the experience of the donor to discount the validity or ethics of mitochondrial donation.

## The status of these techniques elsewhere in the world and their relevance to Australian families

### Accessing mitochondrial donation overseas

The potential for Australians to go overseas to undertake mitochondrial donation was mentioned by many groups at the Senate hearing and, in addition, the AMDF thinks that the suggestion was actually flagged that this might be permitted or encouraged. This latter suggestion is at odds with the majority of submissions and witnesses which express deep concern about the potential for individuals to go overseas for mitochondrial donation, particularly to less regulated countries.

In terms of going to the UK for mitochondrial donation, this is not currently an option. As noted in submission 8, at least one patient has reached out to the UK and has been informed that they are not currently accepting international patients. Given the newness of their processes and the potential uptake, it is anticipated that they will be unable to take international patients for quite some time.

Regardless of the ability to access an appropriately regulated process operating within an acceptable healthcare system, there are many other issues that should be considered in relation to the notion of Australians going overseas to access healthcare. A key issue is that of equity, given that Australian families would need to self-fund and only those with the required financial capacity would be able to access a procedure designed to enable them to bear a healthy baby.

This goes against all the precepts of our healthcare system, enshrined in Medicare and based on the notion of need and equitable access, not ability to pay.

Other issues include the capacity of the Australian healthcare system to be informed and aware of children; the continuity of any counselling or other services provided; and delivering the appropriate follow up.

The AMDF is of the opinion that, given Australia's expertise in the area of IVF technology, our capacity to deliver mitochondrial donation in Australia and appropriate ethics and safety frameworks, that those Australians desiring to undergo mitochondrial donation to avoid transmitting this disease to their children should be legally able to do so in Australia.





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### Counselling and follow up

The AMDF is keen to ensure that an appropriate model is adopted for counselling to families prior to undertaking mitochondrial donation and follow up subsequently. In this regard, the UK model would again offer a good basis and aligns closely with the information provided in Australia regarding IVF procedures with some additions specific to mitochondrial donation.

In terms of counselling, it seems appropriate that advice should be provided to prospective parents about the alternative options available to them in terms of their reproductive options and about the scientific concepts involved, such as pronuclear transfer, maternal spindle transfer, and potential haplogroup matching. In addition, in line with current medical practice regarding IVF, the risks and benefits of the procedures should be outlined.

In terms of follow up, in the UK, clinics offering mitochondrial donation must have a documented process for monitoring children born following mitochondrial donation, including medical follow-up. Mandatory reporting of any adverse events is required, such as birth defects, genetic abnormality or another adverse outcome such as a miscarriage. Health checks for children born of mitochondrial donation in the UK include periodic testing of urine and blood and are subject to parental consent which the regulations require clinics to encourage.

### The current impact of mitochondrial diseases on Australian families and the healthcare sector

The AMDF does not intend to revisit the evidence or submission provided by patients as to the impact of mitochondrial disease on their lives and those of the families. Suffice to say, mitochondrial disease has devastating and long-lasting impacts on individuals and families and the desire to mitigate these impacts is key to the Foundation's support for mitochondrial donation and that of the mitochondrial disease community more generally.

### UK Impact Assessment of mitochondrial donation

Given the interest by Senators in the cost of mitochondrial donation and the maintenance of a regulatory framework for that versus the costs of individuals with mitochondrial disease, we would like to reiterate the analysis undertaken in the UK of The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations.

The Impact Assessment for the Regulations indicated that creating regulations to enable mitochondrial donation to take place in the UK would deliver a net benefit of approximately A\$61 million (GBP33.5 million) per year and A\$575 million (GBP318.1 million) over ten years. This would accrue principally due to the savings in healthcare costs and is based on an estimated 20 individuals



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a year being prevented from inheriting mitochondrial DNA disease.<sup>3</sup> This analysis, being a regulatory impact statement, included the costs involved of the regulatory system needed to provide oversight for mitochondrial donation.

The Impact Assessment analysis did not, however, include the benefits that would accrue due to freeing families and carers from looking after affected individuals, by increased quality of life and by greater contribution to the economy by those no longer affected by mitochondrial disease. Were these social costs to be incorporated into the analysis, it can only be anticipated that the benefits would be significantly higher.

### Costs currently being borne by patients and the Australian healthcare system

Further, given the evidence provided in submissions 5, 8, 11, 15, 29, 32, 36 and 38, it is worth noting the cost impacts currently being experienced by patients. These submissions note operations to eyes; mini or more severe stroke-like episodes; hearing and vision loss; visits to a myriad of medical specialists and allied health professionals; the need for hearing or other aids like pace makers; visits to emergency departments; and hospital admissions including admissions to intensive care units.

In addition to the direct costs to the healthcare system, there are other costs also accrue both to the individual and to the community more generally. Some of these relate to costs, such as the inability to work or the need to work part-time; the requirement for family to act as carers, impacting their capacity to work; and, in some instances, the payment of welfare benefits.

### Consideration of changes to legal and ethical frameworks required if mitochondrial donation was to be introduced

Changes to the legal system are necessary to enable mitochondrial donation to be introduced and the AMDF hopes and trusts that Senators will receive the information necessary for them to act to allow parents to utilise mitochondrial donation in Australia.

### Using the UK framework as a basis

In terms of necessary changes, submissions and the public hearing provide evidence that the UK system provides a good basis for a regulatory system in Australia with some changes, including those noted above. The UK regulatory process reflects significant work and effort over many years in its development and, whilst some tweaking may need to occur, Australia already has a framework in existence that could be adapted to address and regulate mitochondrial donation.

In terms of some observations from the public hearing and reflecting the UK experience, the AMDF would suggest that only a small number of clinics should be licensed in Australia. This would enable

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<sup>3</sup> Department of Health (UK), The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015: Impact Assessment, 2014. [http://www.legislation.gov.uk/ukia/2015/138/pdfs/ukia\\_20150138\\_en.pdf](http://www.legislation.gov.uk/ukia/2015/138/pdfs/ukia_20150138_en.pdf) Accessed 7 May 2018.



the building of an expertise in this field as it emerges and develops and a focus for knowledge and global cooperation and collaboration.

*How this could be adapted to the Australian context*

The AMDF considers that, in line with their existing responsibilities in relation to licensing research on human embryos, it would be appropriate for existing structures within the NHMRC, such as the Embryo Research Licensing Committee, to also provide oversight and licensing for mitochondrial donation in Australia. This recognises the expertise already in existence at the NHMRC and the Licensing Committee's current responsibilities which include to:

- consider applications for licences to conduct research involving human embryos;
- issue (subject to conditions) or not issue such licences;
- maintain a publicly available database containing information about licences issued;
- monitor licensed activities and ensure compliance with the legislation through the appointment of inspectors and take necessary enforcement action, such as cancelling or suspending licences;
- report to the Parliament of Australia on the operation of the *Research Involving Human Embryos Act* and the licences issued under this Act; and
- perform such other functions as are conferred on it by the *Research Involving Human Embryos Act* or any other law.<sup>4</sup>

In terms of responsibility, this would involve issuing licenses for clinics to perform mitochondrial donation and then individual couples to undergo the procedure.

In terms of issuing a license to a clinic, the likely process would be an application on behalf of clinics who wanted to undertake the practice and an assessment of the clinics to specified criteria. Again, the UK's regulations and materials provide an effective and useful basis that could essentially be replicated here. As heard at the Inquiry, it is unlikely that more than a few clinics would apply for licenses and the Committee could work with the Fertility Society and other organisations currently involved in accreditation as appropriate.

In practice, for prospective parents, it would be likely that a system not dissimilar to the UK would actually operate whereby the relevant medical team, which by necessity consists of experts in the field of mitochondrial disease, would refer a couple following counselling and initial assessment to a clinic for mitochondrial donation. Additional assessment and counselling would then occur before an external reviewer or panel of reviewers would then review an application and provide a recommendation. Based on that recommendation and any other material of relevance, the Committee would then have the responsibility, as does the UK's HFEA, of issuing the license.

HFEA's submission to the Inquiry (submission 53a) provides significant detail about the processes and procedures in place in the UK and that could be mirrored effectively here.

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<sup>4</sup> NHMRC, 'Embryo Research Licensing Committee'. <https://www.nhmrc.gov.au/about/nhmrc-committees/embryo-research-licensing-committee> Accessed 29 May 2018.



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### The slippery slope

The AMDF also refutes comments made at the public hearing about the introduction of mitochondrial donation leading to a 'slippery slope' in relation to genetic modification of embryos.

One of the key reasons that the AMDF supports mitochondrial donation and why it was introduced in the UK is its limited relevance and impact. As highlighted above, mitochondria do not influence an individual's looks, intelligence or personality; they simply act to generate energy to fuel the body.

As such, mitochondrial donation is clearly ring-fenced in a scientific sense from broader purposes or intent. The AMDF supports that clear definition and legal restriction.

### Value and impact of introducing mitochondrial donation

#### Enabling Australian families and children to live normal lives

As flagged in our original submission and at the hearing, the key value and impact of introducing mitochondrial donation is to give Australian families and children the opportunity to live normal lives free of mitochondrial disease and its devastating and debilitating effects. Mitochondrial donation offers parents the opportunity to avoid passing this disease to their children and to future generations.

### Other related issues

#### Adoption

The AMDF notes a number of challenges to the recommendation of some submissions that families look to adoption as an alternative to having their own children via mitochondrial donation and these are outlined below.

As the peak body providing support to Australians with mitochondrial disease and their families, the AMDF also notes the importance to many people in the mitochondrial disease community of biological links, something acknowledged as important by a variety of submissions to the Inquiry, including those by ethicists. Biological links are not simply important to parents but also to broader family and family groupings and should not be underestimated. Passing on genetic material, personal characteristics and other elements of an individual is valued by many and having the choice to utilise mitochondrial donation is currently the only way some people can achieve this and have a healthy baby at the same time.



### *Feasibility of adoption as an option*

Adoption was raised at the hearing and in some of the submissions as an alternative to mitochondrial donation for parents likely to transmit mitochondrial disease to their children. The AMDF notes submission 55 which highlights that 'adoption is not a viable alternative to biological reproduction' in Australia.

Submission 55 notes that the number of adoptions have declined by 60% in Australia in the last 25 years and 66% of adoptions are undertaken by carers already responsible for the child concerned. Of the 315 children in need of adoption in 2016-17, the submission notes that only 42 involved adoptions of an Australian child to parents not previously known to them. This numerical level of adoption in Australia and the 'competition' for adoptive children makes this an unlikely option for parents seeking to avoid transmitting mitochondrial disease to their children.

### *Eligibility for adoption*

In terms of adoption, all states and territories have strict eligibility criteria, including health screening and assessment procedures which it is unclear whether people with mitochondrial disease would fulfil.

The AMDF has sought information about eligibility in the states and territories but feedback to date is far from definitive. Advice suggests, however, that prospective parents and their health would be assessed on a case by case basis given that legislation does not tend to include specific preclusions. Given the significant vulnerability of the children involved in adoption however and the family loss and/or trauma that many of them have already experienced, states have preferences toward prospective parents who have the highest possible possibility of seeing children into adulthood.

*Eligibility is not the only, and potentially not the most important, issue however* as the input from birth parents is now critical in terms of choosing adoptive parents. Given that the pool of prospective parents is greater than the number of available children for adoption, it has been suggested to the AMDF that biological parents may preference adoptive parents with no known risk of illness over an adoptive parent carrying an inherited disease, regardless of how well and healthy that person may be at the time of adoption.

### *Relevance of adoption as a comparison*

Whilst the above addresses some of the issues raised by submission, the AMDF must note that eligibility or birth parent choices in relation to adoption should not impact a couple's capacity to access mitochondrial donation just as it does not impact a family's capacity to access IVF.



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The principle behind adoption, as indicated by the WA Department of Communities, Child Protection and Family Support, is 'to provide a new family for a child who cannot be raised by their birth family'.<sup>5</sup>

In contrast, the intent behind mitochondrial donation is to enable a couple to have a healthy child who does not inherit mitochondrial disease from its mother. In the latter situation, the family has made a conscious decision to bear a child together, knowing the health status of the parents and desiring a healthy child of their own.

As the Committee heard from one patient struggling to have their own children, this is a choice and decision that families and couples feel capable of making and want the help of the Australian Government to be allowed to make.

### **Building awareness and understanding of mitochondrial disease and donation**

At the Inquiry, the issue was raised about the awareness and understanding in the community about mitochondrial disease and donation which the AMDF acknowledges is extremely low. This was also reinforced by the submissions, two of which noted little or no knowledge by the treating patient's GP or specialist (submissions 18 and 38).

### **AMDF activities**

The AMDF has long been engaged in raising awareness of mitochondrial disease and to 'increase awareness and understanding of mito by educating the mito community and key decision makers in the wider community to make mito mainstream' is one of our five key strategic goals. We also generate broader awareness and understanding of mitochondrial disease through helping patients communicate their stories more broadly and our awareness and fund-raising activities like the Bloody Long Walk and Stay in Bed Day.

The AMDF also stands ready to help roll out an education and awareness raising campaign in the event that the Senate Committee recommends adoption of mitochondrial donation in Australia. Work has been initiated on this to ensure that external support is provided to legislative change and to ensure that the Australian population is informed and positively brought along the legislative journey. The AMDF is encouraged in this work by the experience we have had to date in engaging with the public, politicians and other stakeholders in regards to mitochondrial donation and the overwhelming support mitochondrial donation receives when people understand it and its ramifications.

### **Supporting the Citizens' Jury**

We are also committed to specific activities and supported (financially and administratively) the Citizens' Jury undertaken by Associate Professor Ainsley Newson on which she reports in

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<sup>5</sup> Department of Communities, Child Protection and Family Support (WA), 'Thinking about adoption?'.  
<https://www.dcp.wa.gov.au/FosteringandAdoption/AdoptionAndHomeForLife/Pages/AllAboutAdoption.aspx#2> Accessed 29 May 2018.



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submission 29. The intent of this was to explore Australian public attitudes to allowing mitochondrial donation and reflected similar activity undertaken in the UK leading up to their legalisation of mitochondrial donation.

The Jury was asked 'Should Australia allow children to be born following mitochondrial donation?' and, after balanced presentations and evidence about mitochondria, mitochondrial disease and the interventions currently available, returned a significant majority verdict answering 'yes' or 'yes with conditions'.

### *The role of legislative change in raising awareness and acceptance*

The role of legislative change in raising awareness and acceptance of mitochondrial donation should also not be underestimated, particularly given the experience in the UK. In the UK, when this became a public issue for the parliament, it generated significant media and other interest with the result that the issue become the subject of greater reporting and public awareness.

It should be noted that this media reporting was generally well-informed and the public response to it overwhelming positive. The AMDF's experience in engaging with media, the public, politicians and other stakeholders would suggest a similar response and outcome in Australia.

## Conclusion

The AMDF recognises and accepts that no new medical technology, and little medical intervention, is without risk. However, given the low risks outlined above and the significant impact of mitochondrial disease on individuals and their families, there seems little reason from this perspective to not pursue the adoption of mitochondrial donation in Australia. This is a view supported by the majority of submissions, including submissions 27, 29, 34 and those made by scientists, researchers and clinicians. Ethically, the AMDF also observes that from our engagement with the Australian public, politicians and others, that mitochondrial donation is broadly accepted as a concept and welcomed as a means to enable parents the choice to not pass this disease onto their children.