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

**Submission by the  
Australian Mitochondrial Disease Foundation**

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

The AMDF supports mitochondrial disease sufferers and their families, funds essential research into the prevention, diagnosis, treatment and cures of mitochondrial disorders, and increases awareness and education about these devastating diseases. This submission provides information regarding the AMDF's support for the introduction of mitochondrial donation in Australia and the reasons for that support.

## Mitochondrial disease and its impact

Mitochondrial disease is a debilitating genetic disorder that starves the body's cells of energy, causing multiple organ dysfunction or failure and potentially death. Mitochondrial disease occurs when a person's mitochondria are not functioning properly. It primarily affects the muscles and major organs, such as the brain, heart, liver, inner ears and eyes, but can cause any symptom in any organ at any age.

Approximately 120,000 Australians carry a mitochondrial DNA mutation that can potentially cause mitochondrial disease, and around one in 200 people may develop mitochondrial disease during their lifetime.

In about half of the cases diagnosed, the disease is caused by changes in mitochondrial genes (mtDNA) which contribute about 0.1 per cent of a child's genetic make-up and are inherited only from the mother. Depending on which parts of a person's body are affected and to what degree, people with mitochondrial disease may: have strokes or seizures; be unable to walk, eat, swallow or talk normally; develop liver disease or diabetes; suffer heart, respiratory or digestive problems; lose their sight or hearing; suffer muscle weakness and pain; and experience developmental delays or intellectual disability.

There are few effective treatments and no cures for mitochondrial disease. The impacts on individuals and families of mitochondrial disease are therefore devastating.

The AMDF is aware that various members of the mitochondrial disease community are providing individual submissions to this Inquiry. Those submissions will undoubtedly provide heart-rending detail about the experiences that parents, children and families go through, and the feelings of helplessness, despair and guilt felt by those involved. The AMDF recognises and acknowledges those submissions and, in addition, provides some patient stories in Appendix One and Two in order to further highlight the impact on both individuals and families with this disease.



## Our growing understanding of mitochondria and their role in the human body

Understanding of our mitochondria and of mitochondrial disease is constantly and rapidly developing as scientific research and knowledge expands. It was as recently as 1962 that the first patient was diagnosed with a mitochondrial disorder, and the discovery that mitochondria have their own DNA (mtDNA) which is different from our nuclear DNA (nDNA) was made the following year.<sup>1</sup>

This information did not necessarily translate rapidly into clinical recognition of either the disease or the role mitochondria played in the human body. The eldest son of the AMDF's Chairman and founder, who himself has a background in medicine, fell ill thirty five years ago and, despite access to the foremost medical experts of the time, was not diagnosed with mitochondrial disease prior to dying at the age of seven. This diagnosis came retrospectively some 20 years later.

Since then, research into mitochondrial disease has become a growing area of interest and one to which Australian researchers contribute significantly. Diagnosis has developed markedly with advances in human knowledge and with the capacity to analyse our genes. Our ability to diagnose mitochondrial disease has increased substantially in the last ten years, becoming both faster and cheaper.

The rapidity of this scientific development can be seen in the studies, reviews and legislative approaches taken to mitochondrial donation as well. When this was last reviewed in Australia in 2010, the science informing it was such that it was not pursued; today the UK has introduced mitochondrial donation as a legal procedure for those people at risk of passing on the disease to their children. Other countries are considering following the UK's lead. The scientific advances that have occurred in the last eight years certainly provide support for this.

## Mitochondrial donation

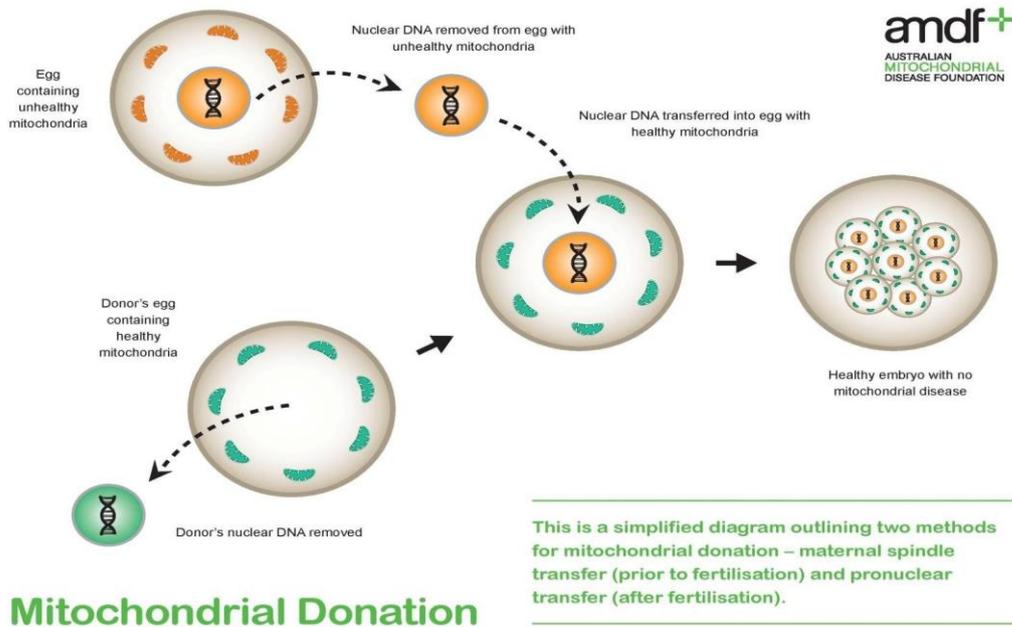
Mitochondrial donation, also called mitochondrial replacement, transplant or transfer therapy, involves transferring the nucleus from the affected mother's egg (either prior to or within hours after fertilisation) into a donor egg that has had its nucleus removed. This donor egg retains its healthy mitochondrial DNA and the resulting child consequently does not inherit mitochondrial disease. A graphic depicting this is included on the next page.

In terms of the number of children and families for whom this technique would be appropriate, it has been estimated the average number of births per year among women at risk for transmitting mtDNA disease is 152 in the United Kingdom and 778 in the United States.

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<sup>1</sup> MitoAction, 'Mitochondrial Disorder Medical Information', Copyright Cleveland Clinic 2005-2011.  
<http://www.mitoaction.org/medical-information> Accessed 7 May 2018.

Assuming a similar age distribution and fertility, this suggests approximately 56 babies could be born each year free from maternally inheritable mitochondrial disease in Australia. These children would, instead of suffering from a dreadful and, ultimately, deadly disease, live 'normal' lives free from mito.



## Options currently available to Australian families affected by mitochondrial disease

Currently, a prenatal diagnosis (with option of terminating an affected pregnancy) or in vitro fertilisation (IVF) using preimplantation genetic diagnosis (PGD) are the only reproductive options available to prospective at risk Australian parents who wish to have a healthy, genetically-related children.

These techniques are not an option for families where most of the woman's eggs carry substantial amounts of a mutated mtDNA such as in maternally inheritable mtDNA disease. This is because PGD can only help if some of a woman's embryos are healthy. PGD can only reduce but not eliminate the risk of mitochondrial disease in the resulting child.

At present many people in Australia choose not to have children in order to avoid the risk of passing on mitochondrial disease. The AMDF is very aware of at risk families who choose this option. It is aware also of the challenges their families face when giving birth to children who are in turn at risk of passing this disease onto their children.

Only mitochondrial donation can ensure that parents with a mtDNA disorder will have a genetically related child who will not inherit mitochondrial disease.

## Overseas experience of mitochondrial donation

### Legislating to allow mitochondrial donation: the United Kingdom

Following an extensive scientific and ethical review process involving ten years of public consultation and three expert reports, in October 2015, the UK Parliament approved regulations to allow mitochondrial donation to prevent maternally inheritable mitochondrial disease. In December 2016, the final regulations governing mitochondrial donation were endorsed by the Human Fertilisation and Embryology Authority (HFEA).

#### *The review process undertaken in the UK prior to the introduction of mitochondrial donation*

*The Human Fertilisation And Embryology (Mitochondrial Donation) Regulations 2015* established the framework under which mitochondrial donation takes place in the UK. The Regulations were introduced following significant scientific review and consultation.

This process, which took approximately ten years, is detailed below in the Timeline section to demonstrate the rigour of the process. Sally Cheshire, Chair of the HFEA, which undertook a number of reviews into mitochondrial donation, commented that the work undertaken to enable mitochondrial donation 'represented a kitemark in terms of the investigation that can and should be undertaken whenever scientific research moves towards clinical practice'.<sup>2</sup>

The UK regulations are very specific in that they allow mitochondrial donation to be used only where there is a 'particular risk that an embryo created using the patient's egg will carry a mitochondrial DNA abnormality and that there is a significant risk that a child born from the use of that embryo will have or develop a serious mitochondrial disease'.<sup>3</sup>

The HFEA also has a responsibility to assess that any clinic that wished to offer mitochondrial donation is competent to offer it; and that each case of treatment is appropriate, using criteria set out in the Regulations.

#### *The UK timeline of activities, reviews and regulatory change<sup>4</sup>*

The following table outlines the timeline towards mitochondrial donation in the UK, incorporating key reviews, reports and licensing milestones.

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<sup>2</sup> Human Embryology and Fertilisation Authority, 'UK's independent expert panel recommends "cautious adoption" of mitochondrial donation in treatment', Press release, 30 November 2016, <http://hfearchive.uksouth.cloudapp.azure.com/www.hfea.gov.uk/10559.html>

<sup>3</sup> Dr Sarah Barber and Dr Peter Border, 'Mitochondrial Donation', House of Commons Library, Standard Note: SN/SC/6833, 29 January 2015.

<sup>4</sup> The following is based on material from the Wellcome Trust's website on this issue, outlining the key dates which led to the licensing of mitochondrial donation - <https://wellcome.ac.uk/what-we-do/our-work/mitochondrial-donation>.



- 2018 February: the first two UK women carrying faulty mtDNA were granted licenses by the HFEA to undergo mitochondrial donation, giving them the opportunity to have children free from mitochondrial disease.
- 2017 March: Clinicians in Newcastle are given the first UK licence to carry out mitochondrial donation treatment.
- 2016 December: The Human Fertilisation and Embryology Authority agrees that clinics can now apply for a licence to carry out mitochondrial donation.
- November: An independent expert panel convened by the Human Fertilisation and Embryology Authority to undertake a review of mitochondrial donation techniques recommends cautious adoption of the techniques in the clinic.
- July: Scientists at the Wellcome Centre for Mitochondrial Research develop a new genetic test for mitochondrial disease that can provide results in 2-3 days.
- June: Published in the journal Nature, scientists at the Wellcome Centre for Mitochondrial Research report the first in-depth analysis of normal human embryos created using a new technique designed to reduce the risk of mothers passing on mitochondrial disease to their children.
- 2015 October: *The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* come into effect and the Human Fertilisation and Embryology Authority publishes provisions for licensing mitochondrial donation.
- January – February 2015:
- In the House of Lords, peers vote by 280 to 48 in support of *The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015*.
  - In the House of Commons, MPs vote by 382 to 128 to pass *The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015*.
- 2014 December: The Government publishes *The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015*.
- September: The House of Commons holds a backbench debate on mitochondrial donation.
- June: The Human Fertilisation and Embryology Authority releases its third scientific review of the safety and efficacy of mitochondrial donation. It reports that there is no evidence to suggest either technique is unsafe and that both techniques have potential to be used to prevent serious mitochondrial disease.
- April: A favourable evaluation of the Human Fertilisation and Embryology Authority's public dialogue and consultation is published.
- March: The Department of Health publishes draft regulations for mitochondrial donation. A public consultation is launched for three months.
- 2013 June: the Department of Health and the Human Fertilisation and Embryology Authority state that draft regulations to permit mitochondrial donation will be issued later in 2013, then taken to further public consultation.



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- March: the Human Fertilisation and Embryology Authority publishes a report on their public consultation and updated scientific review, which concludes that mitochondrial donation techniques have potential to be used if safety and efficacy are refined, and that the public are broadly supportive.
- 2012 September: the Human Fertilisation and Embryology Authority launches a public consultation exploring mitochondrial donation.
- July: the Human Fertilisation and Embryology Authority runs a series of public dialogue events across the UK.
- June: the Nuffield Council on Bioethics publishes a report, 'Novel techniques for the prevention of mitochondrial DNA disorders'.
- May: the Wellcome Centre for Mitochondrial research, based at Newcastle University, is established with the aim of developing a programme of basic and clinical mitochondrial disease research.
- 2011 The Human Fertilisation and Embryology Authority convenes an Expert Scientific Review panel to assess the effectiveness and safety of mitochondrial donation.
- 2010 Researchers at Newcastle University develop mitochondrial donation techniques to prevent diseased mitochondria being passed from mother to child.
- 2008 The Government passes The Human Fertilisation and Embryology Act 2008, allowing researchers to develop techniques to prevent transmission of maternally inherited mitochondrial disease.
- 2005 Researchers at Newcastle University obtain a research licence to work with human oocytes to explore mitochondrial donation techniques.
- The House of Commons Science and Technology Committee publishes an extensive report, 'Human Reproductive Technologies and the Law', which supports further research in the area.
- 2000 The Chief Medical Officer's expert group report, 'Stem Cell Research: Medical Progress with Responsibility', recognises the future potential use of mitochondrial donation.

### *Regulations governing mitochondrial donation in the UK*

The *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* require clinics in the UK to apply to the HFEA for a special licence to undertake mitochondrial donation. In addition, patients must apply individually to the HFEA in order to undergo mitochondrial donation treatment in a licensed clinic.

The *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* also:

- Prescribe the technique to be used for the creation of an embryo, either maternal spindle transfer or pronuclear transfer. No technique that does not match the description laid out in the Regulations may be used. Further no other alterations to the embryo can be made other than those laid out in the Regulations;



- Prescribes the criteria that must be satisfied before a patient can be treated - that there is a particular risk that the patient's egg will carry a mitochondrial DNA abnormality and that there is a significant risk that a child born from the use of that egg will have or develop a serious mitochondrial disease;
- Specifies that a clinic already holding a treatment licence from the HFEA to carry out IVF cannot provide mitochondrial donation treatment without specific prior approval to do so from the Authority. Under these Regulations, the HFEA determines whether clinics are competent to provide mitochondrial donation and individually licenses them to do so;
- Specifies the information that may be given to a person conceived by mitochondrial donation, on application to HFEA, about their mitochondrial donor and states that no identifying information may be disclosed;
- Clarifies that a mitochondrial donor-conceived person is not considered as genetically related to the mitochondrial donor or any person who was born as a result of treatment services using genetic material from the person's mitochondrial donor for the purposes of requesting information about whether an intended spouse, civil partner or person with whom that person has or intends to have an intimate physical relationship is genetically related to them;
- Provides that mitochondrial donors must not be informed that a young person born as a result of their donation has sought non-identifying information about them from the HFEA;
- Specifies what information can be given to a mitochondrial donor, on application to the HFEA, about children born as a result of their donation and states that no identifying information can be disclosed;
- Clarifies that the mitochondrial donor cannot be considered to be a biological parent of a person born as a result of their donation for the purposes of section 31ZE of the Human Fertilisation and Embryology Act 1990, which means that two persons with the same mitochondrial donor are not to be regarded as genetic siblings;
- Provides that a mitochondrial donor cannot withdraw their consent to their donated egg or embryo being used in the treatment of the affected patient once it has undergone the MST mitochondrial donation technique, even if the egg or embryo has not yet been placed in the patient;
- Ensures that for the purposes of the consent provisions in the *Human Fertilisation and Embryology Act 1990*, the resulting egg or embryo is not to be treated as the egg or embryo of the person whose mitochondrial DNA was used to create it;
- Provides that where a child has been born following treatment services a person who donated mitochondria is not eligible to apply for a parental order on the basis of that donation alone; and
- Amends the *Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004* so that they do not apply to information requests under the *Human Fertilisation and Embryology Act 1990* about mitochondrial donation.



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There are also requirements that full information about the procedure, its potential risks and limitations are provided to people considering mitochondrial donation; that genetic testing take place when the embryo is at 15 weeks' gestation; and that the child is monitored over time to enable ongoing capture of information about human mitochondrial biology.

The rigour and depth of the reviews and process undertaken in the UK should provide the Senators with the confidence that mitochondrial donation could be introduced into the Australian context. Whilst some of the regulations adopted in the UK may need to be adapted to align with Australia's specific expectations or current laws regarding IVF, they provide a strong basis from which to work towards offering Australian parents the capacity to access these techniques.

### Other international experience

In April 2018, the Singapore's Bioethics Advisory Committee (BAC) issued a consultation paper, seeking public feedback on the use of emerging technology to prevent mitochondrial disorders. In releasing a public consultation document on the issue, the BAC pointed to the UK experience, noting that it was 'timely and important' for Singapore to review the current research in relation to mitochondrial donation and review their recommendations regarding its use. The consultation is open until June 15.

In January 2017, Ukrainian scientists announced the birth of a baby with donor mitochondrial DNA to a woman with unexplained infertility, but without mitochondrial disease, who had been unable to conceive with conventional IVF.

AMDF does not currently support mitochondrial donation to treat infertility. As far as it is aware, the use of the procedure for purposes other than preventing inheritable disease has not yet been subject to rigorous scientific and ethical review or research, as has been the case for preventing mitochondrial disease.

In September 2016, the first live birth using human oocytes reconstituted by maternal spindle transfer to prevent mitochondrial DNA disease was announced to the media by US scientists, who carried out the procedure in Mexico. The findings were presented at the American Society for Reproductive Medicine Annual Scientific Congress on 19 October 2016.

While this appears to be a promising development in demonstrating a successful outcome for mitochondrial donation to prevent mitochondrial disease, AMDF has concerns about the lack of regulation, independent monitoring or timely peer-reviewed published information involved in this occasion.

The potential for mitochondrial donation to occur in an environment without appropriate oversight or regulation was also raised recently when the AMDF was contacted by a clinic overseas that was planning to start providing mitochondrial donation in Cambodia this past February.



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Members of the AMDF's Scientific and Medical Advisory Panel have expressed significant concern about this development and have consulted with colleagues internationally.

The AMDF Board was also deeply concerned by this development as it became clear that one of the Cambodian body's motivations in contacting us was to try and generate referrals from Australia to its service. This raises an issue that should worry us all – the prospect of 'IVF tourism'.

AMDF supports the regulations governing mitochondrial donation in the UK where there are proscribed clinical procedures which must be carried out in properly licensed institutions, and there are clear guidelines regarding follow-up, adequate disclosure, and advice regarding family relationships and the like. AMDF does not wish to see Australians undergo this procedure without the support and protection of a similar regulatory environment. It would be concerned should families go overseas for mitochondrial donation in unlicensed clinics and bring infants back without the Australian health system being adequately aware.

### Current legislative environment in Australia

The key federal laws in Australian governing research and clinical practice in relation to embryology are the *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002*. These acts do not allow the use of mitochondrial donation techniques in the clinic and research is significantly restricted.

Whilst there are various sections of the law that are relevant to mitochondrial donation, the critical clauses currently prohibit the implantation of a human embryo that contains genetic material from more than two people regardless of whether that material is simply transferred (as in mitochondrial donation) or genetically modified. Further, the legislation does not differentiate between nuclear DNA and mitochondrial DNA. This is important as mitochondrial DNA does not influence our personal characteristics; its sole purpose is to ensure proper functioning of our mitochondria.

### Safety considerations

While no IVF techniques can claim to be 100 per cent safe and effective, the risks and benefits of traditional IVF are well known. Mitochondrial donation has been shown to be safe and effective in numerous animal studies, including monkeys. In addition, experiments in very early human embryos suggest that present techniques allow normal embryo development. The Director of the Wellcome Trust, Dr Jeremy Farrar, stated in 2015 'I don't think there's been any more rigorous look at any scientific endeavour coming into humans'.

The scientific evidence to date thus provides a high level of confidence in mitochondrial donation's ability to enable women to safely have genetically related babies free from mitochondrial disease.

Australia has a long history of expertise and capability in the areas of embryology and IVF, both of which are relevant to mitochondrial donation.



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The AMDF supports the legalisation of mitochondrial donation limited to those institutions and clinics where there is demonstrable expertise, and limited to those people at risk of passing on mitochondrial disease to their children.

### Ethical considerations

The AMDF is aware of the ethical considerations that mitochondrial donation raises and which have been extensively considered in policy and ethical reports globally, including by internationally respected organisations like the Nuffield Council on Bioethics. In Australia the AMDF has been working with Associate Professor Ainsley Newson, Co-Chair of the Human Genetics Society of Australasia's Education, Ethics and Social Issues Committee and Deputy Director at Sydney Health Ethics, Sydney School of Public Health, to engage the Australian community and to understand its views.

Further, AMDF was involved with A/Prof Newson in 2017 in running a Citizens' Jury on the issue of mitochondrial donation. This Citizens' Jury was sponsored by the AMDF and A/Prof Newson will undoubtedly comment in some detail on this in her own submission to this Inquiry.

Over the last two years, members of the mitochondrial disease community and the AMDF have met with many Federal and State MPs, Senators and other relevant stakeholders. The level of support expressed for the introduction of mitochondrial donation has been considerable.

Given this experience and the results of the Citizens' Jury undertaken by Sydney Health Ethics, the AMDF anticipates that this support is mirrored in the broader Australian community.

Lastly, the ethical consequences of not introducing a well-regulated process for mitochondrial donation in Australia should be considered, particularly in relation to the potential risks of Australian families becoming involved in 'IVF tourism'. If they can't get their mitochondrial donation here, the temptation to go overseas to have it in unlicensed clinics will be considerable.

### Impact on the health system

The Impact Assessment of *The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations* indicated that mitochondrial donation 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 a year prevented from mitochondrial DNA disease.<sup>5</sup>

The benefits expected to 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 not modelled by the Impact Assessment.

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<sup>5</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.



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The AMDF believes that in Australia, the costs borne by the health system and families as a result of children having mitochondrial disease are significant, and are both direct and indirect in nature. Whilst we do not have direct data for the cost of mitochondrial disease in Australia, it is worth noting that the figures estimated for lifetime healthcare costs for a child with an inherited rare disease are estimated at around A\$2.5 million in the United Kingdom and about A\$5 million in the USA.

Further, it is likely that the costs associated with mitochondrial donation techniques are only marginally more than for traditional IVF techniques, making the economic impact of mitochondrial donation clear.

When speaking with members of the mitochondrial disease community, AMDF has heard numerous stories that prior to the National Disability Insurance Scheme (NDIS), mito patients and families were paying thousands of dollars out of pocket for therapies, speciality equipment and supplements. Now that the NDIS has rolled out in the majority of cities, the health system will be expected to cover these costs. It has been estimated that costs to tax payers could range up to \$120,000 per month for one individual child with mitochondrial disease.

### Introducing mitochondrial donation in Australia

AMDF supports mitochondrial donation being available under strictly controlled, tightly regulated conditions to women at risk for having children with forms of mtDNA disease that could lead to a child's early death or substantial impairment.

As highlighted above, the rigour and depth of the reviews and process undertaken in the UK means that mitochondrial donation could readily be introduced into the Australian context. Whilst some of the regulations adopted in the UK may need to be adapted to align with Australia's specific expectations or current laws regarding IVF, they provide a strong basis from which to work in designing an Australian specific framework.

Certainly the AMDF supports the concept of having an appropriate body license facilities to undertake mitochondrial donation and that case-by-case evaluation be undertaken to determine eligibility for individuals.

Ensuring that there is appropriate monitoring and licensing of clinics, follow up of individuals and selection of mitochondrial donors is something that needs to form part of a regulatory framework. Safety concerns to increase the likelihood of successful pregnancies and support the birth of healthy children need to be addressed.

### Offering Australian parents' choice and saving lives

AMDF values people affected by mitochondrial disease. While its ultimate vision is to cure mitochondrial disease, its mission is also to support sufferers and their families, fund research, and educate the general public and medical personnel. In advocating for techniques to prevent children



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being born with the disease, AMDF supports the rights of prospective parents to choose to have biological children who will not suffer the debilitating, disabling and potentially fatal consequences of severe forms of mito.

AMDF believes the choice to have mitochondrial donation should ultimately be made by the affected woman or couple. They should be supported to make informed reproductive choices based on a clear understanding of the relevant issues.

AMDF is committed to expanding the reproductive options available to Australians affected by mitochondrial disease as has been done in the United Kingdom. The AMDF also recognises that, whilst being genetically related to your children is not a pre-requisite for parenthood, it is highly regarded and valued by many people.<sup>6</sup>

### Acknowledgement

The AMDF appreciates the Committee's interest in mitochondrial donation and their work in undertaking this Inquiry. On behalf of the community with whom we work, we ask the Committee to acknowledge the significant developments and advances in mitochondrial donation techniques, and to recommend that legislation be changed to allow women the choice to access mitochondrial donation in Australian clinics and to have healthy babies free of the risk of inherited mitochondrial disease.

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<sup>6</sup> There are numerous academic articles and papers exploring this issue. Should the Committee require further information, the AMDF is happy to provide a selection.