



OVERVIEW OF MITOCHONDRIAL DONATION SENATE INQUIRY

AUGUST 2018

On 27 June 2018, the Senate Community Affairs References Committee tabled their Report on *Science of mitochondrial donation and related matters*, identifying a pathway forward towards legislation to allow mitochondrial donation.

Mitochondrial donation is a ground-breaking IVF technique that replaces energy-generating DNA in the mother's egg with donor material. This would allow Australian women at risk of having babies suffering with severe mitochondrial disease will be able to have healthy children.

The Mito Foundation continues to engage with those involved in the Inquiry and other political offices to ensure that momentum is not lost and the recommendations made by the Committee are pursued. Key to these is the involvement of the National Health and Medical Research Council (NHMRC) which the Report recommends be consulted by the Minister as to a public consultation about the introduction of mitochondrial donation into Australia as well as about some scientific issues.

As per standard practice, the Government has yet to respond to the Senate Committee Report. It has been however determined that advice has already been sought from the NHMRC on how to approach the scientific and research issues raised by the Committee. Advice is also being sought from the Department of Health regarding the public consultation recommended.

The Mito Foundation is keen to work with the Government to ensure that the recommendations can be progressed as quickly as possible and that the Senate Report reflects that Senators did not think that the scientific 'review' from the NHMRC need not be extensive.

Listed below are the Committee's recommendations and the Mito Foundation's observations about the Report.

LIST OF COMMITTEES RECOMMENDATIONS

Recommendation 1

5.99 The committee notes the strong potential of mitochondrial donation to address the debilitating effects of inheriting mitochondrial disease. The committee recommends that public consultation be undertaken regarding the introduction of mitochondrial donation to Australian clinical practice. To facilitate this consultation, the committee further recommends the Australian Government prepare a consultation paper, including options for legislative change that would be required. The Minister for Health should seek advice from the National Health and Medical Research Council on the most appropriate timing and format for this consultation.

Recommendation 2

5.100 The committee recommends that the Australian Government task the National Health and Medical Research Council with advising on the following questions:

- Whether mitochondrial donation is distinct from germline genetic modification.
- Is there any new information to indicate that research findings from the United Kingdom, that the science of mitochondrial donation is safe for introduction into controlled clinical practice, cannot be applied in an Australian context?
- Whether other approaches to inheriting mitochondrial disease should also be the focus of Australian research.

5.101 The committee recommends the findings be used to inform future legislative process.

Recommendation 3

5.103 The committee recommends the Minister for Health take the findings of this report to the Council of Australian Governments (COAG) Health Council to progress the implementation of this report's recommendations with the states and territories

Recommendation 4

5.104 The committee recommends, noting the need for community consultation and scientific review, the urgency of treatment for current patients and the small number of patients seeking this treatment, that the Australian Government initiate dialogue with the relevant authorities in the United Kingdom to facilitate access for Australian patients to the United Kingdom treatment facility as an interim measure

MITO FOUNDATION OBSERVATIONS ABOUT THE RECOMMENDATIONS

Whilst the Report did not recommend that the Government progress immediately to legislate to allow mitochondrial donation, it has certainly outlined a way forward that is quite significant. The review requested from the NHMRC in recommendation two is limited in scope and the report notes that it should be 'not lengthy or extensive', i.e., it could be done quickly. The public consultation may take some time but, it is an identified step in the process and does reflect activity undertaken in the UK in the same circumstances.

Recommendation Three actually seeks to involve the states and territories in this issue which will be necessary due to the fact that they also have legislation that relates to IVF and other issues that relate mitochondrial donation. By seeking to put mitochondrial donation on the COAG agenda, the Senate is recognising their role and again identifying a way of involving relevant stakeholders. Unfortunately, COAG can be a slow process but it is equally more effective sometimes than engaging the states one by one.

Recommendation Four is an acknowledgement of the burden that mitochondrial donation has on patients and its inclusion is a tribute to the impact that the patient stories, and the evidence given by those patients who were witnesses at the hearing, had on the Senators.

KEY OBSERVATIONS ABOUT THE REPORT

- The threshold question from the Report would appear to be about safety. The Senators acknowledge the evidence provided and largely accept that mitochondrial donation is safe but do not consider themselves the right people to make that decision from a scientific perspective. Hence the recommendation that the NHMRC convene a body of independent experts to give advice about this.
- The Report states that the Senators believe Australia has the clinical capacity to do this, or ramp up to this which is recognition of the quality of the scientists and clinicians we have.
- The Report states that the scientific techniques used for mitochondrial donation do not raise new ethical questions.
- Children born of this technique will be considered to have two parents only.
- Mitochondrial donation should be considered analogous to organ donation and the genetic material conferred during organ donation has not been shown to be unsafe.
- Those individuals or groups who submitted to the Inquiry opposing mitochondrial donation, such as the Catholic Church, are identified in the Report as opposing all forms of 'interference' with embryos; their opposition is not specifically about mitochondrial donation.

- The UK regulatory regime is appropriate for adaptation to Australia.
- A limited clinical trial could be considered as part of the introduction of mitochondrial donation.
- Countries where mitochondrial donation is not subject to an appropriate regulatory system clearly were of concern to the Senators.
- It is likely that, at the time when legislation is brought forward on mitochondrial donation, the Senate Community Affairs Legislation Committee will undertake an inquiry.
- Parliamentary inquiries do not represent sufficient public consultation on an issue like this and therefore a broader consultation is needed.
- The NHMRC review into the germline question, which is fundamental and threshold to this issue, should not be extensive or lengthy.
- NHMRC should oversight the regulatory system with input from the RTAC of the Fertility Society.

HOW YOU CAN HELP

The Mito Foundation encourages patients and their families who have previously been in contact with their MPs and Senators to reach out again to highlight the fact that the Senate Inquiry has been held and reported, offering a pathway forward to legislation of mitochondrial donation. Further, it would be beneficial to suggest that they might let the Health Minister know that they would support the Government acting on the Report's recommendations so that mitochondrial donation can be available for Australians.

It is not too late to get involved, the Mito Foundation encourages people who are affected by mito to speak to their local MP about mitochondrial donation. [Find out more](#) or contact Rebecca Davis at rebecca.davis@mito.org.au or on 02 8033 4113.

Contact the Mito Foundation for more information