



Australian Government

**Australian Government response to the Senate
Community Affairs References Committee Inquiry into:
The Science of Mitochondrial Donation and Related
Matters**

January 2019

Introduction

The Australian Government welcomes the Senate Community Affairs References Committee report on the *Science of Mitochondrial Donation and Related Matters* (the Report) and thanks the committee for its attention to this important matter.

The Inquiry has raised public awareness of mitochondrial disease and the science of mitochondrial donation and provided valuable information to support further work.

The Senate Committee made four 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.

The Response

The Government acknowledges the work of the committee and thanks all of the witnesses who presented at the public hearing or that made submissions to the Inquiry. In particular, the Government recognises the testimonies from those who have suffered with, or lost a loved one to, mitochondrial disease. Their willingness to share their experiences and the impact that mitochondrial disease has had on their lives, is greatly appreciated.

The Australian Government has an established record of supporting cutting edge research and funding the safest, most clinically and cost effective medical services for the Australian population.

The technology of mitochondrial donation will be of significant interest to the Australian community, for a number of reasons including:

- the technology involves changing the genetic make-up of the embryo,
- may be seen as the first step toward human cloning, and
- the safety and efficacy of this technology is unclear and evidence from clinical practice is unavailable.

For these reasons, it is essential that the process for consultation, design and implementation of any legislative change proceeds with diligence.

In recent years, the Government has acted to establish two major initiatives to embed genomic medicine in the Australian health system.

In November 2017, the COAG Health Council agreed the National Health Genomics Policy Framework (Genomics Framework) to:

- give coherence to, and guide Government activity across, public genomic policy;
- drive improved performance of mainstream genomic services in delivering better health outcomes;
- give visibility to the ethical, legal and social issues associated with genomics; and
- provide national leadership for embedding genomics in the Australian health system.

The 2018-19 Budget committed \$500 million to the Genomics Health Futures Mission (Genomics Mission) which focuses on flagship clinical trials and research collaboration to help save or transform the lives of more than 200,000 Australians. The first research project announced under the Genomics Mission is Mackenzie's Mission, providing \$20 million for a reproductive screening trial for rare and debilitating genetic birth disorders including Spinal Muscular Atrophy and Fragile X. Pre-implantation genetic diagnosis and in vitro fertilisation will be made available to couples participating in Mackenzie's Mission who are at high risk of having a child with one of the included conditions.

These initiatives demonstrate the Australian Government's commitment to research in emerging technologies that may help avoid serious genetic disorders and begin to realise the promise of genomic technologies to help Australians live longer and more healthy lives.

The Senate Committee's report shows that mitochondrial donation may provide a valuable additional option for families seeking to have children without passing on mitochondrial disease. While this is a technically complex procedure, the inquiry heard evidence that there are facilities in Australia that are capable of carrying out the procedure. This technical ability reflects well on Australia's highly skilled and competitive research and clinical industries.

The recommendations of the Senate Committee fall into two broad areas – providing for informed consultation and decision making for the public and governments; and seeking access to international services as a short term solution. This response addresses the recommendations in those terms.

Informed consultation and decision making

The Australian Government supports the recommendations for consultation activities – both with the Australian people and with state and territory governments – and gaining expert advice about the procedure. This is a long and complex task, but an important one. Whilst effective implementation of the consultation process indicated in this response may take up to 18 months, the Australian Government is committed to commencing these activities immediately; a timeline is outlined below.

Expert advice

The Government supports the Senate Committee recommendation to seek expert advice on key questions. The Government notes the Report recommends that an assessment of the UK scientific findings should be made by a panel of Australian experts with relevant scientific and consumer knowledge, to be appropriately constituted and overseen by NHMRC. NHMRC is well equipped to undertake this task and provide advice in line with [recommendation 2](#).

The Government understands that currently experts in Australia and elsewhere agree that the clinical use of mitochondrial donation, where permitted, should proceed cautiously with appropriate oversight and follow-up, and that research in Australia and overseas should continue to confirm which techniques are the most clinically efficacious.

The advice sought may include broader information than that set out by the Senate Committee and it may also inform the consultation process, and any consideration of any possible legislative change, including necessary regulation.

Social and ethical consideration

The Australian Government acknowledges the view of the Senate Committee that, based on submissions and evidence provided during the inquiry, Australians may not find mitochondrial donation controversial. However, it is essential to provide the Australian people, peak bodies and other stakeholder groups, and governments with information about the procedure and the opportunity to respond. This would be the opportunity for consumer advocacy groups, such as the Mito Foundation, to provide input to the discussion. Undertaking a consultation for this purpose will require planning and a detailed understanding of the complex social, legal and ethical issues raised by this procedure.

At this time, mitochondrial donation is a largely experimental procedure. Mitochondrial donation involves a complex manipulation of human genetic material to create an embryo with the nuclear DNA of the couple seeking to have a child and the mitochondrial DNA of a donor.

The Australian Government appreciates the complexity of the discussions about the social and ethical implications of making such a change to the genomic makeup of an embryo, even for the purpose of avoiding a potentially fatal disease. These issues remain, however small the amount of genetic material that is changed, especially where the change can be carried to following generations.

The ethical and social questions raised in relation to this procedure are not entirely unique. NHMRC undertakes functions to provide advice about the ethics of human research through the Australian Health Ethics Committee and to regulate activities relating to certain uses of human embryos through the Embryo Research Licensing Committee. Additionally, the Australian Government is already working through ethical and social questions relating specifically to genetic activity through the Genomics Framework and Genomics Mission to create appropriate ethical and regulatory systems. Information from those initiatives may also inform any consultation process and outcomes.

Legal consideration

The Australian Government notes that the recommendations propose exploring options for the legislative changes that would be required before mitochondrial donation could be introduced into Australian clinical practice.

Mitochondrial donation is not currently legal in Australia and this procedure cannot be provided under any circumstances. While this is the case, techniques for the procedure are not currently treated equally under Australian law and regulation. For example, under the *Prohibition of Human Cloning for Reproduction Act 2002 and the Research Involving Human Embryos Act 2002*, research using one method of mitochondrial DNA transfer (pronuclear transfer) is permissible under a licence issued by the Embryo Research Licensing Committee of NHMRC, whilst another method (maternal spindle transfer) is not. However, completion of this procedure through the implantation of a resulting embryo is not permissible under any method.

The regulatory issues raised by mitochondrial donation are complex. Legislation at Commonwealth, state and territory levels would require amendment as would various ethical guidelines and the accreditation arrangements for assisted reproduction technology clinics administered by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia.

After the outcomes of the consultation phase are known, comprehensive and careful examination of all relevant legal and ethical frameworks would be required to manage any proposals for change and avoid unintended consequences. This includes arrangements at the state and territory level, impacts on other legislation like the *Gene Technology Act 2000*, as well as other review activities such as the *Third Review of the Gene Technology Scheme*.

Public and Jurisdictional consultation

The Australian Government notes that it will be equally important to engage with the public and with state and territory governments on this matter.

The Australian Government supports engaging with the public. This will offer an opportunity to gauge views about the nature and direction, and the use, of genomic technologies, including any social and ethical concerns, as well as building understanding, literacy and acceptance.

There are complex policy and implementation issues relating to legal, regulatory, ethical and social issues that would need to be considered in developing a consultation paper and undertaking a comprehensive and multistage public consultation process.

The Government has sought advice to inform the timing and format for this consultation from NHMRC and Department of Health (including the Office of the Gene Technology Regulator and Therapeutic Goods Administration).

Engagement with state and territory governments will be an important step and progressed through the COAG Health Council in early 2019. The Government notes that a multi-stage process may be required, including an initial discussion with jurisdictional governments on the Australian Government's approach to public consultation.

Following the public consultation process, further consideration by COAG Health Council may be required, particularly in relation to any proposed state and territory legislative or regulatory changes.

[Access to international services](#)

The Australian Government will reconsider the proposal based on consultation outcomes and relevant expert advice.

The Government understands that at present, only one child has been born through mitochondrial donation internationally. The Government is not aware, at this time, of any child being born as a result of mitochondrial donation in UK clinical practice, which has strict regulations applying to this procedure. This technology is at an extremely early stage of transitioning to a clinical setting, and the long-term outcomes are not yet known.

If following consultation this procedure is supported, then introduction may be considered, subject to discussions between governments about appropriate regulatory and funding mechanisms.

Implementation Activities

The Australian Government is committed to progressing the informed decision making and consultation activities associated with this response immediately. It has tasked NHMRC to establish a panel of scientists and other experts, including the Mito Foundation, to provide advice on the legal, regulatory, scientific and ethical issues identified by the Senate Inquiry. This initial work will develop the key questions to underpin community-wide consultation and increase community literacy on issues raised by mitochondrial donation. This initial work will be delivered by April 2019.

The process for conducting the public consultation will be made available by the end of April 2019. It will build on advice from the expert panel and in consultation with NHMRC, the Department of Health (including the Office of the Gene Technology Regulator and Therapeutic Goods Administration), and state and territory governments.

No decisions on regulatory or legislative change will be considered until all input from the public consultation and expert advisory groups has been considered.