Australian Academy of Health and Medical Sciences

Australian Academy of Science

Submission to the Department of Health consultation on Mitochondrial Donation in Australia

The Australian Academy of Science and the Australian Academy of Health and Medical Sciences (jointly, 'the Academies') welcome the opportunity to respond to the Department of Health consultation on Mitochondrial Donation in Australia, comprising the Department's proposed strategy for introducing mitochondrial donation in Australia. We note that the proposed strategy is closely aligned with the recommendations of the Academies' joint submission to the National Health and Medical Research Council (NHMRC) consultation on the 'Mitochondrial Donation Issues Paper: Ethical and Social Issues for Community'.

Support for the proposed strategy

The Academies support the proposed strategy. The strategy represents a cautious, measured approach for introducing mitochondrial donation that balances risks and community concern with support for clinical research. This approach will allow mitochondrial donation to be introduced in a manner that gives full scope to evaluate relevant issues such as informed consent, at-risk population screening, service delivery, cost, safety, community concerns, genetic and epigenetic consequences, and impacts on individuals and families.

UK policy as a guide and model, but not without learning its lessons

As noted in the Academies' submission to the NHRMC consultation and acknowledged in the Public Consultation Paper, the approach taken by the United Kingdom's Human Fertilisation and Embryology Authority (HFEA) provides a useful guide and model for Australian practice. It should be noted that at present, the only licences available from HFEA in the UK are for clinical trials, the equivalent of Stage 1 of the proposed Australian strategy. As far as we currently understand, only one such licence has been issued in the UK and availability is very tightly regulated.

While the UK example is useful, the Australian situation differs in terms of geography, and prevalence and incidence of mitochondrial disease. The UK system should be assessed for its relevance to Australia, and for any efficiencies to be gained in the Australian setting. It is in the interests of patients for the process to be as rapid and timely as possible.

The timeframe for Stage 1 implementation, involving as it does the establishment of a legislative and regulatory framework, state legislation support, funding mechanisms, a clinical pathway, and at least one assisted reproductive technology (ART) laboratory, as well as licences to be issued, is projected to extend at least ten years. Stage 2 will not proceed until evaluation of Stage 1. While we understand the Australian government is working with UK authorities to facilitate access to mitochondrial donation in the UK, this is not a feasible option for many people due to COVID-19 impacts and other factors, and it would therefore be desirable to expedite the legislative and regulatory processes in Australia as much as possible.

Features of the proposed model

The proposed model posits a single clinic at Stage 1 of the introduction of mitochondrial donation to Australia. This clinic will be selected and licensed by a special committee of the NHMRC to deliver mitochondrial donation to impacted couples. As noted, this may be appropriate given the expected low case numbers and the high level of technical expertise required, but care must be taken to

ensure equity of access for all Australians seeking this treatment. In establishing the licensed clinic, care should also be taken to ensure that the clinic is well integrated with existing facilities, networks and expertise.

To achieve this it may be more practical to position the mitochondrial donation facility as a single service rather than a single clinic, since the model will require a public/private partnership between, for example, a medical research institute, a hospital, a pathology provider and an assisted reproductive technology network. The "single service" model allows the concentration of the necessary skills and expertise in an inclusive manner, and will allow, for example, ovarian hyperstimulation and egg harvesting to be performed by licensed practitioners at different sites, with eggs frozen for transport to a central facility. Alternatively, people could receive treatment at these sites, with mitochondrial donation experts flown in as needed.

We would also like to reiterate a point from previous submissions that the NHMRC Embryo Research Licensing Committee (ERLC) has directly relevant expertise and experience. This expertise should be integrated into the decision-making process to provide consistency and continuity with existing practices and a smooth transition to the new arrangements. However, it is important that all relevant expertise is included, and there will be a need for additional specialist representation in Australia.

Prospective parents at risk of having a child with a mitochondrial disorder should continue to be involved at all stages of discussions and decisions about reproductive options. If parents are considering using this technology, they should be informed of its experimental nature, the possible risks and limitations, and areas in which safety and efficacy are still being investigated, as part of more general counselling on reproduction. Consent from potential parents will require discussion of the need for long-term follow up for themselves and any children.

We expect that institutional ethics arrangements will mirror those under the NHMRC ERLC, where a licence will not be issued unless ERLC is satisfied that the proposed activity or project has been assessed and approved by an institutional human research ethics committee. The ethics approval structures should be explicitly described in each proposal. Finally, as noted in our submission to the NHMRC consultation, it is critical to understand the long-term outcomes resulting from mitochondrial donation. Families with children born following mitochondrial donation should be strongly encouraged to have health and developmental surveillance well into adult life, as well as access to reproductive counselling.

If you have any questions about this submission, or to arrange a consultation with Fellows of the Academies, please contact Stuart Barrow (02 6251 9464; stuart.barrow@science.org.au) or Amanda Rush (amanda.rush@aahms.org).