



Senate Inquiry: Mitochondrial Donation

Submission by the Fertility Society of Australia

The Fertility Society of Australia (FSA) is the peak body for those professionals involved in Reproductive Medicine in Australia. Members include; Gynaecologists, Scientists, Nurses and Counsellors. There are currently over 1200 members of our Society. Our fundamental goal is the provision of the best outcomes for parents within fertility and associated illnesses that may be improved by Assisted Reproductive Technologies (ART). Increasingly the ART technologies, in combination with pre-implantation genetic diagnosis (PGD), has enabled many couples to have children born unaffected by disabling or fatal diseases caused by chromosomal mutations. The Fertility Society of Australia supports advances in technology that relieve the burden of illness amongst all Australians.

Mitochondrial disease, while relatively rare has a fatal outcome in childhood for virtually 100% of those affected. Australia has been on the leading edge of developments in ART for the last 4 decades, and the possibility of Mitochondrial transfer to avoid Mitochondrial disease should be part of the services that we offer in the fertility world. There are a number of internationally recognised scientists in Australia in the field of Mitochondrial research. In Australia we are fortunate in having embryologists who have the skills and expertise to undertake the necessary techniques to allow Mitochondrial transfer. The vast majority are members of our society. Through the Reproductive Technology Accreditation Committee (RTAC) laboratory standards are at a world leading level. The introduction of new technology would be closely supervised by RTAC to ensure its appropriate use. With that background, the board of the Fertility Society of Australia are totally supportive of this technology being introduced into Australia.

(a) the science of mitochondrial donation and its ability to prevent transmission of mitochondrial disease;

The Fertility Society of Australia through its scientists and clinicians are aware of the world literature in relation to Mitochondrial transfer which has now reached a point of application for parents likely to produce children with Mitochondrial disease. 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 United Kingdom has had substantial debate on this issue and have allowed it to proceed under restricted conditions. Australian Units with expertise have been accredited under the RTAC umbrella. A methodology for specific accreditation will be possible, perhaps linked in with the NHMRC Committee on embryo research.

(b) the safety and efficacy of these techniques, as well as ethical considerations;

Based on the scientific advice of our membership, we believe that the balance of safety versus risk has been addressed. There is no question that new technology does occasionally bring negative results, but given the fatal nature of Mitochondrial disease we believe that miniscule risk is worth taking. The importance of detailed counselling and appropriate consenting processes must be observed. The FSA through RTAC has demonstrated rigorous counselling and consenting processes for standard IVF treatment as well as the more complex issues around PGD.

Given that Assisted Reproductive Technology is accepted as ethically appropriate by the vast majority of Australians, the FSA would have a view that adding a further technology to that process with all the safeguards of counselling and consent is totally acceptable. Indeed as an industry, we believe that using this technology to avoid disabling or fatal illness is an ethical obligation.

Mitochondrial donation does not result in or enable designer babies; it merely allows Australian families the choice to have children free from debilitating mitochondrial disease.

(c) the status of these techniques elsewhere in the world and their relevance to Australian families;

Australian families with offspring with Mitochondrial disease are no different from the rest of the world. The distress and pain to the families and friends of disabled child are no different to others internationally. To be able to avoid that issue when we have the technology to do so should be our goal. The techniques that have been developed particularly in the United Kingdom are readily transferable to Australian laboratories. Indeed we have scientists in Australia doing this work on animal models. There are scientists working in human ART laboratories to undertake this work.

(d) the current impact of mitochondrial disease on Australian families and the healthcare sector;

(e) consideration of changes to legal and ethical frameworks that would be required if mitochondrial donation was to be introduced in Australia;

The framework put in place by the UK is also rigorous: clinics must apply for a license and will only be granted one if staff at the clinic are properly trained in using mitochondrial donation techniques. This is an appropriate approach.

Mitochondrial donation will not be something that is available at all ART clinics, as it is a highly specialised technique and one which is only relevant to certain women.

Over the last 4 decades in Australia, innovations in ART technology have been regularly embraced by the ART clinics; at times Australian ART clinics have lead the world. Those innovations have pushed the boundaries of ethics and science. The current controls for these advances have occurred without any major issues. The overarching ethical guidelines have been provided by the NHMRC Ethics Committee. The FSA would see that Mitochondrial transfer would be governed by that ethical framework. RTAC is the accrediting body for ART in Australia, and would therefore take on clinic accreditation of this technique. If further legislative oversight was deemed necessary, the NHMRC embryo research licensing committee could require ART clinics to seek accreditation. These levels of controls would see that Mitochondrial transfer was conducted in the most stringent manner to ensure optimal outcomes for the families at risk and society in general.

(f) the value and impact of introducing mitochondrial donation in Australia

The value of introduction of Mitochondrial transfer in Australia will be to relieve the emotional, physical and financial burdens of this disease both to the family and society. The financial burden in hospitalisation is high. Avoiding this cost would be offset by the costs of the technology. For the 60 patients per year that may go through ART cycles, the costs of that technology will be small compared to the medical cost of an affected child. A health economic assessment should be undertaken. To permit Mitochondrial transfer will continue to demonstrate to the world that Australia is a leading nation in the science and medicine of Assisted Reproductive Technology and all that it offers. The investigations undertaken in the UK prior to their introduction of mitochondrial donation were rigorous, extensive and are transferable to the Australian context.

(g) other related matters.

While the UK services offering Mitochondrial Transfer are of high quality and well controlled, clinics in unregulated environments are offering this treatment. There is the high possibility of desperate Australian families travelling overseas to these clinics which may carry significant risks to them and their offspring. This would be avoided if we offer the option in Australia.

