AUSTRALIAN CATHOLIC BISHOPS CONFERENCE
Bishops Commission for Life, Family and Public Engagement

15 March 2021

Ms Paula Pearsall
Director
Mitochondrial Donation Taskforce
mito@health.gov.au

Dear Ms Pearsall

Legalising mitochondrial donation in Australia – public consultation paper

This submission from the Australian Catholic Bishops Conference (**the Conference**) on *Legalising mitochondrial donation in Australia* is prepared by the Bishops Commission for Life, Family and Public Engagement (**BCLFPE**).

The Conference is a permanent institution of the Catholic Church in Australia and the vehicle used by the Australian Catholic Bishops to address issues of national significance.

The BCLFPE is one of several commissions established by the Conference to address important issues both within the Church and in the broader Australian community. The BCLFPE has responsibility for public engagement and life issues.

More than 60 per cent of Australians profess a faith, and more than one in five Australians are Catholic.

The Catholic Church provides Australia's largest non-government grouping of hospitals, aged and community care services, providing approximately 10 per cent of health care services in Australia. It provides social services and support to more than 450,000 people across Australia each year. There are more than 1,750 Catholic schools with more than 94,000 staff providing education to more than 765,000 Australian students. There are two Catholic universities, teaching more than 46,000 students.

The Conference seeks to participate in public debate by making reasoned arguments that can be respectfully considered by all people of goodwill.

Summary

The Conference has grave concerns about the techniques described as mitochondrial donation because:

- The methods used to create and discard new human life do not respect the right to life and the human dignity of the individuals concerned;

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F (02) 6247 6083
T (02) 6201 9862
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- The methods would create a child with three parents, confusing the biological parentage of any children born;
- One of the techniques - pronuclear transfer – is a form of human reproductive cloning, which is unethical;
- There are significant risks and inconvenience to the women who will be asked to provide eggs to enable these procedures;
- There are significant risks to the community because these techniques can change the human germline, which means altered genes might be passed on to future generations. This is potentially dangerous and considered unethical; and,
- There are alternative ways of forming a family while avoiding transmitting mitochondrial disease, including adoption and IVF with egg donation.[1]

Introduction

Mitochondrial donation encompasses several techniques designed to ensure that children whose mothers have abnormal mitochondria can be born free of that condition. Mitochondrial abnormalities can lead to a wide range of medical conditions of varying severity including Leigh syndrome, diabetes, deafness and epilepsy. Our hearts go out to families dealing with these conditions and who have the understandable desire that their children should not also be born with these burdens. It is a natural human longing to spare children of illness and suffering. The hope offered by mitochondrial donation however comes with its own dangers to the human germline, to the natural family by creating three parent human embryos, and to human dignity. Adoption or fostering would offer a simpler and ethically uncompromised path to parenthood. Mitochondrial donation is not in the best interests of parents and children, let alone the broader community.

The Conference opposes mitochondrial donation but given the Government has determined that mitochondrial donation should be legalised, we offer the following thoughts on the consultation paper and how best to minimise the dangers and concerns around this controversial procedure.

Human dignity

The Conference makes these comments with the vital nature of human dignity in mind. Human beings have inherent dignity and their rights as people must be respected including their right to life from the moment that the first cell of the human zygote is formed by whatever means it comes to be.[2]

Human dignity is the dignity unique to human beings and the basis of all human rights. This human dignity is possessed by each and every human being, irrespective of their age, sex, race,

[1] The Conference is not supportive of assisted reproductive technology but acknowledges that IVF with egg donation is prevalent and provides a legal, if not ethical, option.
[2] Instruction Dignitas Personae on Certain Bioethical Questions, 20 June 2008, #4, 6.

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abilities, or any other quality or attribute. Since human life is continuous from conception to natural death, the inherent dignity and right to life of every person must be respected.

What is mitochondrial donation?

Before considering the Consultation Paper, it is important to understand what mitochondrial donation involves. Mitochondrial donation is a method to ensure that mothers who have abnormal mitochondria can give birth to a child who does not have abnormal mitochondria. Mitochondrial DNA (**mtDNA**) is inherited from the maternal line as it originates from ova.[3] mtDNA is an important influence on characteristics such as ageing, memory and combatting disease.[4]

The Consultation Paper explains that the immediate confirmed methods for mitochondrial donation will be pronuclear transfer and maternal spindle transfer (page 10).

Pronuclear transfer (PNT) is where two human embryos are created, one with abnormal mitochondria and the other human embryo created with a donor ovum. Each embryo is enucleated, meaning the nuclear DNA (**nDNA**) is removed. The nDNA is moved from the embryo with abnormal mitochondria and transferred to the healthy embryo.[5] Two human embryos are destroyed in this process to create a third.[6]

The new human embryo would have three genetic parents, nDNA from the father, nDNA from the intending mother with abnormal mitochondria and mtDNA from the egg donor mother who provides the egg.[7]

The Conference objects to the disposing of any human embryos because such actions would instrumentalise human embryos, treating them as part of a production process where they can be kept or disposed of subject to arbitrary judgements.[8] This of course does not show respect for the embryos' inherent human dignity.

[3] Haimes, E and Taylor, K, Sharpening the cutting edge: additional considerations for the UK debates on embryonic interventions for mitochondrial diseases. *Life Sciences, Society and Policy* (2017), 13: 1, page 3.
[4] Cussins, J and Lowthorp, L, Germline modification and policymaking; the relationship between mitochondrial replacement and gene editing. *The New Bioethics*, Vol 24(1), 2018, page 82.
[5] Amato, P et al, Three-Parent IVF: Gene Replacement for the Prevention of Inherited Mitochondrial Diseases. *Fertil Steril*, 2014 January; 101(1) page 31-35; Blesa, JR et al, Ethical aspects of nuclear and mitochondrial DNA transfer. *The Linacre Quarterly*, 83(2) 2016, page 183.
[6] Anscombe Bioethics Centre for Healthcare Ethics, submission to the Human Fertilisation and Embryology Authority's consultation on mitochondrial replacement, 2013.
[7] Haimes, E and Taylor, K, 2017, page 2; Anscombe Bioethics Centre for Healthcare Ethics, submission to the Human Fertilisation and Embryology Authority's consultation on mitochondrial replacement, 2013.
[8] Velez, J, An Ethical Comparison between In-Vitro Fertilisation and NaProTechnology. *The Linacre Quarterly*, Vol. 79(1), page 61.

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T (02) 6201 9862
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Baylis explains "… the micromanipulation techniques involved are the same techniques used for nDNA germline modification and human somatic cell nuclear transfer (i.e. cloning)."[9] PNT is a form of human reproductive cloning prohibited in Australia.[10] The Government is proposing to lift that prohibition.

Maternal spindle transfer (MST) is another technique for ensuring that damaged mtDNA is not passed on to children. In this case, nDNA is moved from the intending mother's unfertilised egg to the egg donor mother's egg which has had nDNA removed. The reconstructed egg is then fertilised to create a human embryo.[11] MST also involves three genetic parents and the difficulties that come from that confused parentage for the child.[12]

Public consultation paper

The consultation paper is disappointing because it avoids detailing many of the aspects of mitochondrial donation which provoke controversy and concern, referring obliquely to "a number of ethical issues and safety concerns" (page 8). The lack of detail means many of the ethical problems associated with mitochondrial donation are not explained clearly, so members of the public are not given the opportunity to grapple with the difficult bioethical issues facing Australia.

The discussion paper claims the Government plans a careful two-step implementation process. But stage one moves straight to implementation of mitochondrial donation for producing children. The paper states that "availability of mitochondrial donation under Stage 1, will allow the relatively small number of impacted families who are ready to start a family now, the choice of using mitochondrial donation." (page 5) This appears to mean that any couple desiring the treatment can access it, though from one provider or "licenced clinic" rather than multiple providers. This is not a staged implementation of a controversial procedure. It is instead a staged increase in the number of clinical licences available to conduct mitochondrial donation.

Given the Public Consultation Paper states that the "immediate and long-term risks for the child and longer term implications for subsequent generations are not yet fully understood" (page 3), it is completely inappropriate to put children and future generations at such risk. There is also a question as to whether prospective parents should have the right to take such risks on behalf of future generations. These experiments are not limited to human embryos but are designed to bring children to birth.

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[9] Baylis, F (2017) Human nuclear genome transfer (so-called mitochondrial replacement): clearing the underbrush. *Bioethics*, Vol 31(1), page 11.

[10] Anscombe Bioethics Centre for Healthcare Ethics, submission to the Human Fertilisation and Embryology Authority's consultation on mitochondrial replacement, 2013; Lane, A et al (2016) "Mitochondrial Replacement" technologies and human germline nuclear modification. *J Obstet Gynaecol Can*, Vol 38(8), page 731.

[11] Amato, P et al, 2014, page 31-35.

[12] Anscombe Bioethics Centre, Response to the Nuffield Council Report on Mitochondrial Donation, 24 February 2012.

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F (02) 6247 6083
T (02) 6201 9862
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church.life@catholic.org.au

The paper refers to a "strict licensing and regulatory regime" (page 8). This is standard rhetoric for reassuring the public given the significant acknowledged risks, but if mitochondrial donation is to be used in Australia, it should be regulated by a clear, genuinely strict and transparent process.

Recommendations

- The Government should seek public comment on draft laws for stage one. The results of the consultation should be published. The draft laws should mandate published annual reports which must be tabled in Parliament.
- The paper promises evaluation of stage 1 (pages 5, 7). This evaluation should include a review of the regulatory framework. The evaluation should be independent, seek public comment and be published before the Health Minister makes a final decision on whether stage 2 will proceed.
- Given mitochondrial disease follows the maternal line, the consultation suggests parents could be given the choice to "… only implant male mitochondrial donation embryos." (page 8). This means that female human embryos would be deliberately destroyed because they might carry disease. This is completely devoid of respect for human life and is an explicit discrimination against the female gender. Deliberately targeting female human embryos should be prohibited.
- The paper acknowledges it is important to "… protect the interests of children born through this process" (page 9), but offers only privacy, ongoing monitoring and mandatory reporting of adverse events. Any adverse events should be published, with appropriate amendments to protect privacy but not to obscure the problem revealed.
- It is good that children will be able to seek access to identifying information about the egg donor, but disappointing the paper dismisses egg donors as not "legal parents" (page 9). They may not be legal parents, but they are certainly biological parents and that fact should be acknowledged.

Three parent children

Both PNT and MST involve creating a child with three biological parents – the intended mother, the intended father and the woman who is an egg donor.[13]

David Albert Jones argues that "the failure to acknowledge the third parent, the (enucleated) egg mother, is not accidental. The whole rationale of MST is to replace the genetic identity of the egg mother as far as possible with the identity of the nuclear transfer mother. The concomitant of

[13] David Albert Jones (2015), page 99; Catherine Mills (2020), Nuclear families: mitochondrial replacement techniques and the regulation of parenthood. Science, Technology and Human Values, page 15; Karen Ludlow (2020), Genetic identity concerns in the regulation of novel reproductive technologies. Journal of Law and the Biosciences, page 16; Calum MacKellar (2015), Representative aspects of some synthetic gametes. *The New Bioethics*, Vol.21(2), page 114.

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this is that the identity of the egg mother is all-but erased so as to deny her real biological contribution and her link to the child."[14]

There is empirical evidence that mtDNA contributes to personal characteristics like a resemblance between donor and child.[15]

Catherine Mills points out that "… donors of mitochondria donate not simply the mitochondrial organelles but rather the whole egg, which is then denucleated to allow transfer of the nuclear DNA from the intended mother. Once fertilized, the egg, including cytoplasmic components other than mitochondria, gives rise not only to the embryo but also to the placenta, which ultimately allows implantation and gestation. In essence, the donor egg helps to make possible in a very literal sense the coming into and ongoing existence of the embryo, through its implantation and development in utero."[16]

The whole point of mitochondrial donation is to produce a genetically related child for the commissioning parents, so the existence of a third genetic parent is both essential to the process, but inconvenient and efforts are made to reduce recognition of this essential role.[17]

Further, the use of donor gametes including gametes from more than two parents threatens the above rights of the child to inherit his or her relationship to natural parents.

Recommendations

- The Government should acknowledge the biological reality that egg donors constitute one of the three categories of biological parents to children produced using mitochondrial donation.
- The Consultation Paper states the Government "… will not permit the manipulation or alteration of the nuclear DNA …" (page 8). It should explain the safeguards to achieve that.
- The Government should not permit germline genetic modification of mtDNA.
- The Government should not permit the sex selection and elimination of female human embryos as a practice to limit the spread of mitochondrial disease, which is an option canvased in the Consultation Paper (page 8).
- The Government must report on the number of human embryos used in mitochondrial donation procedures, including the number of human embryos needed to produce a live birth.

[14] David Albert Jones (2015), The other woman: Evaluating the language of 'three parent' embryos. *Clinical Ethics*, Vol.10(4), page 101.
[15] Reuven Brandt (2016), Mitochondrial donation and 'the right to know'. J Med Ethics, Vol.42, page 683.
[16] Catherine Mills (2020), Nuclear families: mitochondrial replacement techniques and the regulation of parenthood. *Science, Technology and Human Values*, https://doi.org/10.1177/0162243920934542, page 10.
[17] David Albert Jones (2015), page 101; Catherine Mills (2020), page 12..

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Risks to the identity of children and parents

The right of children to know their genetic origin has been agreed by jurisdictions across Australia.[18]

At the same time, mitochondrial donation techniques create "… a genuine risk … that future children brought into existence with such synthetic gametes may be deeply confused and distressed as to the manner in which they understand their origins and self-identity."[19]

Calum MacKellar says that "… from the perspective of a human child, a significant contribution to his or her identity has always been that he or she was procreated by other persons giving him or her an origin, a history and a place in society. In other words, a crucial aspect of the self-understanding and identity of a child is given through knowing how and who brought him or her into existence which can happen through a number of means and not just genetics."[20]

As well as a human need to help us to understand our origins, [21] "… the idea that one is entitled to know one's biological parents should be understood primarily as a (moral) right to know the truth about one's conception as a (or, perhaps, the) fundamental aspect of knowledge of one's own identity."[22]

Where biological parenthood is split between more than two people:

> "Psychologists often refer to the issue of genealogical bewilderment as children, perhaps later in life, seek to discover their origins and to identify their own identity in circumstances in which the genetic parents may be completely unknown to them or become known to them at a later stage. The relationship between a child and his or her parents is complex. So much of our sense of identity is based upon that relationship. When it is fragmented, that can be hurtful and confusing."[23]

Issues of identity are not confined to children as being a mother or a father is also an important part of a person's identity.[24] Parents may find it difficult or impossible to accept that their child born from mitochondrial donation would also like to form a relationship with their egg donor biological mother, in an effort to better understand their own identity.[25] These situations have

[18] Karen Ludlow (2020), Genetic identity concerns in the regulation of novel reproductive technologies. Journal of Law and the Biosciences, page 15.
[19] Calum MacKellar (2015), Representative aspects of some synthetic gametes. *The New Bioethics*, Vol.21(2), page 115.
[20] Calum MacKellar (2017), Kinship identities in the context of UK maternal spindle transfer and pronuclear transfer legislation. *The New Bioethics*, Vol.23(2), page 11.
[21] Calum MacKellar (2017), page 12.
[22] Tobin, B, Donor-conceived people: are they entitled to identifying information about their biological parents? *Bioethics Outlook*, 24(1) 2013: 6.
[23] Associate Professor Nicholas Tonti-Filippini, Submission No.2 to the NSW Parliamentary Inquiry into Inclusion of Donor Details on the Register of Births, 18 November 2011.
[24] Calum MacKellar (2017), page 12.
[25] Calum MacKellar (2017), page 16.

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T (02) 6201 9862
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not been anticipated by the consultation paper, and involve complex personal, identity and emotional challenges, requiring a respectful and thoughtful preparation for all parties.

Recommendation

- The Government should insist that counselling is provided to both children and parents to help them to cope with issues of confused heritage inherent in mitochondrial donation.

The risks of mitochondrial donation

There are important safety issues to be considered with Haimes and Taylor pointing out that "medicines or medical devices that do not behave as safely as expected might well affect the first individuals to receive them, but PNT/MST are interventions of a different order, with the potential to affect the whole human species, rather than a series of individuals, because they change the germline."[26]

Changing the human germline means a person's changed genome is heritable by their children. In the case of mtDNA, the changes are heritable from mother to daughter. This presents unknown risks to future generations.

Ishiia and Hibino point out that not only can "… MMT [mitochondrial manipulation techniques] … result in human germline genetic modification …"[27] but "… all MMT are still experimental in human reproduction."[28]

As hard as these cases might be, is it really wise to be risking changes to the human germline and crossing various ethical boundaries for a handful of cases?[29]

Cussins and Lowthorp warn that "opening the door to the modification of nuclear DNA would be hugely consequential, exacerbating global disparities and likely taking structural inequality to a new, molecular level. Germline modification sold as an 'add-on' at fertility clinics could all too easily establish a system of consumer-based eugenics."[30]

PNT and MST are not cures for disease, but instead reduce the risk that someone is born with a mitochondrial disease or with the potential for an illness to emerge.[31]

Thornburn and Christodoulou acknowledge that "… a small number of maternal mitochondria are carried over, leaving the potential for reversion to mutant mitochondrial DNA. It's also possible

[26] Haimes, E and Taylor, K, 2017 page 7.
[27] Tetsuya Ishii and Yuri Hibino (2018), Mitochondrial manipulation in fertility clinics: Regulation and responsibility. *Reproductive BioMedicine and Society Online*, Vol.5, page 95.
[28] Tetsuya Ishii and Yuri Hibino (2018), page 105.
[29] Lane, A et al, 2016, page 732.
[30] Cussins, J and Lowthorp, L, 2018, page 88.
[31] Blesa, JR et al, 2016, page 187.

GPO Box 368
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F (02) 6247 6083
T (02) 6201 9862
www.catholic.org.au
church.life@catholic.org.au

the donor mitochondrial DNA will be incompatible with the parents' nuclear genes, potentially causing disease."[32]

Without proof of the safety of these techniques, the potential benefits to a number of families would come with a risk to the common good.[33]

Alternatives to mitochondrial donation

There are a number of alternatives for dealing with mitochondrial disease, which include accepting a child with mitochondrial disease and funding the supports the community should offer to such families; adoption and fostering and deciding to not have children.

None of these alternatives are easy to accept and transgress against the strong human desire for genetically-related children. [34] Neither PNT nor MST would be more successful for avoiding mitochondrial disease than the much simpler approach of having an egg donor as part of IVF treatment.[35]

It is important to remember that mitochondrial diseases have varying levels of seriousness. In light of that, "… the women who are the targeted beneficiaries of PNT/MST have mitochondrial disease themselves and yet have a quality of life that has enabled them to get to the point of wanting to start a family."[36]

Recommendations

- Intending parents should have counselling independent of any clinical licence holder so that they can understand the risks inherent in mitochondrial donation, whether the procedure can address their circumstances, the likelihood of the birth of a child in their circumstance and the chance that their child will suffer from mitochondrial disease despite the procedure.
- In order to ensure that the clinical licence holder is more likely to have the interests of the parents and the intended child in mind, the clinical licence holder should only be able offer mitochondrial donation on a cost recovery basis.

Risks to women providing human eggs

There are also risks associated with the provision of human eggs.

[32] David Thornburn and John Christodoulou, (2019) 3-parent IVF could prevent illness in many children (but it's really more like 2.002-parent IVF). The Conversation, 11 November.
[33] Haimes, E and Taylor, K, 2017, page 16.
[34] Haimes, E and Taylor, K, 2017, page 4-5; Lane, A et al, 2016, page 732.
[35] Anscombe Bioethics Centre for Healthcare Ethics, submission to the Human Fertilisation and Embryology Authority's consultation on mitochondrial replacement, 2013; Calum MacKellar (2017), page 16; Tetsuya Ishii and Yuri Hibino (2018), page 107.
[36] Haimes, E and Taylor, K, 2017 page 10.

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T (02) 6201 9862
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Both MST and PNT require significant supplies of human eggs, both for research and for the techniques if they are permitted. Eggs can only be found by seeking out willing adult women to provide their ova. In addition, since neither PNT nor MST have high success rates, they would need more eggs than for IVF.[37]

The significant imposition on the life of a woman providing ova for research or other purposes indicates how difficult it may be to find ova for PNT or MST. This type of process is not in keeping with the dignity of the women who provide ova.[38]

Similar difficulties would also face the intending mother in providing eggs for these procedures.[39]

There's also a serious risk to the health of women providing eggs. Cussins and Lowthorp point out that "egg extraction poses a number of serious risks, including memory loss; depression; joint, muscle, and bone pain; formation of blood clots; seizures; ovarian hyperstimulation syndrome (OHSS); and even death."[40]

There is a concern that any economic incentives set up by paid egg "donation", may lead to the provision of "… oocytes from socioeconomically deprived women for subfertile couples with more financial resources."[41]

Allowing inducements would mean treating the human body and hence the person as a mere commodity. In turn this would undermine the existing social capital in current systems of donation that depend on altruism and a commitment to the common good, while also exploiting the poor who lack alternative ways of earning an income. Individuals and the common good are best protected by maintaining the existing prohibitions on trading in human eggs.

Recommendations

- Clinical licence holders or the organisations that provide eggs to clinical licence holders should not be allowed to provide direct or indirect inducements, such as a monetary payment for human gametes.
- Egg donors should only be compensated for documented expenses which are directly relevant to the donation.[42]

[37] Lane, A et al, 2016, page 733.
[38] Haimes, E and Taylor, K, 2015, 362-3.
[39] Baylis, F, 2017, page 16.
[40] Cussins, J and Lowthorp, L, 2018, page 82.
[41] Lane, A et al, 2016, page 733.
[42] Using the National Statement 1: Payments to Participants in Research, Particularly Clinical Trials. NHMRC, October 2009.

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T (02) 6201 9862
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- Staff employed by Clinical licence holders or the organisations that provide eggs to clinical licence holders and anyone else in a dependant relationship should be prohibited from making donations.
- The Government must report on the number of human eggs used in mitochondrial donation procedures.

Conclusion

The Conference has provided a number of recommendations on how mitochondrial donation might best be implemented in Australia. None of the recommendations can overcome the inherent problem in creating three parent children, including destroying human embryos, genetic bewilderment and dangers for women who donate their eggs. Mitochondrial donation is not a necessary, life-saving technology, but a complex and unproven method designed to ensure a couple can give birth to a biologically related child with a reduced risk of carrying mitochondrial disease. Mitochondrial donation also does not offer greater benefits than adoption or some simpler IVF techniques, given the possibility of passing on abnormal mitochondria. Concerns about safety, ethical practice and efficacy mean that mitochondrial donation should not have approval to proceed in Australia.

I would be happy to answer questions. I can be contacted via Mr Jeremy Stuparich, Public Policy Director at the Conference on 02 6201 9863 or policy@catholic.org.au

Yours sincerely

+ Richard Umbers

Most Rev Richard Umbers
Auxiliary Bishop of Sydney
Bishop Delegate for Life

GPO Box 368
CANBERRA ACT 2601

F (02) 6247 6083
T (02) 6201 9862

www.catholic.org.au
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