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

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Committee Secretary
Senate Standing Committees on Community Affairs
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Dear Sir/Madam

Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021

This submission from the Australian Catholic Bishops Conference (**the Conference**) on the *Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021* 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. Mitochondrial donation is a difficult and contested issue where people of goodwill can differ.

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Summary

1. Mitochondrial donation will not cure children who are sick. If it works, it will only reduce the chance of children with faulty mitochondria being born.
2. Mitochondrial donation has been legal in the United Kingdom (**UK**) for five years but there have been no reported live births in the UK, so it is not clear if this procedure is safe and practical.
3. Mitochondrial donation has the potential to change the human genome, so the changes are heritable over generations.
4. The Government's Consultation Paper says the "immediate and long-term risks for the child and longer term implications for subsequent generations are not yet fully understood." The legislation emphasises this danger by giving immunity from civil liability for adverse events to the Minister and senior public servants. They should not have immunity. If it is too dangerous for the decision-makers, it is too dangerous for the children who might suffer the adverse events.
5. We disagree with the use of IVF with egg donation but note that this is an option for parents to have children which is already legal and has no risk of passing on mitochondrial disease. Mitochondrial donation, which genetically modifies a human embryo or egg, adds issues of safety and ethics with no benefit to health.
6. Mitochondrial donation would produce human embryos who have three genetic parents.
7. Having three genetic parents creates a real risk children will grow up struggling to find and understand their identity and heritage.
8. Mitochondrial donation involves creating and destroying human embryos.
9. The Government's Consultation Paper suggests parents be given the choice of sex-selection so that only male human embryos would be born.
10. Two of the techniques - Pronuclear transfer and Second Polar Body Transfer - create a partial copy human embryo with the intention of bringing about a live birth, which is a form of human reproductive cloning.
11. There is a serious risk to the health of women providing eggs and the development of this procedure will require significant numbers of eggs.

Introduction

Mitochondrial donation encompasses several techniques designed to ensure that women with abnormal mitochondria can have children who are genetically related to them and free of that condition. Mitochondrial DNA (**mtDNA**) is inherited from the maternal line as it originates from human eggs.[1] 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 illness and suffering. But there are alternatives for families to have children without any risk of mitochondrial disease.

There is a risk with all new technology of being swept up in hope and the promise of what might be possible. There are a number of difficulties with mitochondrial donation that mean it may not offer much to families and would pose significant ethical challenges.

What is mitochondrial donation?

Each method of mitochondrial donation involves taking the mother's nuclear DNA (**nDNA**) from the intended mother's egg or from a human embryo made using the intended mother's egg and moving it to replace the egg donor's nDNA either in the donor's egg or in an embryo created with the donor's egg. This means the intended mother's nDNA is placed into an egg or embryo that has the donor's healthy mtDNA.

The legislation mentions five methods:

- germinal vesicle transfer (**GVT**)
- first polar body transfer (**1st PBT**)
- second polar body transfer (**2nd PBT**)
- pronuclear transfer (**PNT**), and
- maternal spindle transfer (**MST**).

In each case the new human embryo would have three genetic parents, containing nDNA from the father, nDNA from the intending mother with abnormal mitochondria and mtDNA from the egg donor mother who provides the egg.[2]

How many families would this help?

The Explanatory Memorandum states that "… approximately 56 children are born each year with a severe form of the [mitochondrial] disease" and that "… some of these instances could be

[1] Haimes, E. and Taylor, K., 2017. Sharpening the cutting edge: additional considerations for the UK debates on embryonic interventions for mitochondrial diseases. *Life Sciences, Society and Policy*, 13(1). Page 3.
[2] 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.

prevented if mitochondrial donation was legalised in Australia for the purpose of minimising this risk."

Mitochondrial replacement would help with fewer than 20 families a year because "… mtDNA mutations are found in no more than 15%-30% of children with mitochondrial disorders."[3]

Given many women may not know that they have faulty mtDNA and, of the women who do, many may not wish to go through the process of mitochondrial donation, the number of families these techniques would perhaps help would be well under 20 each year.[4] This can be seen from the UK data cited in the Explanatory Memorandum which notes that there were only 21 applicants for mitochondrial donation as of November 2020, with only eight of those treatments approved.

For those intending parents who decide to pursue mitochondrial donation, the complex nature of the procedure implies a low success rate. On average, IVF success rates in Australia are less than 30 per cent[5] and mitochondrial donation is a much more difficult procedure. In practice, mitochondrial donation in the UK has not reported any live births.[6] Even ignoring the significant concerns about this technology and acknowledging the good intentions of people who wish to help children, few families are likely to benefit each year from the introduction of mitochondrial donation in Australia.

The Conference has a number of concerns about mitochondrial donation, detailed below.

1. No cure for existing children

Mitochondrial donation will not cure children who are sick. If it works, it will only reduce the chance of children with faulty mitochondria being born.

Indeed, there is a chance a child born using mitochondrial donation would still carry unhealthy mitochondria as it is impossible to move the nDNA without some accompanying mtDNA also being transferred.[7]

[3] Saneto, R. P., 2017. Genetics of Mitochondrial Disease. *Advances in Genetics*, 63–116. Page 67.
[4] Baylis, F., 2017. Human nuclear genome transfer (so-called mitochondrial replacement): clearing the underbrush. *Bioethics*, Vol 31(1), page 15-16.
[5] "Overall, 27 per cent of embryo transfers result in a live birth, but the chances of having a baby via IVF are largely dependent on a woman's age - as well as other individual characteristics - and the IVF clinics treating them." See: Aubusson, K, 2021. Would-be parents given access to IVF predictor, clinic success rates. *The Sydney Morning Herald*, 11 February. See: https://www.smh.com.au/national/would-be-parents-given-access-to-ivf-predictor-clinic-success-rates-20210211-p571q6.html
[6] Stammers, T. 2021. Promises, promises, promises. *Mercatornet*, 10 February. See: https://mercatornet.com/promises-promises-promises/70070/; Cussins, J., Lowthorp, L., 2018. Germline Modification and Policymaking: The Relationship between Mitochondrial Replacement and Gene Editing, *The New Bioethics*, 24:1, 74-94. Page 82.
[7] Thornburn, D., Christodoulou, J., 2019. 3-parent IVF could prevent illness in many children (but it's really more like 2.002-parent IVF). *The Conversation*, 11 November. See: https://theconversation.com/3-parent-ivf-could-prevent-illness-in-many-children-but-its-really-more-like-2-002-parent-ivf-126591

The National Health and Medical Research Council's (**NHMRC**) Expert Working Committee on mitochondrial donation found that "results from some studies using ESCs [human embryonic stem cells] have identified the possibility that mtDNA carryover could lead to reversion to significant levels of maternal mtDNA."[8]

A more recent study found that it seems "… even a small amount of mtDNA carryover can affect the stability of the mtDNA genotype and consequently impair the effectiveness of the MR [Mitochondrial replacement]."[9]

These techniques increase the risk of the child carrying the disease for the sake of having a genetic relationship with the mother.

2. No live births means the procedure is still experimental

Mitochondrial donation is still experimental because despite the procedure being legal in the UK for five years, and the regulating authority having approved pregnancies, there have been no reported live births in the UK using a mitochondrial donation technique.[10]

The NHMRC Expert Working Committee on mitochondrial donation says "… there is no significant new evidence, since the 2016 HFEA [UK Human Fertilisation and Embryology Authority] scientific review, about the safety and efficacy of mitochondrial donation."[11]

The NHMRC Expert Working Committee offered no view on "… whether or not mitochondrial donation should be introduced into Australian clinical practice."[12]

3. Changes to the human genome

This legislation would for the first time allow changes to the human genome, meaning the changes are heritable over generations.

The NHMRC Expert Working Committee said that, "… it is essential to recognise the potential heritability of changes to the genome introduced by mitochondrial donation …" and "… mitochondrial donation can be a form of germline modification, since the modified mitochondrial genome can be inherited by future generations."[13]

[8] Expert Statement: Mitochondrial Donation Expert Working Committee. National Health and Medical Research Council, March 2020, page 27. See: https://www.nhmrc.gov.au/health-advice/all-topics/mitochondrial-donation
[9] Yamada, M., Akashi, K., Ooka, R., Miyado, K. and Akutsu, H., 2020. Mitochondrial Genetic Drift after Nuclear Transfer in Oocytes. *International Journal of Molecular Sciences*, 21(16), p.5880.
[10] Stammers, T. 2021; Cussins, J., Lowthorp, L., 2018, page 82.
[11] Expert Statement: Mitochondrial Donation Expert Working Committee. National Health and Medical Research Council, March 2020, page 5. See: https://www.nhmrc.gov.au/health-advice/all-topics/mitochondrial-donation
[12] Expert Statement: Mitochondrial Donation Expert Working Committee, page 5.
[13] *Expert Statement: Mitochondrial Donation Expert Working Committee*, page 4, 20-21.

The 2018 Senate Committee report acknowledged that "the main legislative barrier to mitochondrial donation is the blanket prohibition on any form of germline genetic modification contained in the *Prohibition of Human Cloning for Reproduction Act 2002*."[14]

There are important safety issues to be considered because "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."[15]

There is a danger the legislation will be seen as a precedent by any scientists who wish to pursue other human germline interventions.[16]

4. The legislation offers immunity for adverse events because of acknowledged risks

The Government's Consultation Paper says the "immediate and long-term risks for the child and longer term implications for subsequent generations are not yet fully understood."[17]

The Explanatory Memorandum states that "the risks for children born using these techniques are not yet fully understood and the available scientific evidence to support this procedure is limited." Notably, the Explanatory Memorandum when considering the human rights implications of the Bill and particularly the Convention of the Rights of the Child makes no reference to these risks to children born.

The draft legislation emphasises the danger for children by granting immunity to a "protected person" from civil liability from any adverse events. The Bills Digest advises that:

> "There are known risks associated with mitochondrial donation, and because of the newness of the mitochondrial donation techniques for human reproductive purposes, there is potential for yet unknown consequences to emerge. Due to these known risks and the potential for yet unidentified risks, the protection afforded to the Commonwealth and a 'protected person' under proposed subsection 47A allows these persons to undertake their administrative tasks without fear of civil liability for adverse events that might arise from the use of a mitochondrial donation technique."[18]

[14] Senate Community Affairs References Committee, *Science of mitochondrial donation and related matters*, 27 June 2018. Paragraph 5.14. See: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation/Report
[15] Haimes, E. and Taylor, K., 2017, page 7.
[16] Baylis, F., 2017, page 7.
[17] Department of Health, *Legalising mitochondrial donation in Australia: Public consultation paper*. Australian Government, 2021. Page 3.
[18] Department of Parliamentary Services, (2021) Bills Digest No.65 2020-2021, Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021. Page 53. See: https://parlinfo.aph.gov.au/parlInfo/download/legislation/billsdgs/8013254/upload_binary/8013254.pdf;fileType=application/pdf

This immunity is given to a number of protected people including the health minister and senior public servants.

The Explanatory Memorandum says, "the prescribed 'adverse events' include a failed embryo development; a miscarriage; a premature birth of a child; the birth of a child with a birth defect, a genetic abnormality, or a diagnosis of mitochondrial disease; or mitochondrial disease appearing later in life."

The minister and other decision-makers should accept responsibility for decisions they make with regard to this technology and should not have immunity. If it is too dangerous for the decision-makers, it is too dangerous for the children who might suffer the adverse events.

5. IVF with egg donation works and is legal now

Intending parents have a number of options to have children without the risk that their children will be born with mitochondrial disease.

We disagree with the use of IVF with egg donation, but this is an option which is already legal and would allow parents to have a child without the risk of having mitochondrial disease. Mitochondrial donation, which genetically modifies a human embryo or egg, adds issues of safety and ethics with no benefit to health.

Parents might also pursue adoption or fostering.

6. Three biological parents

The different methods of mitochondrial donation would for the first time allow the production of a human embryo using genetic material from three people. The embryos created would have nDNA from the father, nDNA from the intending mother with abnormal mitochondria and mtDNA from the egg donor mother who provides the egg.

Egg donors "… 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."[19]

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 also inconvenient, so some advocates argue this third person is not really a genetic parent.[20]

[19] Mills, C., 2020. Nuclear Families: Mitochondrial Replacement Techniques and the Regulation of Parenthood. *Science, Technology, & Human Values*, 46(3), pp.507-527. Page 516.
[20] Jones, D., 2015. The other woman: Evaluating the language of 'three parent' embryos. *Clinical Ethics*, 10(4), pp.97-106.

However, "… empirical evidence suggests that mtDNA might transmit personal characteristics in a manner that results in resemblances between donor and resultant child."[21]

A person's identity depends on more than appearance and other characteristics, but mtDNA is also an important influence on characteristics such as ageing, memory and combatting disease.[22]

7. Confused origin of children

Mitochondrial donation would produce a child with three biological parents, creating "… 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."[23]

The draft legislation provides for a Mitochondrial Donation Donor Register to record details of the donor parent. The details would be available to children once they turn 18. This implicitly acknowledges the important biological connection with the third parent.

The ability of a person to find information about their gamete donor parent may be frustrated because "… research suggests that most heterosexual parents who conceive via donor conception never tell their children."[24]

The International Principles for Donor Conception and Surrogacy, signed by representatives of donor-conceived people, has a list of principles for future laws, including:

- "All donor-conceived and surrogacy-born people have an inalienable right to identifying information about all of their biological parents, regardless of when or where they were conceived or born."
- "All donor-conceived and surrogacy-born people have an inalienable right to identifying information about all of their biological siblings, be they half or full siblings, regardless of when or where they were conceived or born."
- "Comprehensive and complete records of the identity and familial medical history of all parties involved in the conception and birth of donor-conceived and surrogacy-born people must be kept. Such records must be held by each Nation State in which the conception and birth is commissioned and/or occurs, in perpetuity and for future generations. Verification of the identity of donors, surrogate mothers, and intending parents must occur."

[21] Brandt, R., 2016. Mitochondrial donation and 'the right to know'. *J Med Ethics*, Vol.42, page 683.
[22] Cussins, J., Lowthorp, L., 2018, page 82.
[23] MacKellar, C., 2015. Representative aspects of some synthetic gametes. *The New Bioethics*, Vol.21(2), page 115.
[24] Power, J., 2015. Secrets and lies: why donor-conceived children need to know their origins. *The Conversation*, 3 July. See: http://theconversation.com/secrets-and-lies-why-donor-conceived-children-need-to-know-their-origins-44015

- "Parents should be encouraged and supported to tell their children of their donor-conceived or surrogacy-born status as early as possible, and preferably from birth. This should be coupled with efforts to reduce stigma related to infertility."[25]

The Register should require donors to provide their medical history at the time of the donation, so that information is not lost. The Register should also allow donor-conceived people to make contact with their biological siblings as part of their right to know their family. It is not clear how best to ensure children are told about their origins.

8. Human embryos created and destroyed

The different methods of mitochondrial donation lead to human embryos being created and destroyed, both for research and for clinical work.

The legislation would for the first time allow human embryos to be created and destroyed purely for research and training.[26]

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.[27]

This does not respect the human dignity of embryos.

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.[28]

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, 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.

9. Promotes sex-selection

Given mitochondrial disease follows the maternal line, the Government's consultation paper suggests parents could be given the choice to "… only implant male mitochondrial donation

[25] See principles 3, 4, 8 and 11: Making Humans: International Principles for Donor Conception and Surrogacy, https://www.change.org/p/united-nations-making-humans-international-principles-for-donor-conception-and-surrogacy
[26] Amendments to section 12 of the Prohibition of Human Cloning for Reproduction Act 2002 as detailed in the Department of Parliamentary Services, (2021) Bills Digest No.65 2020-2021, Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021. Page 36. See: https://parlinfo.aph.gov.au/parlInfo/download/legislation/billsdgs/8013254/upload_binary/8013254.pdf;fileType=application/pdf
[27] Vélez, J., 2012. An Ethical Comparison between In-Vitro Fertilization and NaProTechnology. *The Linacre Quarterly*, 79(1), pp.57-72. Page 61.
[28] Instruction Dignitas Personae on Certain Bioethical Questions, 20 June 2008, #4, 6.

embryos."[29] Using sex-selection to deliberately target female human embryos is unethical and should be prohibited.

10. Creates a partial copy human embryo

This bill would authorise a form of human reproductive cloning in that PNT (pronuclear transfer) and 2nd PBT create a partial copy human embryo by transferring nDNA, with the intention of bringing a child to birth. This process is undoubtedly cell nuclear transfer (hence the NT of PNT) and in this way resembles the Somatic Cell Nuclear Transfer technique used to generate Dolly the sheep. It is also nuclear transfer for the sake of bringing about live birth.[30]

11. Dangerous for women who donate their eggs

There is a serious risk to the health of women who provide eggs for mitochondrial donation research and clinical work. "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."[31] Since mitochondrial donation does not have high success rates, researchers would need more eggs than for IVF.[32]

There is a shortage of donor eggs in Australia.[33] It is unclear how enough eggs would be made available.

The 2018 Senate Committee said eggs would "… most likely come from excess eggs that were donated after in vitro fertilisation procedures or from women who were close to the family."[34]

Such sources of eggs were not sufficient in the UK. To source adequate eggs, the UK program pays £750 per cycle plus expenses[35] and also operates an "egg sharing for research" scheme where women are given £1500 off the price of a cycle of IVF in exchange for some of their eggs.[36]

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[29] Department of Health, *Legalising mitochondrial donation in Australia: Public consultation paper*. Australian Government, 2021. Page 8.
[30] Amato, P et al, 2014. Three-Parent IVF: Gene Replacement for the Prevention of Inherited Mitochondrial Diseases. *Fertil Steril*, January; 101(1) page 31-35; Blesa, JR et al, 2016. Ethical aspects of nuclear and mitochondrial DNA transfer. *The Linacre Quarterly*, 83(2), page 183; Anscombe Bioethics Centre for Healthcare Ethics, 2013.
[31] Cussins, J., Lowthorp, L., 2018, page 82.
[32] Lane, A et al., 2016. "Mitochondrial Replacement" technologies and human germline nuclear modification. *J Obstet Gynaecol Can*, Vol 38(8), page 733.
[33] Koplin, J., 2021. How should mitochondrial donation operate in Australia? *BioNews* (1090), 12 April. See: https://www.bionews.org.uk/page_155799.
[34] Senate Community Affairs References Committee, Science of mitochondrial donation and related matters, 27 June 2018. Paragraph 4.50. See: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation/Report
[35] Taylor, P., 2015. Three parent babies: unethical, unnecessary, unsafe. *BioNews*, [online] (790). 16 February. Available at: <https://www.bionews.org.uk/page_94923>. See also: https://www.newcastle-mitochondria.com/egg-donation/
[36] Haimes, E., Taylor, K., & Turkmendag, I., 2012. Eggs, ethics and exploitation? Investigating women's experiences of an egg sharing scheme. *Sociology of Health & Illness*, 34(8), 1199–1214.

Human gametes should not be commercialised. The NHMRC's ethical guidelines only allow altruistic donation, but it is not clear what altruistic donation might mean.[37]

For example, a Senate Committee found that "in a case that was cited by a number of submitters, Reproductive Medicine Albury sought to offer a package to a number of Canadians in 2003 that included return airfares, accommodation for two weeks and an allowance of $150 each day in exchange for sperm donations. It was estimated that the total package was valued at about $7,000 at that time. While it appears that the NHMRC was involved in overseeing the ethics of this offer, it is unclear whether the clinic ultimately proceeded with the offer."[38]

Exploitation of women for their eggs would not respect their human dignity and remains a danger arising from this legislation given mitochondrial donation would need a significant number of eggs for research, training and clinical work.

Conclusion

The Conference has detailed a range of concerns about the legislation, but in particular notes that while the legislation seems unlikely to help many families, it would open the door to three ethically contentious practices:

- The first time researchers would be allowed to change the human genome, meaning any changes are heritable over generations;
- The first time that human embryos would be created and destroyed purely for research and training; and
- The first time that a human embryo could be created from the genetic material of three people (three-parent embryos).

Each of these firsts would have serious implications, but the draft legislation proposes Australia cross these thresholds even though there is doubt about whether mitochondrial donation is safe and practical.

The Conference opposes the legislation, but at the very least asks that the legislation be paused so there is time to assess the progress of work in the UK's mitochondrial donation program. If the UK's program cannot show significant success, there appears little reason for Australia to follow the same path.

[37] National Health and Medical Research Council, *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, 2017, section 5.4. See: https://www.nhmrc.gov.au/art

[38] Senate Legal and Constitutional Affairs References Committee, Donor conception practices in Australia, 10 February 2011. Paragraph 4.11. See: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Completed_inquiries/2010-13/donorconception/report/index

I would be happy to answer questions. I can be contacted via Mr Jeremy Stuparich, Public Policy Director at the Conference

Yours sincerely

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