Position Statement to the Australian Law Reform Commission

Subject: Legal Reform to Permit the Use of Normothermic Regional Perfusion (NRP) in Donation after Circulatory Determination of Death (DCDD) Organ Donation in Australia

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Executive Summary

This submission recommends that the Australian Law Reform Commission review and support changes to current legislation that prevent the use of Normothermic Regional Perfusion (NRP) in Donation after Circulatory Determination of Death (DCDD) abdominal organ donation.

NRP is a transformative technology that dramatically improves transplant patient outcomes, reduces healthcare costs, and increases donor organ utilisation. Of particular importance, NRP allows increased access & utilisation of better-quality donor organs to be utilised by both Adult and Paediatric Transplant recipients.

Australia's current legal restrictions on NRP are completely discordant with international practice and compromise the potential to save the lives of Australian Adults & Children requiring a liver &/or kidney transplant. The implementation of NRP serves to respect and honour Australian organ donors and their families, by actually utilising their precious gift of life (their donated organs).

Of note, it is now the standard of care to perform NRP at DCDD abdominal organ retrievals in the United Kingdom (started in 2010), Spain (started prior to 2010), France, Norway, Italy (& many other European Countries), USA (in many states), Canada, and New Zealand (starting NRP program in 2026). To re-emphasize, Australia's current legal restrictions on NRP are completely discordant with international clinical practice and compromise the potential to save the lives of Australian Children requiring a kidney (&/or liver) transplant.

The practical implementation of NRP into routine clinical practice requires careful coordination and collaboration between both cardiothoracic and abdominal transplantation teams in order to maximize the outcomes of each organ of interest.

Background

Deceased donor Adult & Paediatric abdominal organ transplantation (Liver, Kidney, Pancreas) in Australia primarily relies on donation after neurological determination of death (DNDD), which offer optimal outcomes. However, with the growing number of patients awaiting transplants and a persistent shortage of donor organs, DCDD donors have become a critical alternative despite being associated with higher complication rates.

Innovations such as NRP allow clinicians to improve the quality and viability of DCDD organs, addressing many of the historical limitations. However, despite the mounting international evidence of NRP's benefits, Australia's current legal framework prohibits its use in DCDD donors due to concerns surrounding the reestablishment of circulation post-mortem.

Position

We strongly advocate for reform of the current legal prohibitions surrounding NRP in Australia, particularly for liver and kidney transplantation, to align with international clinical standards and best practice in transplantation.

Supporting Evidence

1. Increased Utilisation of Donor Organs

- NRP results in a significant increase in the utilistation (and transplantation rates) of deceased donor kidneys compared to standard (Non-NRP) DCDD donor kidneys.
- NRP enables real-time assessment and resuscitation of organs, allowing transplant centres to utilise DCDD livers that would otherwise be discarded. Centres employing NRP have demonstrated up to a 40% increased liver utilisation rate.

2. Improved Outcomes following Kidney Transplantation

- Clinical studies have shown NRP significantly reduces the rate of delayed graft function following kidney transplantation. NRP kidneys have at-least a 35% lower chance of developing delayed graft function than non-NRP kidneys (odds ratio, 0.65; 95% CI, 0.465-0.901).
- After adjusting for known risk factors, use of NRP is significantly associated with superior graft survival. Standard DCDD (Non-NRP) donor kidneys have a 3.5 times higher chance of suffering graft failure within 1 year (compared to NRP DCDD donor kidneys).
- NRP DCDD donor kidneys (compared to Non-NRP DCDD kidneys) have significantly higher eGFR at 1 year. In risk-adjusted analyses, the expected value of eGFR at 1 year increased by 7.6ml/min/1.73m2 (if NRP was used). This results in an estimated two-three years of graft life and patient independence from dialysis.

3. Improved Outcomes following Liver Transplantation

- Clinical studies have consistently demonstrated that the use of NRP is associated with significantly reduced rates of:
  - Ischaemic cholangiopathy (the rate of ischaemic cholangiopathy is 2-3x lower following NRP - compared to any other available machine perfusion technology).
  - Early allograft dysfunction
  - Primary non-function
  - Need for re-transplantation

As a result, a significant improvement in both survival and quality of life for transplant recipients is demonstrated when NRP is utilised.

3. Cost-Effectiveness

- NRP is a cost-effective alternative to ex-situ machine perfusion, with a single intervention supporting multiple organs at once (e.g., liver, kidneys, pancreas, heart).
- The utilisation of NRP has resulted in significant organ retrieval associated cost savings (compared to standard DCDD organ retrievals), with £1.17M in savings per 100 donors. (UK experience)
- NRP markedly reduces the long-term health-care cost burden associated with post-liver transplant complications. It is far more cost effective to utlilise NRP DCDD donor livers (compared to standard Non-NRP DCDD donor livers).
- For kidney transplantation, NRP adds an estimated two-three years of graft life and patient independence from dialysis, equating to a potential GBP 300,000 per patient in savings. (UK experience)

Healthcare Improvement Scotland. The cost effectiveness of organ retrieval using in situ normothermic regional perfusion (NRP) for liver transplantation. https://shtg.scot/media/1854/organ-retrieval-using-in-situ-normothermic-regional-perfusion-nrp-for-liver-transplantation-shtg-ev-snth-02-19-gen-and-gastro.pdf

NHS Blood and Transplant Advisory Group. DCD Kidney retrieved with or without NRP – Activity and Outcomes. RAG(22)08. Statistics and Clinical Research. Feb, 2022.

International Precedent

NRP is currently approved and widely practiced in countries such as the United Kingdom, France, Spain, and Italy, and is mandated in some jurisdictions as the standard of care for DCDD donation. Australia is now an outlier among developed nations in prohibiting this evidence-based, ethically applied practice.

Recommendation

We recommend that the Australian Law Reform Commission:

1. Review current legal barriers to the application of NRP in the context of DCDD donation.
2. Support legislative amendments to permit NRP under ethically governed clinical protocols.
3. Encourage the National Health and Medical Research Council (NHMRC) and relevant clinical bodies to establish national NRP guidelines and governance frameworks.

Conclusion

Lifting the prohibition on NRP would represent a significant advancement in Australia's transplant capability. It also serves to respect and honour Australian organ donors and their families, by actually utilising their precious gift of life (their donated organs). It is an ethical, clinically validated, and cost-effective technology that can increase life-saving transplants (for all Australian children currently waiting for a deceased donor kidney (&/or liver) and reduces burden on the healthcare system. Law reform in this area is both urgently needed and eminently justified.

References:

Oniscu G, Mehew J, Butler A, et al. Improved organ utilisation and better transplant outcomes with in situ normothermic regional perfusion in controlled donation after circulatory death. Transplantation. 2023;107:438–448.

Watson CJE, Kosmoliaptsis V, Randle LV, Russell NK, Lozanovski VJ, Krug S, et al. Normothermic perfusion in the assessment and preservation of declined livers before transplantation: hyperoxia and vasoplegia—important lessons from the first 50 cases. Ann Surg. 2019;270(4):747–53.

Mergental H, Perera MTPR, Laing RW, Muiesan P, Isaac JR, Smith A, et al. Transplantation of discarded livers following viability testing with normothermic machine perfusion. J Hepatol. 2020;72(4):785–96.

Schlegel A, Muller X, Dutkowski P. New paradigms of liver graft preservation: from static cold storage to dynamic machine perfusion. Lancet Gastroenterol Hepatol. 2020;5(7):632–42.

Hudson A, White SA, Wilson CH. Cost-effectiveness of normothermic regional perfusion in donation after circulatory death liver transplantation: a UK-based economic evaluation. Transplantation. 2023;107(5):979–87.

Nasralla D, Friend PJ, Selzner M. Normothermic and hypothermic machine perfusion in liver transplantation: do we need both? Nat Rev Gastroenterol Hepatol. 2021;18(3):173–85.

Moers C, Pirenne J, Paul A, Ploeg RJ; Machine Preservation Trial Study Group. Machine perfusion or cold storage in deceased-donor kidney transplantation. N Engl J Med. 2012 Feb 23;366(8):770-1.