Issues Paper – Review of Human Tissue Laws- June 2025

Response from Transplant Surgeons and Physicians
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Introduction:

We thank the Australian Law Reform Commission (ALRC) for giving us the opportunity to submit a response to the Issues Paper regarding the review of the Human Tissue Laws in Australia[1]. As transplant physicians and surgeons at Royal Prince Alfred Hospital, (RPAH) New South Wales (NSW), we have a strong interest in this reform process and have listed our key objectives, principles for reform and what we consider a key priority to focus on in this response.

Key Objectives:

- We believe the key objectives for laws governing human tissue should be to increase the quality and quantity of organs available for transplantation using the best evidence available.
- We believe it is important to wherever possible respect the wishes of the donor (and /or their family) to donate organ and tissue while ensuring optimal transplant outcomes for patients.
- The dead donor rule must be respected, i.e the donor is legally declared deceased prior to commencement of organ retrieval, and no resuscitative i.e Cardio-Pulmonary resuscitation (CPR) efforts are to be made.

Principles Guiding Reform:

- Respect for the persons and their wishes to donate organs successfully.
- Maintaining trust from the public, the individuals who wish to donate and those who undergo organ and tissue transplantation.
- Laws need to be well designed and provide a framework for guidelines in each jurisdiction

Priority Focus Areas:

- We believe a key area for consideration of reform is permitting the use of Normothermic Regional Perfusion (NRP) Technology in the deceased circulatory death donor (DCDD) in NSW and Australia.
    - The New South Wales (NSW) NSW Health Organ Donation after circulatory Death guideline, 2021 in section 4, 'Retrieval surgery', stipulates that "The Commencement of Extra Corporeal Membrane Oxygenation to simulate physiologic function as a post-mortem donor management tool (such as augmentation of oxygen delivery to reperfuse organs) is not permitted in NSW at this time."[2]
        - The NSW DCD guidelines were written at a time when the evidence for DCDD NRP was limited, not because there were concerns about the definition of death
    - NRP has successfully increased the organ donation, utilisation and transplantation rates in Europe, the United Kingdom, and the United States in recent years [3-5].
    - NRP can expand the pool of donors and organs which would otherwise fall outside of acceptable DCDD donation criteria [6].

    - NRP is standard practice in some European countries (France, Italy, Norway, Spain).
    - In the United Kingdom (UK), the Guidelines on transplantation from deceased donors after circulatory death recommend that Abdominal-NRP (A-NRP) should be used in all DCD retrievals where there is a trained team to perform it [7].
    - Australians with end-stage organ diseases are missing out on vital organs which could be recovered with DCDD NRP.
    - Australia will continue to fall behind in organ donation rates and transplantation rates compared to global standards if new technologies such as NRP are not adopted and permitted.
    - There is a risk that international studies in Europe, UK and the United States based on NRP DCDD organs will not be applicable to the Australian DCDD context. This can disadvantage Australian organ recipients as we fail to meet international standards in DCDD and miss out on emerging treatments.
- If DCDD NRP was permitted in NSW/ Australia, then appropriate guidelines and governance will need to be established for implementation.
- There needs to be consistency with what constitutes 'ante mortem intervention'
    - NSW Human Tissue Amendment (Ante mortem interventions) Act 2024 [8], No 13, lists NRP as a type of antemortem procedure. "ante-mortem procedure means the following medical procedures, other than normothermic regional perfusion, carried out to determine, maintain or improve the viability of tissue for a relevant purpose..."
    - This is a misunderstanding of NRP, as it is a postmortem procedure, not an antemortem intervention, and thus should not be included in this HTA amendment.

Comments on Current 'Priority reform areas'

61. "How should death be defined?"

- Definition of death
    - Laws should ensure that once a person is declared dead, then they are dead.
    - There should not be ambiguity after death is declared.
    - The means of determining death should be outlined in guidelines by specialist medical professionals/groups

63: The definition may need to be updated to account for and possibly facilitate new technologies such as normothermic regional perfusion

- DCDD NRP may be achieved within the current definition of death i.e without changing the current definition of death
    - NRP commences post-mortem after the donor is determined legally dead through the DCDD pathway and including 5 minutes of stand down.
    - In situ NRP in DCDD is a postmortem intervention.
    - After the withdrawal of life support and after cessation of circulation occurs, there is a mandatory 5 minute 'no touch/stand down' period before the person is declared legally dead through the DCDD pathway and donor surgery commences. Cannulas are placed in the large vessels (inferior vena cava and aorta) and connected to an external device (which warms and oxygenates blood via an extra corporeal membrane oxygenator and pump (i.e ECMO

circuit). The NRP involves the perfusion of warm, oxygenated blood to organs via the cannula for a period of time (prior to the cold perfusion of organs and then organ extraction). It is limited to either the abdominal cavity in Abdominal-NRP (A-NRP) and extends the thoracic cavity in Thoraco-abdominal NRP (TA-NRP) [9]. In either case, perfusion to the brain is prevented by clamping [10].

- NRP is not equivalent to resuscitating the person to restore life.
- We are mindful that the research and innovation in organ donation, transplantation and novel perfusion technologies constantly evolves. Future technologies cannot be predicted, nor may it be accounted for in the current law reform process (much like the ALRC 1977 and NSW HTA 1983, definition of death which could not have accounted for the advent of NRP).

- Changing the definition of death may be difficult as:
    - Linguistically, death is a categorical phenomenon, however, biologically dying is an incremental process. Our difficulties with having a universally satisfying definition of death in this context is a function of the limits of natural human language and the precision that is required for the purposes of organ transplantation. We need to recover, maintain, and restore function to the transplanted organs at a point in time when the organs are still viable (i.e not after the onset *rigor mortis*, when death is not contentious, but the organs are not useable).
    - "We need to abandon both the idea of death as a concrete event and the search for its definition; instead we must face the fact that our practical problems can only be solved by difficult judgements, based upon complex cost-benefit analysis, concerning the value of lives that may or may not be prolonged" – Leon Kass [11]

- Current controversies regarding the definition of death and NRP:
    - Some have argued that NRP re-establishes circulation and so invalidates the "irreversibility" of circulatory death, by literally reversing it.
        - If word 'irreversible' implies 'no potential' then any DCDD pathway donor would not be said to be deceased because all these donors could potentially have circulation artificially re-established by machine/CPR/ reinstating the life support just withdrawn. Use of the word 'permanent' is no less ambiguous.
        - Donors are selected for DCDD pathway when ICU treatment is considered futile, even if circulation was restored (via CPR or artificial means), it would only reinstate the person to a state of futility of treatment.
    - Others suggest that exclusion of the cerebral circulation before establishing NRP changes the death definition from a circulatory one to one resting on neurological criteria in a way that constitutes an intention to cause death, [12] and is functionally inconsistent with the ability to determine death by neurological criteria[13].
        - Donors are declared dead prior to commencement of NRP. Clamping vessels maintains the lack of perfusion of blood to the brain, it does not cause the death of donor.

Summary:

It is evident that the Australian Law Reform Commission of 1977 [14] and the ensuing state based Human Tissue Acts, written decades ago, could not have predicted the advancement of technology which has now extended to include circulation of blood in organs for the purposes of optimising organ and tissue for transplantation of the sick and dying. It is beholden to us, in the medical profession to utilise the best evidence-based practice as it evolves, and ensure our donors wishes to donate are satisfied, organs are not wasted, and patients are provided with the best possible treatment options to improve overall outcomes.

We believe that the current best evidence for optimising organ and tissue donation for transplantation lies with the use of novel perfusion technology, including Normothermic Regional Perfusion. We therefore believe NRP should be considered as a priority in the reform process by the ALRC.

As transplant professionals, we suggest two potential ways to resolve the impediment of NRP in DCDD: An overarching statement that once death has been declared, the donor is deceased and this cannot be undone, and, or NRP is permitted to occur in the context of the Human Tissue Laws.

We thank the ALRC again for the review and consideration of our response.

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