Australian Law Reform Commission: Discussion paper 90, Review of Human Tissue Laws.

Response from the Liver and Kidney Transplant Services clinicians, Royal Prince Alfred Hospital, New South Wales.

We thank the Australian Law Reform Commission for the opportunity to respond to the Discussion paper 90 (Nov 2025).

We see an urgent need to improve the rates of organ and tissue donation and improve transplantation outcomes in Australia.

Our aim is to continue to perform organ donation via the donation after neurological determination of death (DNDD) and donation after circulatory determination of death (DCDD) pathways and we strongly advocate for normothermic regional perfusion (NRP) to be permitted within a legally acceptable framework which will increase organ utilisation and safety.

Australia continues to fall behind other nations in terms of organ donation rates and quality of organs transplanted. We therefore stress the importance and urgency of allowing NRP technology to occur across the states and territories, either within the context of the current definition of death, or a newly proposed definition of death.

We support a harmonised or unified definition of death across the states and territories. This is to ensure consistency across the nation, and remove barriers, particularly in the context of organ and tissue donation. Whilst we support national consistency, we do not support additional layers of bureaucracy which may increase costs, reduce efficiency and delay access to organ and tissue donation and transplantation.

The proposed brain based functional definition of death is supported, as long as the clinical determination of death is applicable to all situations and is made clear according to medical standards. Any definition should support deceased organ donation, respect the wishes of organ donors and serve the transplant need, rather than make progression from death to donation impractical or impossible.

The reform proposals are thorough, and we will respond to some of the key reform themes to highlight priority areas for change, in order to:

- Increase the quality and quantity of organs available for transplantation using the best evidence available.
- Respect the wishes of the donor (and or their family) to donate organ and tissue while ensuring optimal transplant outcomes for patients.
- Respect the dead donor rule, ensuring no ambiguity to the declaration of death and the commencement of organ retrieval surgery.
- Allow Normothermic Regional Perfusion (NRP) in donation after circulatory determination of death (DCDD) to occur in Australian States and Territories.
- Allow NRP to occur as soon as possible to align with international practice and improve organ donation and transplantation for those suffering from organ failure.
- Reduce barriers to implementing reforms

Comments to Proposals:

- **Proposal 1**. We welcome the goal to maintain national consistency of human tissue laws across states and territories.
- **Proposal 3: National Regulator or alternative**
  - A national regulator may create additional levels of bureaucracy with additional costs. A national regulator may overlap with current existing bodies including the Organ and Tissue Authority (OTA), National Blood Authority (NBA) and the National Health Medical Research Council (NHMRC).
  - **Point 1.18: Alternative options to a National Regulator** including establishing a ministerial council to agree on uniform and consistent legislation across the states and territories is supported. Each state and territory will ultimately need to agree to adopt any changes to legislation, thus having expertise within each jurisdiction to agree on harmonisation of legislation may be more effective than a new regulatory body/national regulator.
- **Proposal 4**: We support the commonwealth, states and territories should come to an intergovernmental agreement to implement national uniform legislation.
- **Proposal 5:** We agree with The Objects of human tissue laws
  - **Chapter 3**: Promoting Equity and Removing barriers: We do not think there is anything additional required aside from the definitions of next of kin and disclosure of information of families of deceased donors
- **Proposal 10**: We support the new statutory provisions for determining death, whereby a 'a person dies when there has been a permanent cessation of the person's critical brain functions, determined in accordance with Section Y, determination of death'
  - We agree with the definition of permanent
  - We support Section Y the determination of death must be made according to accepted medical practice.
  - Professional standards for determining death, through the establishment of guidelines by specialist societies (Such as the ANZ Intensive Care Society) must be explicit in the criteria for determining an individual be deceased.
- **Proposal 11**: We support an intergovernmental agreement for a consistent legal standard for determining death (as per proposal 10).
  - **Question 9:** We note the legal frameworks suggested (uniform death act, new legislation or intergovernmental agreement). We support one which ultimately leads to harmonisation of the definition of death across the states and territories and allows for a consistent approach to future amendments to the human tissue act
- **Proposal 13:** We support the dead donor rule. Confirmation of death must occur prior to any activity related to organ or tissue removal or donation from the body.
  - We emphasise the need for professional standards for determining death, as in clear and explicit criteria for death need to be established by specialist medical societies and supported by accepted medical practice.
- **Proposal 13 (3)**: "Where the deceased person's respiration is not being maintained by artificial means: a) a registered medical practitioner must confirm in writing that they have carried out a clinical examination of the person and in their opinion, there has been a permanent cessation of the critical functions of the person's brain, within the meaning of section X"
  - The criteria for death must be clarified by accepted medical practice in the way of guidelines for determining death.

- Whilst the brain-based definition of death is functional, there still needs to be strict diagnostic criteria, as per medical standards and guidelines, to ensure death is determined appropriately. These criteria will be determined by specialty societies, outside of legislation. This may or may not include existing criteria as outlined by the ANZICS such as apnoea, absence of pulse or brain death testing, the latter which may not be applicable in all contexts outside organ donation (e.g. on the street, or on the ward).
    - For example the United Kingdom , Academy of Medical Royal Colleges provides a Provides a definition of death (Chapter 2) and also the diagnostic criteria for the confirmation of death (Chapter 3) "There is only one definition of death, but three sets of diagnostic criteria"[1].
    - Ideally in the context of DCDD after a period of circulatory standstill (e.g. 5 minutes), it is accepted and agreed that there is no perfusion to the brain and there is therefore permanent cessation of brain function [2].
    - We do not advocate for the brain death testing for DCDD donors
    - We agree that the person declaring death (in the context of organ donation): b. the medical practitioner confirming death cannot be involved in or responsible for: i. the removal of tissue or medical care of a recipient of the removed tissue, or ii. any medical, educational or scientific use of the removed tissue.
- **Point 5.66 and 5.67: Allowing for NRP to develop in Australia**
    - We welcome the acknowledgement of the potential benefit of NRP, and that Australia falls behind international standards in organ donation and transplantation as a result of barriers to NRP.
    - We welcome the statement that 'NRP should not be legally prohibited despite the continued ethical concerns'
    - We support the need for robust protocols that are ethical and safe for the implementation of NRP in Australia
    - We support an intergovernmental agreement to adopt NRP technology and local applied guidelines/protocols in the states and territories.
    - We believe that NRP should be permitted to occur in an individual who has consented for organ donation and is declared legally deceased via circulatory death criteria, based on the current definition of death or the new proposed definition of death.
    - Once an individual is declared deceased, they are deceased, this is a final. There should be no confusion as to whether the person is not deceased. Any post – mortem interventions, such as NRP cannot 'reverse' this declaration of death, therefore it should be permitted to occur with the current or new proposed definition of death.
    - There should not be any uncertainty about the declaration of death meaning anything other than the person is dead (i.e with current or proposed new definition). Such uncertainty as to whether the declaration of death could be violated at all is confusing for those involved in organ donation surgery and potentially the public, regardless of the use of any post-mortem intervention.
    - We therefore support any definition of death that is finite and absolute to allow for a declaration of death to be made confidently and clearly. This is to support staff declaring death, the patient and next of kin, and those involved in organ and tissue donation procedures and surgery.

- **Chapter 7: Reforms relating to deceased donation**
  - **Proposal 23**: we agree that an adult may give valid consent for the removal of their tissue after their death for the purpose of transplantation or for other medical, educational or scientific purposes (or authorised decision maker).
  - **Question 17 Proposal 23 removes the role of the designated officer, who under current legislation is required to authorise tissue removal when a person dies in hospital. Do you agree the role of the designated officer is no longer necessary?**
  - Designated officers may authorise tissue removal form the bodies of people who die in hospital, particularly in the situation of no 'next of kin' or alternative decision maker. The role would be to safeguard organ and tissue donation from deceased individuals.
- **7.60 & 7.61 Pre mortem interventions**
  - The current New South Wales guidelines are confusing and contradictory and will need to be amended following any legislative change.
  - The New South Wales HTA, Part 4A Ante-mortem procedures for donation of tissue after death "ante-mortem procedures means the following medical procedures, other than normothermic regional perfusion, carried out to determine, maintain or improve the viability of tissue for relevant purpose…[3]"
  - Normothermic regional perfusion is currently listed as a prohibited action under 'ante-mortem' despite it being a post-mortem intervention, therefore should be permissible in the postmortem state

We thank the ALRC again for the opportunity to comment on Discussion paper 90, as part of the review of Human Tissue Laws.

Signed by

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References

1. Colleges, A.A.o.M.R., *A Code of Practice for the diagnosis and confirmation of death 2025 Update*. 2025, Academy of Medical Royal Colleges: London.
2. Bernat, J.L., et al., *Understanding the brain-based determination of death when organ recovery is performed with DCDD in situ normothermic regional perfusion.* Transplantation, 2023. **107**(8): p. 1650-1654.
3. Government, N., *Human Tissue Amendment (Ante-mortem Interventions) Act 2024 No 13 [NSW]*, N. Government, Editor. 2024.