Australian Law Reform Commission (ALRC) Review of Human Tissue Laws - Discussion Paper

Submission: Associate Professor Helen Opdam

Intensive Care Specialist, Austin Health Melbourne

Director, Intensive Care, Warringal Private Hospital

National Medical Director, Australian Organ and Tissue Authority

Past President, International Society for Organ Donation Professionals

13 February 2026

Table of Contents

Reforms relating to the determination of death

Proposal 10 - New statutory provisions for determining death

The proposed statutory provisions for determining death have the following advantages:

- Consistent with current medical and scientific understanding of death, which is a unified brain-based concept.
- Would permit normothermic regional perfusion (NRP), which is currently not possible in Australia disadvantaging some individuals wishing to donate organs after death and those awaiting organ transplants (as compared with other countries where NRP is possible).

There are, however, the following disadvantages:

- The provision is overly long and complex, potentially making it difficult for the general public to understand. Of concern, discussions in several fora have revealed that the provision is also not understandable to a large proportion of specialist medical practitioners with considerable knowledge and expertise in death determination, donation and transplantation.

- The current wording, including the lack of mention of circulation, has led some medical specialists to question whether the provision is only for death determination in the setting of brain death and does not include death determination following circulatory arrest. It has also been asked whether this provision wording would prohibit donation after circulatory determination of death.

- The lack of mention of circulation has led some medical specialists to ask whether there will be an interpretation that, in order to meet the provision, all death determination will require examination to demonstrate an absence of brain function (rather than absent circulatory function), which is not rational when circulatory criteria are being used.

- If this provision or a similar provision were adopted, guidelines would be required to provide clarity to individuals who determine death in the vast majority of circumstances. The only guidance currently available is provided by the Australian and New Zealand Intensive Care Society (ANZICS) in the form of the Statement on Death and Organ Donation.[1] This guidance caters for the narrow set of circumstances where death is being determined using neurological criteria and where death is being determined using circulatory criteria following withdrawal of cardio-respiratory support, with an emphasis on the setting of planned donation after circulatory determination of death. It does not provide guidance for death determination in the vast majority of deaths, which are undertaken outside of intensive care units, including death determined on general hospital wards and in

[1] Australian and New Zealand Intensive Care Society (ANZICS) Statement on Death and Organ Donation, Edition 4.1, 2021. Available at: https://www.anzics.org/death-and-organ-donation-app-content/

community settings. Deaths in such settings are determined by other medical practitioners, nurses, other health providers and other non-health providers.

- It is not clear what constitutes a "valid end-of-life decision". It may not be necessary to include *clause 1.b. ii. "intervention would violate a valid end-of-life decision made by or on behalf of the person"* as this would already be covered by *clause 1.b.iii. "intervention or the continuation of intervention would be contrary to accepted medical practice in end-of-life care"* – that is, it is contrary to accepted medical practices in end-of-life care to violate a valid end-of-life decision made by or on behalf of the person.

Other definitions that should be considered include:

- Definition submitted by ANZICS in response to the Issues paper was as follows:

  "A person has died when there is permanent cessation of the critical functions of a person's brain, including the brainstem.

  This can result from devastating brain injury or from cessation of blood circulation in the brain after circulatory arrest.

  The determination of death must be made according to accepted medical standards.

  Critical functions of a person's brain include the complete absence of any form of consciousness (wakefulness and awareness) and the absence of brainstem function, including the ability to breathe independently."

- McGee et al proposed definition (draft paper – currently not published):

  Meaning of Death for Any Law

  1) In any law, a person has died when there is permanent cessation of the critical functions of a person's brain, including the brainstem.

  2) For subsection 1), permanent cessation of the critical functions of a person's brain can result from cessation of blood circulation to the brain after circulatory arrest or from devastating brain injury.

  3) The determination that a person has died must be made according to accepted medical standards.

  4) In this section—

  Critical functions of a person's brain include the complete absence of any form of consciousness (wakefulness and awareness) and the absence of brainstem function, including the ability to breathe independently.

- Suggest including in the ANZICS or McGee definitions above, an explanation of the term "permanent". For example, "Permanent means that brain function will not resume spontaneously and will not be restored through intervention."[2] This is

[2] Shemie SD, Wilson LC, Hornby L, et al. A brain-based definition of death and criteria for its determination after arrest of circulation or neurologic function in Canada: a 2023 clinical practice guideline. Can J Anaesth. 2023 Apr;70(4):483-557. doi: 10.1007/s12630-023-02431-4. Epub 2023 May 2. PMID: 37131020; PMCID: PMC10203028.

simpler than what is in the current ALRC proposal (under *1.b.i to iii)*, and this alternate proposed wording is sufficient.

Proposal 11 - consistent legal standard for determination of death

Support consistent legal standard for determining death.

Question 8 - Consequences of a determination of death provision that applies for all purposes

It is extremely important that the provisions for death determination apply for all purposes and that they not be specific for circumstances of donation/human tissue laws.

Question 9 - Statutory locations for provisions relating to determination of death

In question 9 option (a) is preferable. Option (b) continues to link provision for death determination with human tissue laws, which is highly undesirable given the need for provisions for death determination to have general application. Similarly with option c, there is a risk that some jurisdictions will continue to include provisions for death determination in human tissue laws (as is currently the case for the majority of jurisdictions).

Proposal 12 - Post-mortem interventions

It is suggested this proposal is important, however further consideration is required to determine if it should be located in legislation. If this statement is meant to deal with the issue of potential post-mortem procedures, such as NRP or other procedures that are part of the organ retrieval surgical procedure, then this type of statement is preferable to that of including specific requirements in law regarding any specific post-mortem procedures. This includes avoiding requirements in legislation for authorisation/consent for specific post-mortem procedures beyond that required as part of the general consent for deceased donation. The general consent for deceased donation and information provided for informed consent should be guided by good medical practice rather than stipulated in legislation.

Proposal 13 - The Dead Donor Rule

The requirements under *part 2.b.i. and ii and part 3.b.i and ii* of this proposal are unnecessarily restrictive and have the potential to create problems for the care of patients in intensive care units. Most laws and guidelines include a requirement that the medical practitioners determining death not be involved in the tissue removal or the allocation of tissue (organs) for transplantation. Current Australian human tissue laws require that medical practitioners permitted to determine death by neurological criteria must not be involved in tissue removal. The NSW Act states a further requirement that the medical practitioners not be "*responsible for the care of the person who is the intended recipient of the tissue*" and in Queensland the medical practitioners not be "*attending a person who is to be the recipient of tissue*."

Canadian guidelines state "*In all cases of potential organ donation, clinicians determining death must not have an association or active involvement in transplant procedures, organ allocation, or care of the intended transplant recipients*".[3]

The UK Code of Practice for the Diagnosis and Confirmation of Death states "*Those diagnosing and confirming death should not be acting on behalf of the organ retrieval and transplant service at that time and must not be involved in the allocation of any of the patient's organs or tissues that may subsequently be donated for transplantation*".[4]

Note: allocation of organs is determined by transplant units and does not involve intensivists.[5]

In hospitals providing both donation and transplantation services, the provision as it currently stands may create difficulty in medical rostering, particularly in paediatric units where long inpatient stays for both potential organ donors and transplant recipients may occur.

Further refinement of the wording is needed. A clearer formulation could use "*medical care of an intended recipient*" or align with UK or Canadian requirements.

The requirement at *part 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...."* is also be unnecessarily restrictive, in requiring that it be a medical practitioner who determines death. There are instances, where death occurs outside of a hospital setting where deceased donation of tissue is to occur for transplantation (e.g. eye or other tissue – not organs) or for other medical, educational or scientific purposes and death might be determined by non-medical practitioners (e.g. nurses, paramedics, etc).

Reforms relating to deceased donation

Proposal 23 - Consent and authorisation for removal of tissue after death

Compared with existing Human Tissue Laws, proposal 23 relegates the importance of prior expressed wishes/decisions of the person regarding donation, including for those who have registered to donate on the Australian Organ Donor Register (AODR). The *elements c and d of "valid consent"* will realistically rarely ever be met in the setting of deceased donation by the deceased individual. This means it will always be the

[3] Shemie SD, et al. A brain-based definition of death and criteria for its determination after arrest of circulation or neurologic function in Canada: a 2023 clinical practice guideline. Can J Anaesth. 2023 Apr;70(4):483-557. doi: 10.1007/s12630-023-02431-4. Epub 2023 May 2. PMID: 37131020; PMCID: PMC10203028.

[4] Academy of Medical Royal Colleges. A Code of Practice for the Diagnosis and Confirmation of Death. 2025 Update. https://www.aomrc.org.uk/2025-code-of-practice-for-the-diagnosis-and-confirmation-of-death

[5] Australian and New Zealand Intensive Care Society (ANZICS) Statement on Death and Organ Donation, Edition 4.1, 2021. Available at: https://www.anzics.org/death-and-organ-donation-app-content/

authorised decision maker (and broader family) who will decide whether donation will proceed.

Current legislation gives primacy to the individual's preferences about donation, with it sufficient to proceed with donation if the person had in advance expressed a wish or given consent to donation. Although practice in Australia is not to proceed in the face of family objection, even if the individual was registered to donate on the AODR, the current legislative framework arguably allows for greater advocacy for the individual's decision to be respected.

The current approach to family communication for individuals registered to donate is that families are informed of this and information is shared about the donation process with an expectation that donation will proceed. Despite this, families currently object to donation in approximately 18% of instances (an increase from about 11% prior to the Covid-19 pandemic years), for a variety of reasons. These include family not wanting to wait the time for donation to be organised, families not liking the idea of donation, or not wanting the patient to "suffer" any longer, family objecting to surgical procedures, cultural and religious reasons, decision makers unable to agree (in reality and different to what the law requires, families usually seek consensus and do not proceed if a family member opposes donation), as well as family believing the person had changed their mind or did not actually want to donate.

Proposal 23 does require that the "*authorised decision-maker must have primary regard to the adult's known beliefs, values, and preferences regarding tissue donation, if any, and make the decision they believe the adult would have made in the circumstances*". Nonetheless, this places the requirement on the authorised decision maker to abide by this primary regard.

The approach in Australia by health professionals to family communication regarding donation has evolved over time, with now considerable advocacy to respect the individual's expressed wish about donation (usually based on AODR registration to donate).

Were proposal 23 to become the new standard, it is likely that, the nature of communication by health care professionals with families of potential donors will change with less advocacy for the individuals prior expressed wishes. It can be envisaged that, the registration status of the person will be shared as well as an exploration of their prior expressed views about donation etc. It will also be conveyed that ultimately it is the family's/authorised decision-maker's decision and, although guidance may well be provided that the family decision about donation should accord with the potential donor's preferences, it will be noted that any such expressed view will have been made without all the details required for valid consent, which only the family are in a position to take into account.

One of the most common complaints voiced by community members (e.g. on talk back radio and other fora) is that family can overturn a person's decision to donate.

It is also debated whether the standard of informed consent should be required for donation of organs and tissue after death.

In the United States, the Uniform Anatomical Gift Act outlines the requirements for organ and tissue donation after death, or the gift of one's body for medical, scientific or

other purposes. A verbal or written expression to donate is sufficient, so called "*first person authorisation*". This legislation has been adjusted over time with strengthening of language regarding one's right to decide for themselves to consent for organ donation, making it harder for a person's wish to be overridden after their death. The approach when a person is registered to donate is to inform the family that donation will proceed, and for donation to go ahead often even in the face of ongoing family objection.[6,7]

The legal status and ethical arguments for respecting an individual's decision to donate or to accept a family's objection and not proceed with donation has been written about extensively.[8, 9] Most clinicians in Australia would not support a United States approach, however, many would also have a view that the individual's preferences about donation should take priority. Arguably proposal 23 does do that, however, it lessens the prioritisation given to the individual's stated preferences as compared to current legislation.

The current proposal for consent and authorisation for removal of tissue after death should be further considered, including whether giving primacy for an individual's expressed view about donation can be strengthened and/or whether the components for valid consent (components c and d) are required for deceased donation when individuals have indicated a desire to donate.

Question 16 - Designated Officer

The existing Designated Officer (DO) role was established when organ and tissue donation and transplantation arrangements in Australia were still developing. With significant advancements in organ donation practices, the implementation of robust policies and processes, and the increasing professionalisation of donation roles, the unique value the DO now provides, especially in relation to improving safety and ensuring compliance with legal and ethical standards for deceased organ donation, is no longer clear. Some stakeholders may perceive some persisting value in the role and, if so, it should be clarified whether the DO role is the best means for any perceived need to be met.

It has been suggested that when eye donation occurs within the hospital setting, the DO provides a useful oversight, given that the process involves an individual from the eye donation service attending the hospital to undertake the eye retrieval. However, speaking with personnel from the eye donation service, they are often having to guide the DO through their role, the DO often introduces delays to the process (in accessing

---

[6] Iltis AS, Denny B. First-Person Authorization and Family Objections to Organ Donation. J Med Philos. 2025 Apr 18;50(3):212–24. doi: 10.1093/jmp/jhaf008. Epub ahead of print. PMID: 40249157; PMCID: PMC12097891.

[7] W.J. Chon, et al. When the Living and the Deceased Cannot Agree on Organ Donation: A Survey of US Organ Procurement Organizations (OPOs), American Journal of Transplantation, Volume 14, Issue 1, 2014, Pages 172-177, ISSN 1600-6135, https://doi.org/10.1111/ajt.12519.

[8] Shaw, D. et al. Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions. Transplantation 101(3):p 482-487, March 2017. | DOI: 10.1097/TP.0000000000001536

[9] Toews M, Caulfield T. Evaluating the "family veto" of consent for organ donation. CMAJ. 2016 Dec 6;188(17-18):E436-E437. doi: 10.1503/cmaj.160752. Epub 2016 Nov 14. PMID: 27920112; PMCID: PMC5135519.

the DO and having them undertake the authorisation process), and the view conveyed was that the DO does not really add any improvement to the process, given the processes are well established. Note: this check is not in place where eye donation occurs in non-hospital settings.

If the DO role is kept, there should be a clear rationale for which settings the role is required, noting the reason for the existing demarcation of "in-hospital" deaths requiring DO authorisation and those out-of-hospital" not requiring DO authorisation is not currently clear.

Question 17 - Autonomy of the individual

Proposal 23 shifts away from respecting the autonomy of the individual toward prioritizing the views of the family.

Question 18 - Form of consent to deceased donation

These requirements as stated in current Human Tissue Laws have always been problematic. As suggested in the discussion paper Victoria's legislation where it is stated "*during the last illness orally in the presence of two witnesses*" is not possible in the vast majority of circumstances. In writing at any time before their death has been a limitation in providing sufficient weight to the decision of individuals registered to donate on the AODR, given most of these registrations are not "in writing". There should be flexibility and modernisation in the manner in which individuals can express their choice about donation, noting the current and possible future means of registering donation preferences on the AODR.

Proposal 24 - Voluntary assisted dying (VAD)

DonateLife agencies in collaboration with jurisdictional health departments and services have developed protocols and guidelines to support organ donation in the context of VAD. National best practice clinical guidelines are being explored and work with VAD practitioners continues to understand the guidelines and community education needed.

Authorised decision-maker

Question 19 - Hierarchy of decision-makers

Agree with the aim to modernise and, where possible, align the hierarchy of substitute decision makers for deceased donation with other legislation. The proposed list based on the *NT HealthCare Decision Making Act 2023* seems reasonable. Consideration is required regarding *part b. "a guardian of the person appointed under Guardianship legislation*", who may not be sufficiently familiar with the person's beliefs, values, and preferences to be best placed to make a decision about organ and tissue donation. The inclusion of *part i. "a friend of the person who has a close and continuing relationship with the person"* is useful, as in many instances where there is no immediate family, such a person is well placed to convey the views and wishes of the person.

Question 20 - Authorised decision-makers hierarchy

In practice, when there is lack of agreement by family members, even those without decision making authority, donation seldom proceeds.

Pre-mortem interventions

Question 21- pre-mortem interventions definitions

It is important to recognise that no internationally agreed definition of pre-mortem interventions currently exists. However, a broad approach is generally recommended. Attempts to define pre-mortem interventions too narrowly tend to result in arbitrary distinctions regarding what qualifies as a pre-mortem intervention and what does not.

Notably, international consensus work led by the European Society for Transplantation (ESOT) in 2024–2025 has produced a draft consensus definition: "*An ante mortem intervention is any activity, procedure, or investigation undertaken before death for the purpose of donation that would not otherwise occur, including those to determine, maintain or improve the viability of organs and tissues for transplantation*".

Question 22 - Specific pre-mortem interventions

An approach that avoids prescribing permissible pre-mortem interventions directly within legislation is highly desirable. Recent international consensus work led by the European Society of Transplantation to develop recommendations that provide ethical, clinical, and operational guidance for establishing and sustaining adult controlled donation after circulatory determination of death (cDCDD) programs (*in process of publication*) has high consensus for the following statement: "*Legislation for deceased donation should not detail specific permissible ante-mortem interventions, so as to avoid unintended constraints on future practice given the continuous evolution of medicine and transplantation*".

Recent amendments in NSW, Victoria and Queensland legislation have been beneficial in some respects, although include components that are problematic.

The detailed specification of permissible pre-mortem interventions should be in guidelines developed by professional organisations with relevant expertise. For example, the ANZICS submission to the ALRC cites the *UK Donor Actions Framework*, a potential foundation which is recognised internationally and favourably regarded within Australia. ANZICS proposes an Australian version of this framework to be incorporated into the ANZICS *Statement on Death and Organ Donation*.

It is also important to highlight that a critical issue concerning the permissibility of pre-mortem interventions is the process of obtaining consent or authorisation from authorised decision makers and/or the DO.

With a broad definition of pre-mortem interventions, it is essential to recognise that certain interventions must occur before it is feasible to obtain consent. For instance, preliminary assessment of donor suitability or the continuation of physiological supportive treatments (mechanical ventilation and drugs that maintain blood pressure and circulation) for donation purposes.

Proposal 49 of the Discussion Paper that relates to preliminary assessment of donor suitability or donor screening could also be considered a pre-mortem intervention. Proposal 49 seeks to allow certain people to access and share information for identification and screening purposes: "medical practitioners, health authorities, and DonateLife staff can access and share with each other relevant information for donor identification and screening". This could be considered an "activity" performed on a

living person solely for the purpose of tissue donation after death, including to assess organs for transplantation and to fall within the definition for a pre-mortem intervention (proposal 26), which would be prohibited (proposal 27).

The *UK Donor Actions Framework* offers a categorisation of donor actions based on consent status ('before consent' and 'after consent')[10]. The listed donor actions prior to consent for donation (pre-mortem interventions) considered 'very likely' or 'likely' to be in a patient's best interests include:

- Identifying potential organ donors and alerting the donation team.
- Gathering and sharing clinical information with the donation team or Coroner.
- Speaking to the patient's family about donation.
- Temporarily continuing life-sustaining treatments and clinically stabilising the patient in an appropriate critical care setting while a decision regarding donation is made.
- Confirming death using neurological criteria.
- The introduction of routine intensive care treatment to maintain physiological stability such as introducing inotropic support, anti-arrhythmic or the siting of central and arterial lines.
- The taking, storage and testing of blood or other samples (e.g., urine or respiratory samples) for the purpose of transplantation from patients known to be willing to donate.

The current wording in proposal 27 could mean that donation would not be able to be supported in many situations where it currently is, due to prohibition of various activities required to preserve or explore the opportunity for donation prior to it being feasible to obtain valid consent.

A solution is required. An option is to modify the authorisation requirements, so that valid consent is not required for those activities related to the identification and/or preservation of the opportunity for donation. Also perhaps to refer to good medical practice or similar and use existing authorities and/or professional clinical organisations to provide policies/guidelines on what pre-mortem interventions are acceptable, including prior to consent.

Question 23 - Pre-mortem interventions safeguards

It is worth noting that even with valid consent, some pre-mortem interventions would not be considered ethically and medically acceptable. For example, those with the potential to cause significant harm or for which there is no clear clinical indication. Therefore, some reference to good medical practice and use of existing authorities and/or professional clinical organisations to specify what pre-mortem interventions are acceptable is necessary.

[10] A Professional, Ethical and Legal Framework for Deceased Organ Donation Actions, June 2022, version 1.0. Available at: https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donation-actions-framework/

Coronial consent to donation

Question 24 - factors coroners should take into account

A substantial number of deceased donation opportunities are lost due to coronial refusal for donation, as well as refusal for specific organs and/or tissues through partial coronial restrictions, particularly the heart and eye tissue. The legislation delineating the responsibilities of the coroner emphasizes the necessity for the coroner to establish the cause of death. Coroners frequently collaborate with forensic pathologists to decide whether to permit, refuse or partially restrict organ and/or tissue donation. Reasons given for refusing or restricting donation are that the organ donation retrieval procedure might interfere with the assessment of the cause of death, including the post-mortem examination.

Modern medical imaging and other investigative techniques have rendered post-mortem examinations (autopsies) largely unhelpful in determining the cause of death. It is noteworthy that there has been no published report indicating a significant impact on death determination or trial outcomes caused by organ retrieval[11]. The organ donation workup process often yields additional valuable information, including extra imaging such as functional imaging (e.g. heart echocardiography), which would not be information otherwise available to forensic pathologists and coroners. The very fact that organs are deemed suitable for transplantation implies that they are unlikely to have contributed to the cause of death, or at least not in a way in which their preservation for a post-mortem examination would elucidate. Forensic pathologists are able to attend the organ retrieval operation, and photos/videos relevant to investigations can be taken upon request of the coroner and forensic pathologist.

Permitting donation enables the provision of information arguably far superior to that which might be obtained by restricting donation for the purpose of having organs to assess at a post-mortem examination.

Additionally, literature states some coroners worry that the occurrence of donation could be exploited in the defence during criminal cases related to the death, despite a lack of evidence to support such claims.[12]

Variability in coronial refusals is evident, with such refusals appearing less frequently among more experienced coroners and forensic pathologists. Donation clinicians invest considerable effort in sharing information and educating local coroners and forensic pathologists, to support further understanding of the rarity of donation opportunities. This educational effort is particularly crucial for heart donation, especially in the paediatric context. In Australia in 2024, 105 heart transplants were performed, and only a small number were child recipients who require a size matched organ.

---

[11] Nunnink L, Wallace-Dixon C. The impact of organ donation on coronial processes and forensic investigation: A literature review. J Forensic Leg Med. 2020 Apr;71:101940. doi: 10.1016/j.jflm.2020.101940. Epub 2020 Mar 13. PMID: 32342910.

[12] Nunnink L, Stobbs N, Wallace-Dixon C, Carpenter B. Does organ donation impact on forensic outcomes? A review of coronial outcomes and criminal trial proceedings. J Forensic Leg Med. 2019 Nov;68:101860. doi: 10.1016/j.jflm.2019.101860. Epub 2019 Aug 27. PMID: 31525621.

Each coronial refusal to allow the transplantation of a vital organ results in the death of a person who could have otherwise benefited from that transplant. Unfortunately, coroners and pathologists are often reluctant to acknowledge this reality.

Legislation should ensure that coroners are required, whenever possible, to facilitate organ donation, with all effort undertaken to minimize coronial declines.

Proposal 49 - Allowing certain people to access and share information for identification and screening purposes

It is important to provide legal clarity to support the recommended practice of routinely screening patients approaching end of life for donor suitability, that is, undertaking preliminary donor suitability assessment using available information (e.g. reviewing the hospital medical record) prior to raising donation with the family/authorised decision maker (that is, prior to seeking valid consent for donation).

Note also that the activity of accessing and sharing information for donor identification and screening purposes might be considered to fall within the definition of a pre-mortem intervention (as per Proposal 26).