

The Australian and New Zealand Intensive Care Society (ANZICS) response to the Australian Law Reform Commission Discussion Paper 90 titled:

## **Discussion Paper of the Review of Human Tissue Laws**

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As stated in the ANZICS response to the Issues paper, ANZICS is the leading binational advocate on all intensive care related matters. Since 1993 ANZICS has set the medical standards for the determination of death in the setting of organ donation in Australia and New Zealand through the ANZICS Death & Organ Donation Committee (DODC). The ANZICS DODC is a sub-committee of the Board of ANZICS (<https://www.anzics.com.au/death-and-organ-donation/>). The committee members are all practising intensivists representing all Australian jurisdictions and New Zealand. The majority of committee members also have close links or paid positions in relation to the OTA or Organ Donation New Zealand.

**Our response to selected questions is as follows, in *italics*:**

### **1. A nationally harmonised regulatory framework**

#### **National legislative framework**

##### **Proposal 1**

The retrieval, storage, and use of human tissue in Australia for medical, educational or scientific purposes should be regulated either:

- a. with substantial consistency across states and territories through a coordinated and harmonised set of state, territory, and Commonwealth legislation; or
- b. uniformly by Commonwealth legislation.

##### ***ANZICS response:***

*Definitely as Commonwealth legislation which has a legally overriding impact across all jurisdictions and ensures consistency of practice, particularly given that intensive care clinicians work in different jurisdictions and organs and tissues cross borders and will, therefore, have the same retrieval, storage and use in all jurisdictions. This should be at high level and enable regulation at a jurisdictional level.*

*A single National Regulator should be established (Proposal 3) and responsible for setting codes of practice, guidelines and standards, and for enforcing compliance.*

##### **Proposal 2**

The regulatory framework established by Proposal 1 should be structured so that:

- a. the substance of any obligation, right, entitlement, or prohibition conferred or imposed, is dealt with in legislation; and
- b. any necessary corresponding detail is dealt with by delegated legislation, or codes of practice, guidelines or standards set by the National Regulator (Proposal 3) or other responsible agencies or organisations.

##### ***ANZICS response:***

*Given the changes in medical and scientific knowledge, technology and practice are constantly changing it is best to leave as much of the detail in codes of practice, guidelines or standards. An*

*excellent example has been the fact that the legislated definition of death has worked well for 50 years, with the medical requirements to correctly determine death, particularly brain death, has been successfully managed by the ANZICS Statement.*

## **National Regulator**

### **Proposal 3**

The Australian Government should establish a National Regulator by:

- a. expanding the powers and functions of the Organ and Tissue Authority by amending the Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth); or
- b. establishing a new statutory regulatory body, which would incorporate the Organ and Tissue Authority as a branch within the new statutory regulatory body; or
- c. establishing a new statutory regulatory body, which would supplement and support the existing powers and functions of the Organ and Tissue Authority in a way that is consistent with the goal for national governance set out in the National Strategy for Organ Donation, Retrieval and Transplantation.

The National Regulator could have the following powers and functions:

- set national policies in relation to human tissue;
- create binding codes of practice and standards;
- provide guidelines for medical practitioners, researchers, and organisations that retrieve, store or use human tissue;
- provide educational material for the general public about tissue donation;
- accredit and license entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors;
- monitor, collect data, investigate, and enforce compliance with human tissue laws and codes using both civil and criminal penalties.

To avoid duplication of responsibility for areas that are already regulated, in establishing the National Regulator, regard should be had to the scope of other regulatory entities in Australia, such as the:

- Therapeutic Goods Administration;
- National Blood Authority; and
- the Organ and Tissue Authority.

The Human Tissue Regulator should be adequately funded to carry out its powers and functions.

### ***ANZICS response:***

*There is a need to have better regulation of the operational side of organ donation and transplantation and this would be best served with option c of proposal 3. The National Regulator should be independent of OTA and report to the Federal Health Minister. Options a. and b. could result in real and/or perceived conflicts of interest. OTA and the organ and tissue transplant sectors have the roles of developing and implementing policies and practices and the independent National Regulator oversee the performance of OTA and the organ and tissue transplant sectors.*

*ANZICS does not support the National Regulator writing the guidelines and codes of practice (like in the UK) as these roles are already well conducted by the experts in the existing groups within OTA and the organ and transplant sectors.*

*The roles of the National Regulator would include the oversight of the donation practice in each hospital currently performed, with greatly varying competence, by the Designated Officers (see response to Proposal 23, question 16).*

*To be effective the National Regulator must be adequately funded and resourced.*

## **Implementing a national legislative framework**

### **Proposal 4**

To implement Proposals 1–3, the Commonwealth, states, and territories should come to an intergovernmental agreement to implement national uniform legislation. The structures of national uniform legislation that could be implemented include:

- a. referred legislation;
- b. applied legislation;
- c. mirror legislation; or
- d. hybrid legislation — referred/applied legislation or mirror/applied legislation.

### **ANZICS response:**

*ANZICS is agnostic to the structure of the legislation but emphasises that there be agreement across all jurisdictions to adopt similar (as close to identical as is practicable) legislation such that clinical and operational practice is identical for intensive care clinicians and organ donation practitioners in all jurisdictions and that the implementation of the new laws occurs as close to the same time as possible across all jurisdictions in order to facilitate education and training to all staff.*

## **2. The objects of human tissue laws**

### **The objects of human tissue laws**

#### **Proposal 5**

New human tissue legislation should include an opening section explaining that the objects of the legislation are to:

- a. modernise and ensure adaptability and consistency in the laws and regulatory frameworks governing the donation of human tissue, and use of human tissue for medical, educational and scientific purposes;
- b. increase access to human tissue, and to the benefits of human tissue donation, transplantation and use;
- c. ensure that the donation, and use of human tissue for medical, educational or scientific purposes, is consistent with Australia’s international human rights obligations;
- d. promote equity and reduce inequities in access to human tissue and the benefits of human tissue use;
- e. ensure respect for individual dignity and autonomy, and for the human body;
- f. prevent the exploitation of individuals in relation to how their tissue is removed, and used for medical, educational and scientific purposes; and
- g. promote public trust in the laws and regulatory frameworks that govern human tissue donation and use for medical, educational or scientific purposes.

#### **Question 1**

Do you agree with the objects listed in Proposal 5 for human tissue legislation?

**ANZICS response:**

Yes

**Question 2**

Aside from the objects set out in Proposal 5, should new human tissue legislation include other objects?

**ANZICS response:**

No comment

**National Regulator to have regard to the objects**

**Proposal 6**

In carrying out its functions, including in relation to the creation of guidelines and codes of practice, the National Regulator (or alternative) (Proposal 3) must have regard to the objects of the new human tissue legislation.

**ANZICS response:**

No comment

**3. Removing barriers and promoting equitable access to human tissue**

**Promoting equity**

**Question 3**

Is there a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use?

**ANZICS response:**

No comment

**Removing barriers**

**Question 4**

If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (Question 3), what are the specific barriers that new human tissue legislation needs to address?

In considering this question, please ignore:

- definitions of senior next of kin that may be outdated and unsuitable (we address these in Proposal 25); and
- disclosure of information provisions that in some jurisdictions prevent the families of deceased donors talking about their family member's experience (we address these in Proposals 46 and 48).

**ANZICS response:**

No comment

## 4. Reforms relating to the definition of tissue

### Definition of human 'tissue'

#### Proposal 7

New human tissue legislation should include a definition of human 'tissue' (or an alternative label for human tissue) that is broad and provides for a flexible mechanism to adjust the definition.

#### Question 5

How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad?

In your response, you might consider the following options:

- a. tissue means material which consists of, includes, or derives from human cells (a definition based on section 54 of the Human Tissue Act 2004 (UK)); or
- b. tissue means the human body or any constituent material, substance, or part removed from a human body that is, includes, or derives from human cells (a definition based on section 7 of the Human Tissue Act 2008 (NZ)).

#### **ANZICS response:**

*No comment*

#### Question 6

In new human tissue legislation, should the word 'tissue' be replaced with another label?

In your response, you might consider alternative options such as:

- a. 'substance of human origin';
- b. 'human material'; or
- c. 'cell, organ, and tissue'.

#### **ANZICS response:**

*Support the continued use of the term "tissue" as long as it is correctly defined in legislation. Legislation for non-lawyers, eg clinicians, is hard enough to read as it is and, therefore, the use of longer options, such as suggested above, simply lengthen the legislation and make reading and following multiple clauses unnecessarily more difficult.*

### Adjusting the scope of the definition

#### Proposal 8

The human tissue regime should have a mechanism to adjust the scope of the definition of 'tissue' (or an alternative label) by authorising the National Regulator (or alternative) to make delegated legislation for this purpose.

#### **ANZICS response:**

*There is no evidence that the current definition of “tissue” in the existing Human Tissue Acts or similar is inadequate. Nor is there evidence that human tissue is going to change. If there is evidence that the current definition of “tissue” is not broad enough then the definition in the NZ Human Tissue Act 2008, as shown in table 4, should be adopted.*

## **Guidelines to support the definition**

### **Proposal 9**

The National Regulator (or alternative) should, as part of its function, create guidelines to provide interpretive guidance and clarity about the definition and scope of ‘tissue’ (or an alternative label).

#### **ANZICS response:**

*No comment*

## **Exclusions from the definition**

### **Question 7**

Should any of the following materials be excluded from human tissue laws, or excluded from the operation of human tissue laws for particular purposes, circumstances, or provisions of the new human tissue legislation?

- Human milk.
- Foetal tissue.
- Faecal tissue.
- Gametes (from deceased donors).
- Cell lines.

If you think some of the above materials should be excluded from human tissue laws (either completely or for particular purposes, circumstances, or provisions), why?

Are there other types of tissue that you think should or should not be regulated by human tissue laws?

#### **ANZICS response:**

*No comment*

In your response, you may want to consider Proposal 5 (the objects of human tissue laws) Proposals 40–44 (reforms relating to the prohibition of domestic trade) and Proposals 32–39 (reforms relating to tissue donation for research).

## **5. Reforms relating to the determination of death**

### **New statutory provisions for determining death**

#### **Proposal 10**

Statutory provisions for determining death should contain the following:

**Section X** When death occurs

1. For the purposes of the law, a person dies when there has been a permanent cessation of the person's critical brain functions, determined in accordance with section Y, where 'permanent' means:

- a. that the critical functions of the person's brain cannot resume on their own; and
- b. that the critical functions of the person's brain will not be restored through intervention because:
  - i. it is not possible to restore those functions through intervention; or
  - ii. intervention would violate a valid end-of-life decision made by or on behalf of the person; or
  - iii. intervention or the continuation of intervention would be contrary to accepted medical practice in end-of-life care.

2. In this section

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

### **Section Y** Determination of death

1. A determination that a person has died under section X must be made according to accepted medical practice.
2. Regulations may identify professional standards or guidelines for the purpose of determining accepted medical practices under (1).
3. To determine the death of a person where the person's respiration is being maintained by artificial means, two registered medical practitioners, one of whom is a specialist and both of whom have been registered medical practitioners for a period of at least five years, must each confirm in writing that they have carried out a clinical examination of the person and, in their opinion, the person has suffered a permanent cessation of the critical functions of the person's brain, within the meaning of section X.

### **ANZICS response:**

1. *ANZICS supports a unified definition of death centred on the death of the brain as it is consistent with the understanding that a person's circulation can stop for a period of time (eg cardiac arrest, severe hypothermia, circulatory arrest during some cardiothoracic surgery) and the person can recover without brain damage. It may also assist in correcting the public misunderstanding that a patient has apparently died when their heart has temporarily stopped, or that restoration of circulation in someone whose brain has permanently ceased to function does not mean that they have been restored to life.*
2. *The primary intention of changing the definition of death is to ensure that it corresponds with current medical understanding of the unified definition of death and aligns with the clinical guidelines and codes of practice of similar respected international medical organisations. A secondary benefit of this change is that it will enable normothermic regional perfusion of organs in the deceased potential organ donor, a procedure that is not compliant with the current definition of death.*
3. *Having reviewed Proposals 10 and 13, ANZICS responds as follows:*
4. *The proposed definition of death, modified from the ANZICS response to the Issues Paper, is:*

5. **Section X** “For the purposes of the law, a person has died when there is permanent cessation of the person’s critical brain functions as a result of a devastating brain injury or cessation of circulation of blood in the brain after circulatory arrest, as determined in accordance with **section Y**.”

*A cessation of the critical functions of a person’s brain requires the complete absence of any form of consciousness (wakefulness and awareness) and brainstem functions, including the ability to breathe independently.*

*Where ‘permanent’ in **section X** means that brain function will not resume spontaneously and will not be restored through intervention.<sup>1</sup>*

#### **Section Y** Determination of death

*A determination that a person has died under **section X** must be made according to accepted medical practice.*

*To determine the death of a person where the person’s respiration is being maintained by artificial means, two registered medical practitioners, one of whom is a specialist and both of whom have been registered medical practitioners for a period of at least five years, must each confirm in writing that they have carried out a clinical examination of the person and, in their opinion, death has occurred within the meaning of **section X**.*

*To determine the death of a person where the person’s respiration is not being maintained by artificial means a registered medical practitioner (or suitably qualified health practitioners) must confirm in writing that they have carried out a clinical examination of the person and, in their opinion, death has occurred within the meaning of **section X**.*

6. The legal definition of death set out in sections X and Y achieve the following:
  - a. A unified definition of death
  - b. A definition of death that is independent of human tissue legislation, including the “Dead Donor Rule”, so that the definition can apply to all deaths in Australia irrespective of organ donation.
  - c. It maintains the ability of general practitioners, hospital doctors, paramedics, etc to determine death based on circulatory arrest, which is more than 99% of death determinations in Australia.
  - d. It mitigates the widespread confusion that arose in hospital medical practitioners with the definition of death proposed in the discussion paper, which included many thinking that, in order to determine death in a person whose circulation had ceased, that they would need to undertake neurological assessment of the person’s brain.
  - e. It permits the institution of normothermic regional perfusion as part of the organ retrieval surgery.
7. The confusion amongst non-ICU hospital doctors referred to in 6. d. could not be corrected by the ANZICS Statement or similar as the target for these documents is ICU doctors.

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<sup>1</sup> 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

8. *In section X, we recommend “a person has died” rather than the ALRC phrase “a person dies’ because the determination of death is always after the event. It is at a point in time that the determination is made, not an event that is captured at the moment that it occurs.*
9. *ANZICS does not support the proposed ALRC definition of permanent - it is confusing, too detailed, and unnecessary and may create problems. An explanation of “permanent” is necessary and we have provided a simpler definition that derives from the Canadian definition with a reference at the bottom of page 8.*

## **New statutory location for the determination of death provisions**

### **Proposal 11**

Commonwealth, state and territory legislation should contain a consistent legal standard for determining death, as set out in Proposal 10. By an intergovernmental agreement, measures should be put in place to maintain consistency of this definition over time.

#### ***ANZICS response:***

*Agree*

## **Consequences of a determination of death provision that applies for all purposes**

### **Question 8**

If the proposed determination of death provisions apply for all purposes rather than only for the purpose of human tissue laws, will there be any adverse and unintended consequences in areas of law other than human tissue laws?

We note that with the exception of Queensland, current state and territory legislative provisions relating to the determination of death apply for all purposes rather than only for the purpose of human tissue laws.

#### ***ANZICS response:***

*Agree*

## **Maintaining national consistency**

### **Question 9**

To maintain national consistency, which of the following statutory locations or approaches would be most appropriate for provisions relating to the determination of death, assuming that these provisions apply for all purposes?

- a. A ‘Uniform Death Act’, adopted as national uniform legislation in each state and territory; or
- b. New human tissue legislation (Proposal 1); or
- c. Each state and territory decide where to locate the determination of death provisions but make an intergovernmental agreement that there be a consistent approach to future amendments to these provisions.

#### ***ANZICS response:***

*Option a.*

## **Post-mortem interventions**

### **Proposal 12**

The following provision should be included in new human tissue legislation:

When tissue will be removed for the purpose of transplantation into the body of another person or for other medical, educational or scientific purposes, any post-mortem interventions must be conducted in accordance with accepted medical practice.

For the purpose of determining accepted medical practice, regulations can specify professional standards or guidelines to be complied with.

#### ***ANZICS response:***

*Agree. Do not put details about post-mortem interventions into legislation. Enable regulations to specify that professional standards and guidelines are to be complied with.*

## **The Dead Donor Rule**

### **Proposal 13**

New human tissue legislation should include provisions that provide safeguards to ensure deceased donation only proceeds after it has been determined that a person has died. These provisions should provide that:

1. Where deceased donation of tissue is occurring for transplantation or other medical, educational or scientific purposes, tissue cannot be removed from the body until there has been a confirmation of death in accordance with this section.
2. Where a deceased person's respiration is being maintained by artificial means:
  - a. the confirmation of death requirements under section Y(3) must be met; and
  - b. neither medical practitioner confirming death can 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.
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; and
  - 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.

#### ***ANZICS response:***

ANZICS does not support the current wording of clauses 2. and 3. in Proposal 13. We recommend the following amended wording:

2. Where a person has been determined to be dead under section Y of Proposal 10, the medical practitioner(s) involved in the determination of death cannot be involved in or be responsible for:

- a. the removal of tissue, or
- b. any medical, educational or scientific use of the removed tissue or
- c. the allocation of the tissues to potential recipients

*For the purposes of organ donation the roles and qualifications of medical practitioners involved in determining the death of the potential donor can be set out in Proposal 13. The wording regarding the role of the medical practitioner needs to be carefully considered. The decision as to who receives the retrieved organs is solely that of the transplant unit physicians and surgeons. The intensive care doctors have never participated in that decision even if the potential recipient is being cared for in the ICU. If the proposed legislation prohibits an ICU specialist who is caring for a potential recipient in an ICU that cares for patients with severe heart, lung or liver failure, from being able to determine death in another person in the same ICU, then this will have major implications on the staffing and running of many ICUs in Australia, particularly paediatric ICUs. There has never been any actual or perceived conflict of interest in this regard.*

*In the UK Code of Practice for the Diagnosis and Confirmation of Death, it 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.*

*In the setting of the proposed unified definition of death it will be of paramount importance to ensure that there is rigid guidance and regulation regarding normothermic regional perfusion (NRP) to be in no doubt that there is no restoration of blood circulation to the brain caused by NRP.*

## **6. Reforms related to the donation of tissue by living persons**

### **Consent and authorisation for removal of tissue from living persons**

#### **Proposal 14**

New human tissue legislation should provide:

1. That an adult may give valid consent to the removal of tissue from their body for the purpose of transplantation into the body of another person, or for other medical, educational or scientific purposes;
2. Valid consent is:
  - a. given voluntarily;
  - b. given at a time when the adult who is consenting has decision-making capacity;
  - c. given after the adult who is consenting has been informed about the nature, effect, and material risks of the removal;
  - d. given after the adult who is consenting has been informed about the intended use of the tissue after it has been removed; and
  - e. able to be withdrawn at any time before the removal of the tissue.

3. Valid consent is sufficient legal authority for the removal and use of the specified tissue for the specified purpose(s).

4. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in Proposal 32 must be met.

### **Additional safeguards**

#### **Question 10**

Are there additional safeguards aside from those set out in Proposal 14 that should be set out in new human tissue legislation?

#### **ANZICS response:**

*No comment*

### **Definition of 'adult' and 'child'**

#### **Proposal 15**

New human tissue legislation should define an adult as a person who is 18 years of age or older, and a 'child' as a person who is under 18 years old.

#### **ANZICS response:**

*No comment*

### **Donation of blood**

#### **Proposal 16**

New human tissue legislation should provide that for the purpose of blood donation, a child aged 16 years or older is deemed to be an adult.

#### **ANZICS response:**

*No comment*

### **Donation of tissue by children**

#### **Proposal 17**

New human tissue legislation should:

- a. allow a parent or guardian of a child, or a child with decision-making capacity, to bring an application to a Committee constituted under the legislation to determine if tissue can be removed from the child's body for the purpose of transplantation, or for other medical, educational or scientific purposes; and
- b. provide that an application to the Committee is not required for the removal of tissue for use in research that satisfies the requirements of Proposal 35.

#### **ANZICS response:**

*No comment*

#### **Proposal 18**

The Committee (Proposal 17) should have the power to authorise removal of tissue if it is in the child's best interests. For the purpose of determining whether a valid application has been made by a child, the Committee should be empowered to determine if the child has decision-making capacity.

**ANZICS response:**

*No comment*

**Proposal 19**

New human tissue legislation should provide that in determining if removal of tissue for transplantation or for other medical, educational or scientific purposes is in a child's best interests, the Committee (Proposal 17) should apply a broad interpretation of 'best interests' that takes into account, among other considerations:

- the child's views, if any, given, where appropriate, directly by the child;
- the child's age and level of understanding;
- the child's physical and psychological wellbeing;
- the child's relationship with the intended tissue recipient;
- the views of the child's parent(s) or guardian(s) or other persons who have a significant relationship with the child;
- the support available for the child after removal of their tissue; and
- the availability of an alternative donor.

Additionally:

- Where a child does not have decision-making capacity, donation should only be approved with the consent of a parent or a guardian.
- If a child has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.

**Question 11**

Are the considerations listed, and the guidance provided, in Proposal 19 appropriate? Are there additional considerations that the Committee (Proposal 17) should take into account?

**ANZICS response:**

*No comment*

**Question 12**

Aside from the removal of tissue from a child for use in research (Proposal 35), are there situations where the removal of tissue from a child should not require approval by a Committee, and where new human tissue legislation should require only parental consent, or individual consent where a child has decision-making capacity?

**ANZICS response:**

*No comment*

**Donation of tissue by adults who do not have decision-making capacity**

## **Proposal 20**

New human tissue legislation should enable a legally authorised substitute decision-maker or guardian of an adult who does not have decision-making capacity to bring an application to a Committee constituted under the legislation to determine if tissue can be removed from the person's body for the purpose of transplantation or for other medical, educational or scientific purposes.

### ***ANZICS response:***

*No comment, as this relates to donation by living persons.*

## **Proposal 21**

The Committee (Proposal 20) should have the power to authorise donation if it is in the proposed donor's best interests.

### ***ANZICS response:***

*No comment*

## **Proposal 22**

New human tissue legislation should provide that in determining if a donation is in the best interests of an adult who does not have decision-making capacity, the Committee (Proposal 20) should apply a broad interpretation of 'best interests' that takes into account, among other considerations:

- the proposed donor's views, given, where appropriate, directly by the proposed donor, or from sources reflecting the proposed donor's views from a time when they had decision-making capacity;
- the proposed donor's physical and psychological wellbeing;
- the proposed donor's level of understanding;
- the proposed donor's relationship with the intended recipient;
- the support available for the proposed donor after the removal of their tissue; and
- the availability of an alternative donor.

Additionally, if the proposed donor has consistently expressed an unwillingness to have their tissue removed, the Committee must not authorise the removal.

## **Question 13**

Are the considerations listed, and the guidance provided, in Proposal 22 appropriate? Are there additional considerations that the Committee (Proposal 20) should take into account?

### ***ANZICS response:***

*No comment*

## **Question 14**

Are there situations where donation from adults who do not have decision-making capacity should not require approval by a Committee and where new human tissue legislation should require only consent by a legally authorised substitute decision-maker?

See also Question 28 where we are seeking feedback on whether specific consent requirements should exist to allow adults without decision-making capacity to donate tissue for research purposes.

**ANZICS response:**

*No comment*

## **Composition of committee**

### **Question 15**

What is an appropriate composition for a Committee under Proposals 17 and 20?

We are seeking input about the qualifications and/or experience of people who should be on the Committee; and also if there should be a national Committee or multiple state and territory Committees.

**ANZICS response:**

*No comment*

## **7. Reforms relating to deceased donation**

### **Consent and authorisation for removal of tissue after death**

#### **Proposal 23**

1. New human tissue legislation should provide that:
2. 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.
  - a. If an adult is close to death and does not have decision-making capacity, or dies without having provided valid consent, the adult's authorised decision-maker may give valid consent to the removal of tissue from the adult's body for transplantation or for other medical, educational or scientific purposes.
  - b. When deciding whether to give consent, 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.
3. If a child is close to death or has died, the child's authorised decision-maker may give valid consent to the removal of tissue from the child's body after death for transplantation or for other medical, educational or scientific purposes.
4. Valid consent is:
  - a. given voluntarily;
  - b. given at a time when the person consenting has decision-making capacity;
  - c. given after the person consenting has been informed about the nature and effect of the removal of the tissue;
  - d. given after the person consenting has been informed about the intended use of the tissue; and
  - e. able to be revoked at any time before the removal of the tissue.
5. Valid consent is sufficient legal authority for the removal of the specified tissue and for the specified uses.

6. Where tissue is removed for use in research, the requirements under this section do not apply, and the requirements set out in Proposal 36 must be met.

**ANZICS response:**

*The proposal may have the result that very few individuals will realistically have provided “valid consent” prior to their death, because the standard required for such consent (as stated) is high. In particular, the requirement that the person has been informed about the nature and effect of tissue removal and intended use of the tissue may not be able to be clearly demonstrated for someone registering on the Australian Organ Donor Register (AODR), potentially diminishing the authority of such registration. In fact point 7.44 (page 76) indicates that this proposal may be in response to concerns that joining the AODR may not meet the standard for valid consent, but a reduction in the value of registration may not be desirable given its strong association with consent to donation is the current system. In effect, the view of the authorised decision maker (family) will potentially take priority.*

*It is not clear whether the proposed legislation will mean that first person consent to OD replaces registration as an intended donor, or whether the two systems will be complementary.*

*Our recommendation is not to introduce first person consent as the main route to consent for OD and tissue donation.*

*Informed consent requires the person to consider the process and mechanisms of OD and tissue donation, and this is a bespoke and a myriad of variations depending on the context (BD, Circulatory determination of death), where WLST occurs and consenting around this, the timing, organs and tissues retrieved, context of donation procedure (OT, mortuary) and use of the body, tissues or organs. Currently, we offer a bespoke, patient and context specific consent thru the surrogate or less commonly, first person consent (in VAD and conscious withdrawal of life sustaining therapies).*

*It is impractical to consent a patient for every possible way that it can play out. Only 1/50 deaths are possible for OD, so that is 50 wide ranging consents for every first-person consent that is acted on. This is a very labour intensive and resource intensive process.*

*First person consent should only be offered where there is imminent death and the patient is conscious: VAD, conscious withdrawal of life sustaining therapies and palliation where the context of death is imminent.*

*If first person consent is introduced, there are already over 7 million registered intents and the integrity and status of these registered intents has to be maintained. This mechanism, whereby an intent and general support for OD is registered, should remain the main route of documentation of wishes, recognising this falls short of consent.*

*It is important that as well as recording intent, that a person should be able to nominate surrogates, who agree to act in this role.*

*The hierarchy for consent for organ donations could be:*

*First person (if introduced widely) for specific contexts (as above).*

*Surrogate acting according to registered, recorded or expressed wishes*

*Surrogate acting according to their belief of what the persons wishes would have been, if known, or what the surrogate believes the best interests of the person would be.*

*Where there is no legal surrogate, then an appointed or designated officer acting according to registered, recorded or expressed wishes of that individual, or what officer believes the best interests of the person would be.*

#### Comparison with Existing Human Tissue Laws

*When compared to current human tissue laws, Proposal 23 significantly alters how individual wishes regarding organ and tissue donation are prioritized:*

*Current laws prioritize the expressed wishes of individuals, allowing for the donation to proceed if a person has previously indicated their desire to donate. Where there is evidence that the person would choose to donate, this should have legal primacy in consideration.*

*A person should also be able to nominate who will have surrogate decision role and those persons should accept this role (in the same document). Much like a Powers of Attorney or Executor: these can be nominated by the patient and accepted voluntarily (with the conditions to follow their known wishes).*

*An additional point relates to a potential role of a Designated Officer in this process and the implications of removing this role. An authorised decision-maker is instructed under the proposal to have regard for the patient's values, beliefs and preferences, and a Designated Officer could have a role to independently be satisfied of this. Communication and Family Objections*

*Effective communication with families is vital to the organ donation process, and Proposal 23 will likely alter this dynamic:*

*Current Practices - 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, currently about 18% of families object to donation, a figure that has increased from 11% prior to the COVID-19 pandemic. Reasons 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, and decision makers unable to agree, as well as family believing the person had changed their mind or did not actually want to donate.*

*Changes Under Proposal 23 - Although the proposal requires authorized decision-makers to consider the deceased's known beliefs and values, the ultimate decision rests with them. This may lead to a shift in how families are engaged regarding the deceased's preferences, emphasizing that the family's decision is final, even if the deceased had previously expressed a desire to donate.*

#### Community Concerns

*A key issue raised within the community is the ability of families to override a deceased person's decision to donate.*

#### International Comparisons

*The Uniform Anatomical Gift Act in the United States allows for a simple verbal or written expression of intent to donate (e.g., during driver's license registration). This model emphasizes the individual's right to make a decision about their own body, making it more challenging for family objections to override the deceased's wishes.*

#### Historical Context in Australia

*The historical context of organ donation legislation in Australia is important for understanding the implications of Proposal 23. In 2004, Australian Health Ministers reviewed the organ donation system, aiming to ensure that the wishes of the deceased, whether consenting or objecting, were respected. A significant recommendation was to change the AODR from a register of intent to one of explicit consent or objection. Many registrations on the AODR do not meet the legal consent standard, as most were collected through driver's license systems rather than direct registration.*

*It is the most important documentation of the potential donors patient's wishes and supports families decision process. Communication with families remained largely unchanged, focusing on family decisions prioritizing individual donation preferences.*

#### *Ethical and Legal Considerations*

*There is extensive literature discussing the legal and ethical arguments for respecting individual decisions versus the rights of family members to object to donation.*

*The hierarchy suggested in the first section should account for this.*

*While many clinicians in Australia may not support the U.S. approach, there is a common view is that individual preferences regarding donation should be given priority.*

*If first person and specific consent in the rare circumstances it is obtained, this covenant should be unable to be overturned, and no surrogate decision sought.*

*Where intention is registered, surrogates should have to acknowledge their understanding of the wishes of the deceased (as recorded on the AODR, drivers licence or end of life choices document), prior to vetoing the intent to donate.*

#### *Possible impact of Proposal 23*

*Although Proposal 23 aims to place some emphasis on the deceased's preferences, it arguably lessens the prioritization compared to current legislation, raising ethical concerns about the autonomy of individuals in making decisions about their own bodies.*

#### *Suggested modification to the proposal:*

*ANZICS does not recommend legislating a system that relies on first person informed consent except in exceptional circumstances. If introduced, the covenant of first-person consent for OD and tissue donation should be specific and unable to be overturned by surrogates.*

*We suggest a requirement that seeks to strengthen acknowledgement of a person's stated wishes regarding donation, accepting that in most instances valid consent (as defined in the Discussion Paper) will only be possible by a substitute decision maker.*

*We would recommend that in circumstances where the substitute decision-maker (as per the list recommended at 7.33 that includes as first priority a person with health care authority appointed by the person to whom the authority relates under an advance care directive) does not make a decision consistent with a documented decision by the person, that they be asked to acknowledge this in writing. That is, if the substitute decision-maker does not consent to donation when a person is registered to donate on the AODR, that they be shown evidence of the registration status and asked to acknowledge in writing or digital media that: they have seen evidence of the wishes of the person, know their responsibilities (in having primary regard to the adult's known beliefs, values, and preferences regarding tissue donation), and that they do not consent to donation.*

## Question 16

Proposal 23 removes the role of the Designated Officer, who under current legislation is required to authorise tissue removal when a person dies in a hospital. Do you agree the role of the Designated Officer is no longer necessary?

- If you agree that Designated Officers are no longer necessary, please explain why.
- If you think the Designated Officer role remains necessary, please explain why.

### **ANZICS response:**

*It is important to require authorisation to remove tissue be provided from an appropriately trained person who is independent of those who are undertaking tissue retrieval and transplantation. The role of the Designated Officer (DO), in theory, and as stated in human tissue acts around Australia, is to ensure that all processes have been followed correctly and the rights of the potential are being protected before authorising removal of tissue.*

*This is, however, far from the reality.*

*Firstly, there is no standard of training, knowledge or practice amongst DOs across Australia. In one state there is mandatory training that takes several hours, in another state there is the availability of an online learning module but in all other jurisdictions there is no or minimal provision of training or provision of written material to provide the required knowledge or understanding to new people appointed within their hospital.*

*Secondly, hospitals vary greatly in whom they appoint as a DO. In some it is the Chief Medical Officer or Medical Director, in others it is a nursing executive, in others it is the on-call physician. It has even been simply the medical registrar on-call for medical admissions for that day!*

*Thirdly, in all jurisdictions there are multiple reports of the donation specialist nurses having to talk the DO through what their role is and explaining the decisions that they have to make and the authorisations that they have to give. The State Medical Directors for DonateLife also report that they frequently receive questions from DOs about their roles and how to deal with specific situations.*

*Fourthly, many DOs provide authorisation based on the information that they are provided over the phone by the donation specialist nurse. They do not see the document confirming determination of death and they do not see medical records of the potential donor or the signed consent form from the authorised decision-maker. So the authorisation is provided on face value.*

*Fifthly, the DOs can be hard to contact which introduces delays in the donation process, whether it be for organs or eyes. They can also be obstructive, predominantly due to a lack of knowledge or due to misunderstanding the process, and then not displaying an appreciation of the 'time-critical' nature of the donation process and the need for prompt authorisation.*

*It is, therefore, not realistic to consider that the existing DO role, of independently assessing the donation process and authorising tissue removal as per the HTA, is being conducted in a consistently competent manner.*

*The only solution is to move the regulatory 'check-and-balance' role of the DO to a central group of properly trained, knowledgeable practitioners who provide competent independent oversight of the process and appropriate authorisation as is required by the legislation. The central group could either be nationally based and managed, such as through a National Regulator, or could be based in each jurisdiction but must be independent of the individual hospitals.*

*They could also oversee the removal of tissues, including eyes, from those who die outside of hospital and the removal of tissues from living donors.*

*This is actually an urgent and ongoing problem.*

#### **Question 17**

Does Proposal 23 strike the right balance between the autonomy interests of individuals, the need for flexibility to accommodate unforeseen circumstances, and respect for a deceased person's next of kin? What are the advantages and disadvantages of this approach?

#### **ANZICS response:**

*See response on pages 15-18*

#### **Question 18**

Should new human tissue legislation specify the form that consent to deceased donation should take? If so, what form of consent should be required?

For example, Victoria's legislation allows a person to give consent to donation:

- in writing at any time before their death; or
- during their last illness, orally in the presence of two witnesses.

#### **ANZICS response:**

*No comment*

#### **Proposal 24**

The National Regulator (or alternative) should develop protocols or guidelines for deceased tissue donation by people accessing voluntary assisted dying, and people who have decision-making capacity and who are requesting withdrawal or cessation of life-sustaining therapy.

#### **ANZICS response:**

*This is important but should be left to the existing organisations such as OTA and ANZICS*

#### **Authorised decision-maker**

#### **Proposal 25**

New human tissue legislation should replace current HTA definitions of 'senior available next of kin' with a definition of 'authorised decision-maker' that sets out a hierarchy of decision-makers modelled on section 13 of the Health Care Decision Making Act 2023 (NT).

#### **Question 19**

How should the hierarchy of decision-makers in Proposal 25 be tailored to the deceased tissue donation context?

#### **ANZICS response:**

*It is important to use the same hierarchy of authorised decision-makers to apply both before and after death.*

#### **Question 20**

How should new human tissue legislation address situations where authorised decision-makers with equal decision-making status in the hierarchy in Proposal 25 disagree about whether to consent to donation?

**ANZICS response:**

*No comment*

**Pre-mortem interventions**

**Proposal 26**

New human tissue legislation should define pre-mortem interventions to mean any activity, procedure or investigation that is performed on a living person solely for the purpose of tissue donation after death, including to assess, maintain, or improve the viability of organs for transplantation.

**Question 21**

Is the definition in Proposal 26 an appropriate definition for pre-mortem interventions? Why or why not?

**ANZICS response:**

*The proposed ALRC consent requirement for pre-mortem interventions and broad definition for pre-mortem interventions proposed, is problematic. It will mean that activities and supportive treatments that fall into the proposed ALRC definition of pre-mortem interventions and which can only occur prior to formal consent, will then not be able to be undertaken.*

*The ban will include preliminary suitability assessment for donation, as currently occurs at routine notification to DonateLife when patients are approaching end of life. It will also ban the ability to continue supportive treatments for the purpose of preserving the opportunity for donation until communication with the family occurs and conducting suitability assessments. This could decimate organ donation. We, therefore, refer you to the draft ANZICS document below for a thorough appraisal of pre-mortem interventions and the recommended solutions,*

*ANZICS provides the attached document title **Ethical and professional guidance regarding pre-mortem interventions in relation to organ donation in Australia and New Zealand**, partly based on a similar document developed by the UK NHS.*

*Please note: as this is a **draft** which is provided to ALRC to inform the response to the discussion paper, we do **NOT** want this draft to be publicly available on your website. Please confirm.*

*This document will be attached to the ANZICS Statement on Death and Organ Donation as a supplement. Once the ALRC process is complete and changes to legislation known, then the supplement will be incorporated into the Statement, either within the existing structure or as a new chapter.*

**Proposal 27**

New human tissue legislation should provide that a pre-mortem intervention is prohibited unless valid consent has been given to it. If the person to whom the intervention will be administered does not have decision-making capacity, valid consent can be provided by the person's authorised decision-maker (Proposal 25).

In determining whether to consent on behalf of an adult person, the authorised decision-maker must have primary regard to the person's known beliefs, values, and preferences, if any, and make the decision they believe the person would have made in the circumstances.

#### **Question 22**

We have heard that it is sometimes necessary to conduct a minor procedure such as a blood test to determine a person's suitability to donate tissue after their death, and that it may not be practical to obtain prior consent. Should new human tissue legislation contain an exception to the need for consent? If so, how should the exception be expressed, and what limits should there be on it?

#### **ANZICS response:**

*See answer to question 21*

#### **Question 23**

Should new human tissue legislation have any additional safeguards for the use of pre-mortem interventions beyond the need for valid consent? If so, what safeguards should it have?

#### **ANZICS response:**

*No comment*

### **Respectful and dignified treatment of deceased body**

#### **Proposal 28**

New human tissue legislation should provide that, when removing tissue from a deceased body, any person involved in the removal must treat the body with the highest level of respect and dignity that is practicable in the circumstances.

#### **ANZICS response:**

*Agree*

#### **Proposal 29**

New human tissue legislation should provide a mechanism enabling medical practitioners and authorised technicians to remove certain types of tissue from deceased bodies, including musculoskeletal, cardiovascular, eye and skin tissue. The National Regulator (or alternative) should by delegated legislation specify the relevant qualifications required for technicians, and any additional type of tissue that technicians are authorised to remove.

#### **ANZICS response:**

*Agree*

### **Coronial consent to donation**

#### **Question 24**

Should new human tissue legislation provide factors for coroners to consider when deciding whether to consent to donation of tissue from human bodies under their jurisdiction? If so, what factors should a coroner take into account?

#### **ANZICS response:**

*In up to 54% of potential organ donors the death is reportable to the coroner.<sup>2</sup> There is significant variation across jurisdictions regarding coronial refusal of organ donation or refusal of specific organs. In the last five years coronial refusal of donation or coronial imposition of restrictions on specific organs is as low as almost 0% in one jurisdiction to as high as 20% of requests in others. The inability to donate organs has a direct, and indirect, adverse impact on the subsequent deaths of potential organ recipients who do not receive a transplant. This would appear to run counter to the ultimate goal of the coronial process to reduce deaths.*

*There is no published evidence that organ donation impedes the process of determining the cause of death.<sup>3</sup> Furthermore, a study published in 2019 showed that the coronial refusal did not subsequently assist in coronial findings.<sup>4</sup>*

*It is well recognised that the coroner's responsibility is to determine the cause of death but the significant variability of refusal across jurisdictions confirms that other factors are impacting on their decision-making. This does not need to be a binary choice of 'determining cause of death' versus 'organ transplantation' as there are multiple strategies that have been shown to facilitate organ donation whilst not impeding the coronial investigation of the cause of death. These include:*

- *confirmation with the individual transplant units, on a case-by-case basis, that the function of a particular organ is so well preserved that it is transplantable (eg the echocardiogram is normal and the potential donor requires no cardiovascular support and the heart transplant unit are keen to transplant into a patient dying from heart failure)*
- *inviting the forensic pathologist to attend the organ retrieval operating theatre to witness the beating heart before retrieval and inspect it with the surgeon once the heart has been retrieved. Giving the forensic pathologist to witness or inspect the retrieved organ while it is still working in-situ would, understandably, be much more useful than inspecting a post-mortem organ.*
- *the forensic pathologist discussing the clinical course of the potential donor's illness with the organ donation doctors and the treating team*
- *offering to monitor the post-transplant functioning of the organs (eg offering to provide information regarding significant cardiac arrhythmias or unexpected results from post-transplant cardiac biopsies)*

*It is worth noting that next of kin can object to a post-mortem examination, and where "the coroner decides that the postmortem examination or whole organ retention concerned is necessary or is desirable, the coroner must" notify the NOK of their decision in writing immediately, and also inform the NOK that they can "apply to the Supreme Court for an order that a post mortem examination not be conducted" (see, for instance, NSW Coroners Act 2009, S 97).*

*There should be an expectation that the coroner must outline the reasons for refusal of donation in writing, as well as providing recourse for appeal to the Supreme Court.*

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<sup>2</sup> ANZOD 2025 report Table 3.2

<sup>3</sup> 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.

<sup>4</sup> 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.

## **12. Reforms relating to how information can be disclosed and shared**

### **Prohibiting non-consensual public disclosures of a tissue donor's or tissue recipient's personal information**

#### **Proposal 46**

New human tissue legislation should prohibit the public disclosure of a human tissue donor's or human tissue recipient's 'personal information', unless consent to disclosure has been provided in accordance with Proposal 48.

'Personal information' is information that identifies an individual, or that makes an individual reasonably identifiable.

#### ***ANZICS response:***

*Agree*

### **Permission for health practitioners to disclose a tissue donor's personal information in limited circumstances**

#### **Proposal 47**

New human tissue legislation should provide that it is permissible for medical practitioners to disclose a human tissue donor's personal information to a potential human tissue recipient provided:

- a. the information is clinically relevant to the potential tissue recipient's decision about whether to accept tissue for transplant; and
- b. the information is disclosed in a manner that mitigates the risk of the donor being identified to the greatest extent possible without compromising the ability of the potential recipient to make an informed decision.

#### ***ANZICS response:***

*Agree*

### **Who can consent to the disclosure of a tissue donor's or tissue recipient's personal information**

#### **Proposal 48**

New human tissue legislation should provide that consent to the disclosure of a human tissue donor's or human tissue recipient's personal information may be given by:

- a. the human tissue donor or the human tissue recipient themselves; or
- b. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is deceased; or
- c. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is a child or an adult who does not have decision-making capacity.

#### ***ANZICS response:***

*No comment*

**Allowing certain people to access and share information for identification and screening purposes**

**Proposal 49**

New human tissue legislation should use sections 45(4)–(6) of the Human Tissue Act 1982 (Vic) as a model to ensure that medical practitioners, health authorities, and DonateLife staff can access and share with each other relevant information for donor identification and screening.

***ANZICS response:***

*Agree*