DONATELIFE QLD RESPONSE
TO REVIEW OF HUMAN TISSUE LAWS DISCUSSION PAPER

Introduction

This response represents the views of the medical director of DonateLife Qld, Dr Leo Nunnink and the nurse agency manager Tina Coco AO. Our area of domain experience is within deceased organ donation, and to a lesser extent deceased tissue donation. We have confined our responses to proposals relevant to those areas.

Proposal One:

We agree that there should be consistency across across state, territory and Commonwealth legislation.
Without being experts in the Law, we believe that creating mirror legislation in each state may be preferable. Creation of uniform Commonwealth legislation may have unexpected consequences through interaction with related legislation that differs between states and territories such as Powers of Attorney Acts, Guardianship Acts, Privacy Acts, Electronic Transactions Act and others.

Proposal Three:

A national regulator is required for tissue products but is not required for organs. The Therapeutic Goods Administration (TGA) currently provides sufficient regulatory oversight for safety and quality in tissue products. The primary function of the Organ and Tissue Authority (OTA) is to increase organ and tissue donation rates through improvement in clinical practice. Adding a regulatory role to the OTA's remit would be a significant departure from their current function and there may be instances where their regulatory role could be in direct conflict with their primary role.
A number of roles proposed for the 'National Regulator' do not require regulatory power, such as creating national policies, providing educational material and providing guidelines. These roles would better rest with other bodies. Guidelines for practitioners are currently developed by peak clinical bodies such as the Australia and New Zealand Intensive Care Society (ANZICS) and the Transplant Society of Australia and New Zealand (TSANZ). Having these guidelines developed independently of OTA (although in consultation with them) preserves the independence of these guidelines. It maintains their credibility with the medical community and prevents accusations of conflict of interest being levelled at OTA.
It is our opinion that there is no requirement for a National Regulator or additional regulatory oversight beyond that currently provided by the TGA.

Proposals Seven and Eight and Questions Five, Six and Seven:

Human tissue should be defined broadly, such as 'Any substance or material derived from human origin.' The definition should be flexible, given that the nature of human tissues used therapeutically is likely to change over the lifespan of the legislation. The TGA would be an appropriate body to modify the scope of the definition if needed.

We recognise that there may be unintended implications if gametes are included due to the importation of gametes.

Proposal Ten:

Section X: When death occurs
The proposed definition is very useful for determining neurological death but is not fit for purpose as a definition of death for everyday use. The vast majority of people are determined to be dead via cessation of circulation and this needs to be captured in the legislation. A junior doctor seeking to certify death in an everyday situation (not a ventilated patient in ICU) would struggle to do so using the proposed definition, as would a police officer at an accident scene. **Cessation of circulation must be included as a sufficient but not necessary condition to establish that there has been permanent cessation of the person's critical brain functions, establishing that the person is dead.**

Section Y: Determination of Death
Where death of a person whose ventilation is being maintained by artificial means is being determined, we agree that one medical practitioner should be a specialist. However the requirement that both be qualified for five years is unnecessary. A five-year period of practice does not guarantee experience of neurological death. The five-year requirement is not currently in place in Qld and would be unworkable in regional centres where there may not be such a practitioner available in addition to the treating specialist.

The requirement to confirm 'in writing' that a clinical examination has been carried out is problematic. Digital methods are replacing the written word as a means of medical record keeping. In the interest of future-proofing, the legislation should not be proscriptive about how it is confirmed that an examination has been performed.

Question Nine

In Queensland we have uniquely problematic legislation in that death is only defined in the Transplantation and Anatomy Act, and the definition of death is prefaced with the phrase, 'For the purposes of this Act, death occurs when…' This generates uncertainty about whether death has actually occurred after neurological determination in patients who are not under the auspices of the T&A Act, eg when there is no family consent to donation. We would strongly support the adoption of a Uniform Death Act to overcome this issue.

Proposal Thirteen

With regard to 2.b(i) and 3.b(i):
Some intensive care units provide care for patients who may need urgent transplants. It is occasionally the case (particularly after hours) that there is one ICU specialist in the ICU who happens to be caring for a patient who is in urgent need of a transplant. If a potential donor is also in the same ICU, this can make it difficult to ensure that a medical practitioner confirming death is also not involved in the medical care of a potential recipient. This requirement is in existing legislation and is currently observed where possible, but it would be ideal to address the challenge presented by having one ICU specialist who may be caring

for a potential donor and a potential recipient at the same time. It is worthy to note that an ICU specialist is not involved in choosing the potential recipient for any transplant. This is solely the role of a transplant physician/surgeon.
Therefore, 2.b (1) and 3.b (1) we suggest to keep "the removal of tissue" but delete "or medical care of a recipient of the removed tissue".

With regard to 3:
The phrase '…must confirm in writing…' should be broadened to permit digital means of record keeping.

Proposal 23:

Dot point 2 and Dot point 4 require clarification with regard to an adult who provides valid consent. There are two circumstances wherein an adult may provide consent for donation. In the first instance, a person whose death is proximate gives consent for donation after their death. Examples include a person pursuing voluntary assisted dying, or the infrequent circumstance where a ventilator-dependent conscious person requests withdrawal of life sustaining therapy (eg following high spinal cord injury causing paralysis). In those circumstances the person's consent meets the five conditions stipulated under dot point four.

A different situation arises where a person whose death is not proximate provides consent for donation in the event of a future circumstance where they are likely to die and may become a donor. The commonest example of this is signing on to the Australian Organ Donor Register (AODR). If it is the case that Proposal 23 is intended to include AODR registration as a legal and valid consent, **which we strongly recommend**, then it should explicitly specify that. In that case not all conditions of dot point 4 would be met – it is not possible for a person signing on to a register to know about 'the nature and effect of removal of tissue' nor is it possible to know what the intended use of the tissue is, at the time of their registration. Which organs can be donated and how they will be used will depend upon the circumstances that apply at the time the person is close to death, which may be decades after they sign on to the register. If it is the intention that AODR registration is intended to be captured under Proposal 23, then dot point 4 needs to be modified accordingly by removing points c) and d). If it is not the intention, then a specific proposal relating to AODR registration should be drafted.

With regard to AODR registration, the primacy of a person's prior first-person consent via registration over a substitute decision maker's refusal should be established in legislation. It is a frequent sticking point in the community that a family member can override an individual's expressed wish for donation which creates a negative view of the value of signing on to the AODR. In the Australian context, even with legal primacy it is highly unlikely that donation would go ahead against a family member's strong objection to donation. However, it would be beneficial to have the individual's expressed wish to have precedence in law. This is an extremely important point when considering the life span of this legislation and ensuring that community views and expectations of consent during life are respected and upheld.

Question 16:

We agree that the role of Designated Officer (DO) in Qld does not currently provide meaningful oversight of the application of the Law. The DO merely signs off that written consent has been provided. They do not have the means to establish that the authorised decision maker has 'primary regard to the deceased's known beliefs, values and preferences.' In many hospitals an individual Designated Officer will act in that capacity once a year or less, meaning that training and maintaining currency are challenging. They are trained by Donate Life agencies, who are the most familiar with the legislation and so the DOs do not truly act independently. In the current context they do not provide an additional safeguard, and no safeguard is needed beyond the mechanisms in the proposed legislation.

From a practical point of view, the appointment process for DOs is not clear and there can be some reluctance within Health Services to facilitate the DO role due to an unwillingness to take on legal responsibility.

In other states, the DO can authorise donation in the absence of a SANOK where the donor has a previously expressed wish to donate. This is not the case in Qld under current legislation. It would be desirable for the new consent legislation to explicitly authorise donation where a person has expressed a wish, even in the absence of a SANOK.

We recognise that tissue banks operate under different circumstances and may have differing views on the role of the Designated Officer.

Question 18:

New legislation should not specify the form that consent should take. Digital means should be valid, for example for AODR registration.
For people who are conscious and whose death is proximate, the physical act of signing is frequently impossible. Patients are often clearly able to express their wishes but are unable to physically sign due to weakness following paralysis or neurodegenerative disease. Stipulations in existing laws that consent must be provided 'in signed writing' are overly restrictive and ignorant of the context in which consent is being provided.

<u>Proposal 24</u>:

Developing protocols for donation after voluntary assisted dying (VAD) or patients who are requesting withdrawal of life sustaining therapy is not within the role of a Regulator. Peak bodies exist for clinical practitioners involved in the care of patients pursuing VAD (eg VADANZ) and patients dependent on cardiorespiratory support (eg ANZICS). These, rather than a Regulator, are the appropriate source for independent, ethically sound clinical guidelines and protocols.

Proposal 25:

Ideally, the hierarchy of decision makers for deceased organ donation would mirror the hierarchy of substitute decision makers for an adult with impaired capacity – those outlined in the individual state's Guardianship Act or Powers of Attorney Act or equivalent. Otherwise the decision maker after death can be different for the decision maker while the patient is alive, a clearly undesirable circumstance. Given that the hierarchies vary from state to state, it would be difficult to apply a particular template. The template legislation for the proposed new Human Tissue Act could reference the individual state's decision making hierarchy for substitute decision making in life. However, the hierarchy does need to be broad, possibly encompassing more possibilities than may be considered in the state's PoA Act or Guardianship Act.

The hierarchy should include family members beyond the nuclear family eg grandparent, cousin, aunt or uncle, in situations where there is no parent, child or sibling present. It is occasionally the case that only (for example) a cousin can be found, and not infrequently they have an enduring relationship with the potential donor. In the proposed hierarchy a 'friend' is given decisional authority but not an extended family member. In the absence of either family, extended family or friend, a carer or guardian should have decision making authority.

With regard to the NT legislation, in our opinion it provides excessive weight to a culturally determined or customary decision maker. It is difficult for hospital staff to ascertain whether a self-declared 'customary decision maker' is indeed that person. Family and spousal relationships should take precedence over someone who declares themselves to be the decision maker through culture or custom.
The Qld Transplantation and Anatomy Act currently provides definitions that include cultural and customary relationships in Part 1.4.(1):

- A person who, under Aboriginal tradition or Island custom, is regarded as a parent of the child/sibling, and
- A person who, under cultural traditions of their community, is regarded as a parent/sibling of the child.

Question 20:

Where there is a situation wherein two family members with equal hierarchical status disagree about consent for donation, this should be resolved through negotiation rather than legislation. It is routine to attempt to achieve a mutually acceptable consensus position. In practice a veto often has overriding power, but this should not be stipulated in legislation.

Question 21 and Proposal 27:

The definition proposed is too broad. Most activities to assess organ function are minimally intrusive and are mandatory for donation to occur – for example collection of blood specimens, chest radiography and so forth. To consent to donation is to consent to these interventions. Requiring specific separate consent creates the undesirable possibility that a

decision maker consents to donation but declines consent to necessary tests, meaning that donation cannot proceed.

Question 22:

Yes, routine investigations should be included as an exception prior to donation consent. These should be defined as minimally invasive procedures and tests that help determine organ suitability for transplantation prior to gaining formal consent. Accessing appropriate clinical information prior to consent should also be permitted.

Question 23:

No additional safeguards are required for antemortem interventions. The NSW and Victorian legislation regarding antemortem interventions added additional burdensome steps including a second medical opinion and a requirement for Designated Officer signoff. This has added hours of additional delay even for routine tests, adding to the burden on donor families who are generally keen for donation to go ahead as quickly as possible once they have provided consent.

The recently assented *Health Legislation Amendment Bill (No. 3) 2025* Qld does not require any additional safeguard for antemortem interventions beyond family consent. That legislation was drafted mindful of the experience that had occurred in NSW and Victoria after the introduction of their unnecessary safeguards.

Proposal 29:

Removal of tissue after death requires training but does not require a 'qualification' as proposed. With appropriate training, morticians and nurses can remove tissue for donation. The new legislation should specify that anyone removing tissue be adequately trained but should not stipulate a qualification as no such qualification currently exists.

Question 24:
The new legislation should provide factors for Coroners, as coronial consent to donation is currently highly variable, with substantial variation between individual states and variation between individual Coroners.[1] Decision making is inconsistent, with Coronial decline sometimes occurring despite clear imaging evidence that establishes cause of death and makes a physical autopsy unnecessary. There is no published evidence of a case where organ donation has altered the outcome of a criminal trial. Coroners sometimes express concern that a criminal will go free if they permit organ donation, but this has never been reported.[2]

Legislation should establish the primacy of organ donation (which has the capacity to save lives) over coronial processes, particularly when there is sufficient evidence of cause of death through medical imaging, testing, or police involvement. If there is sufficient medical evidence of normal organ function, deeming them suitable for transplantation, then it is unlikely that the organ in question was the cause of the death of the decedent.

The proposed legislation should create an imperative for Coroners to honour the wishes of potential donors and their family members. When challenged, Coroners sometimes cite their own legislation, which (in Qld) sets out the role of the Coroner as being first and foremost to establish cause of death, and does not recognise donation's competing interest in the bodies of the deceased. An Act that sets out legislative primacy for donation in reportable deaths may potentially provide a source of comfort for Coroners who would then feel legally protected in the unlikely circumstance that organ donation interferes with cause of death determination.

There are a number of actions that may help facilitate donation in reportable deaths – for example requiring the forensic pathologist to attend the person in the intensive care unit, or attend the donation operation. These could be considered. Alternatively, there could be a requirement for the forensic pathologist / Coroner to clearly stipulate what evidence will be contributed by a post-mortem examination that could not be gleaned through imaging or investigation prior to donation.

Although it is hypothetically possible that organ donation may impede coronial cause of death determination, this is rarely consequential. The tangible benefits of donation and transplantation are to be weighed up against the theoretical risk of an inconclusive autopsy result. One strategy that is under-used is that of shared decision making, involving the family of the deceased in the decision. The consent process may include phrases such as "the Coroner may not be able to determine a cause of death if donation proceeds." That way the family can decide whether the benefits of donation would be more or less important than complete autopsy results to the decedent.

At the very least, legislation could establish a review and audit process for coronial decision making to ensure accountability in coronial decisions regarding donation consent. Currently when Coroners decline donation there is a life-altering consequence for the potential transplant recipient who is denied a transplant, but none for the one making the decision.

Question 27:

Yes, exclusion of small samples from explicit consent will help future proof the proposed legislation.

<u>Proposal 36</u>:

We agree with the proposal. The hierarchy of decision makers for consent for research should be the same as the decision makers for donation consent, as consent for research is generally requested during the same conversation as donation consent.

<u>Proposal 37</u> and Questions 29 and 30:

When obtaining consent for research, it is routinely the case that it is not known what specific research studies may be undertaken on the donated tissue. Family members provide generic consent for 'research,' not for involvement of the donors tissue in research study x,y or z. At the time of the donation/ research consent conversation, family members are

experiencing acute grief, are often overwhelmed and do not want to hear specific details about specific research projects. They are either happy for research to occur or not. If consent is provided that should suffice for any proposed research use for the donated tissue. For example, the language of explanation for consenting for tissue for research can be explained as thus:
"Therapeutic, medical or scientific purposes means the donation of tissue for use in Ethics Committee approved medical research, education or training programs. These programs lead to medical and scientific advances and improvements in patient care and the treatment of disease."

Question 31 and 32:

Yes, national oversight of tissue in biobanks would be beneficial.

Proposal 40:

Reimbursement of expenses for organ donors is important, and legislation should retain that possibility. Expenses that may be incurred include repatriation of the body after donation, or donation-associated medical costs for non-Medicare eligible international visitors. No-one should be left personally out of pocket following organ donation by a family member.

Proposal 48:

The intention of this legislation is not entirely clear. Is it intended to permit contact, with consent, between donor family members and transplant recipients? If so we do not object, provided an adequate framework (with support and oversight) for such contact exists. If this contact will involve donation agencies then there should be legal safeguards for those staff involved.

Proposal 49:

Permitting donation staff to access a person's medical record *prior to consent* has considerable community benefit in that it can avert unnecessary (and potentially burdensome) donation conversations for family members of potential donors who may have a medical contraindication. Legislation that permits donation staff to access a medical record would be welcome, however it should specify that this can occur **without prior SANOK consent** provided adequate safeguards exist. Additionally the legislation should specify that it takes precedence over any other legislation given that medical records may be protected by multiple different Acts – eg Hospital & Health Board Acts, privacy legislation and so forth.

References

1. Nunnink, L. and C. Wallace-Dixon, *The impact of organ donation on coronial processes and forensic investigation: A literature review.* J Forensic Leg Med, 2020. **71**: p. 101940.
2. Nunnink, L., et al., *Does organ donation impact on forensic outcomes? A review of coronial outcomes and criminal trial proceedings.* J Forensic Leg Med, 2019. **68**: p. 101860.