Response of ANZICS Death & Organ Donation Committee to the ALRC Review of Tissue Laws Issues Paper

1. *What is your personal experience of how human tissue is obtained or used in Australia?*

This submission is on behalf of the ANZICS Death & Organ Donation Committee

ANZICS, the Australian and New Zealand Intensive Care Society, 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.

The ANZICS DODC publishes the ANZICS Statement on Death and Organ Donation (https://www.anzics.com.au/wp-content/uploads/2022/04/ANZICS-Statement-on-Death-and-Organ-Donation.pdf) . The main purposes of the Statement are:

• to provide a standard for intensivists and other health professionals in relation to the determination of death and the conduct of organ and tissue donation, including donation after circulatory determination of death

• to provide assurance to the Australian and New Zealand communities that determination of death and the conduct of organ and tissue donation are undertaken with diligence, integrity, respect and compassion, and in accordance with available medical evidence and societal expectations.

In addition to producing the ANZICS Statement, the ANZICS DODC is responsible for writing and maintaining the ANZICS Statement on Care and Decision Making at the End-of-Life for the Critically Ill (https://www.anzics.com.au/wp-content/uploads/2018/08/ANZICS-Statement-on-Care-and-Decision-Making-at-the-End-of-Life-for-the-Critically-Ill.pdf).

The ANZICS DODC provides advice on strategies to improve organ and tissue donation, providing advice on the educational needs of intensive care doctors with regard to brain death and organ and tissue donation and liaising with other organisations, groups, and Government on issues related to organ and tissue donation.

2. *What is your personal experience of how human tissue laws work in Australia?*

The Australian jurisdictional human tissue acts were introduced in the 1980s and in general have served the community well over the intervening 40 years. They have failed, however, to keep pace with changes in society and in medicine. A review would ensure that meet contemporary and future needs. There are four important areas that ANZICS DODC suggests need revision:

- Harmonisation of legislation across jurisdictions to minimise variation and ensure that Australians are confident in the processes and procedures regarding how tissue is obtained and used regardless of where the potential donors and recipients live. Given that tissue donated in one State or Territory can be used in any other State or Territory it is not ideal that the legislative requirements under which that tissue has been obtained differs.

- Update the definition of individuals permitted to provide consent to the removal of tissue from persons after their death (currently the “Senior available next-of-kin”) to recognise changed family and kinship relationships in modern Australia, and to limit differences from legislated hierarchies in medical consent / Guardianship laws. This change is referred to elsewhere in this submission.

- Legislation should support organ and tissue donation, when medically possible, as a preferred option at end-of-life, including recognition of the donation after circulatory determination of death (DCDD) pathway to deceased organ donation and the requirement for antemortem procedures.

- Update the definition of death in light of modern medical understanding of the process of death and changes in organ preservation processes.

3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?
You might think about aims such as:

- *increasing the amount of tissue available for transplantation and/or other uses;*
- *creating a transparent and easy to navigate tissue donation system;*
- *making sure tissue donation happens safely;*
- *making sure people have a good understanding of what is involved in donating*
- *tissue;*
- *making sure people understand how their tissue will be used;*
- *equity, and removing barriers faced by some individuals or groups to human tissue*
- *donation or transplantation;*
- *making sure how human tissue is obtained and used is consistent with respect for persons and the human body.*

The Australian Government announced a National Reform Program for organ and tissue donation in 2008 and this commenced in 2009. This has been a very successful initiative, and in the following 10 years was associated with a 122% increase in deceased organ donors and an 81% increase in transplant recipients. Despite this success, the waiting list for organ transplants has not decreased and the demand for transplant organs well exceeds the supply.

The success of the National Reform has been principally related to changes in practice in hospitals, in both intensive care units and emergency departments, through:

- increased recognition of potential donors,
- early notification of potential donors to donation agencies
- early checking of the Australian Organ Donor Register to determine if a potential donor has registered their preference,
- improved approaches to families to request donation and
- improved support for families agreeing to donation.

In addition, Donation after Circulatory Determination of Death (DCDD) has been carefully introduced nationwide as a pathway to donation such that it is now seen as an accepted practice and makes up approximately a third of all donations, compared to being very rare prior to 2009. The review of the tissue laws is a timely exercise to ensure that the nationwide legislation, in all jurisdictions, supports, rather than impedes, the processes that optimise donation and transplantation and respects the wishes of all patients at end-of-life regarding donation.

Repeated public surveys reveal that around 80% of Australians support organ and tissue donation and transplantation[1] Recognising the public support and the ongoing need for these tissues to improve and save the lives of fellow Australians, ANZICS believes that legislation should support and promote organ and tissue donation, where it is possible, at end-of-life. Although the public are able to reflect their wishes to donate in the Australian Organ Donor Registry, many do not avail themselves of this opportunity. This does not mean, however, that they should not be given the chance to have their wishes honoured at the end of their life. There is no other time for those wishes to be explored and actioned.

At all stages in a person's life health care professionals should do their best to act in the patient's best interests. Beneficence, non-maleficence and respect for autonomy are three of the abiding ethical principles in the Western healthcare system.[2] A person's best interests include previously expressed wishes regarding medical treatment, along with their personal values, beliefs and preferences, including what happens to their body following death. [3] In the same way that health professionals are expected to seek and honour a person's "values directive" at a time when a patient may not have decision-making capacity, they should also seek the views of a patient at the end of life regarding organ and tissue donation. If the patient does not have decision-making capacity, then this is done by checking the AODR and by asking the patient's family.[4]

If the patient's family are not consulted in an appropriate and skilled manner while the patient's physiological condition could still support organ donation, then the opportunity is lost. The loss is to the potential donor's wishes, to the potential organ and tissue recipients, and to the potential donor's family who will often ask later "why didn't the doctors ask us about organ donation?"

In support of organ and tissue donation being "the right thing to do", we note that the National Reform, initiated in 2009, has continued to be a priority for Commonwealth governments, with the aim to ensure that donation is considered as part of end-of-life care. Having this recognised in law would provide security and reassurance for health professionals in hospitals to identify potential organ and tissue donors at end of life, to undertake preliminary suitability screening (make enquiries, perform simple laboratory tests) and to notify donation agencies of the possible donor. HTAs could include a clause stating that it is in a person's best interests to preserve the opportunity for exploring donation preferences and suitability at end-of-life through initiation and maintenance of life support, and that this can occur even before the person's wishes are known or have been explored with next-of-kin.

Current human tissue laws are structured to permit persons to provide consent on behalf of a deceased person (a relative / next-of-kin) to donate tissue for transplantation or other purposes. There is no provision for persons to provide such consent in respect of a living

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[1] O'Leary MJ et al. An Australian Survey on Public Opinion Regarding Death And Organ Donation: Relationship of Demographic Factors To Opinions. Int Med J 2022; 52:238-248

[2] https://www.anzics.org/wp-content/uploads/2018/08/ANZICS-Statement-on-Care-and-Decision-Making-at-the-End-of-Life-for-the-Critically-Ill.pdf

[3] Medical Treatment Planning and Decisions Act 2016

[4] 'family' means those closest to the person in knowledge, care and affection, including the immediate biological family; the family of acquisition (related by marriage or contract); and the family of choice and friends (not related biologically or by marriage or contract). From NHMRC. *Ethical guidelines for the care of people in post-coma unresponsiveness (vegetative state) or a minimally responsive state.* Canberra: National Health and Medical Research Council; 2008.

person who is about to die in the context of the withdrawal of life-sustaining treatment – the usual pathway to DCDD. This was not taken into account in human tissue laws in the 1980s as this pathway to donation was not a consideration. There are additional problems in relation to this, as the hierarchy of individuals permitted to provide consent to medical matters for living persons is usually determined by Guardianship or medical consent laws, and this is generally different from the hierarchy in human tissue laws, and moreover, Guardianship / medical consent laws may not permit "persons responsible" to provide consent on matters that cannot directly benefit the health or wellbeing of the individual.

Decision making at end-of-life and consent to organ donation are governed by different legislative Acts. Nationally, the Consent to Medical Treatment and Palliative Care Acts, the Advance Care Directive Acts (in SA) and Medical Treatment Planning and Decisions Act (Vic) and the Transplant and Anatomy acts give different hierarchies of the family decision makers.

Consent for organ donation is mostly given by a patient's family. It is not uncommon for family groups not to be unanimous in the donation decision. Due to the existing legislation the family member who consents to pre-mortem procedures may well be different to SANOK who consents to organ retrieval. For example, a patient may have appointed their sister as a nominated substitute decision-maker (SDM) in life and who is supportive of the donation process (as they have previously indicated to them), however the parents (as SANOK) may not be supportive of organ donation. In this scenario, the parents are higher in the HTAct hierarchy and can overrule the sister as SDM.

When deceased organ donation is being considered certain investigations and treatments may be required to both determine the suitability of organs for transplantation and to maintain the physiology of the potential donor and health of their organs to facilitate organ retrieval and transplantation. The majority of organ donors undergo donation workup after declaration of brain death. Referred to as Donation after Neurological Determination of Death (DNDD), this process has broad ethical and legal support. For DCDD, however, these interventions are antemortem and may be regarded as undertakings that are not strictly in the patient's best interests. Although it has been argued that interventions that facilitate a patient's wishes to be a donor are indeed acting in their best interests (similar to an advance care plan) this still has significant legal and ethical implications in the eyes of many, and it is vital that this is recognised in law and is permitted to occur using an appropriate legal framework.

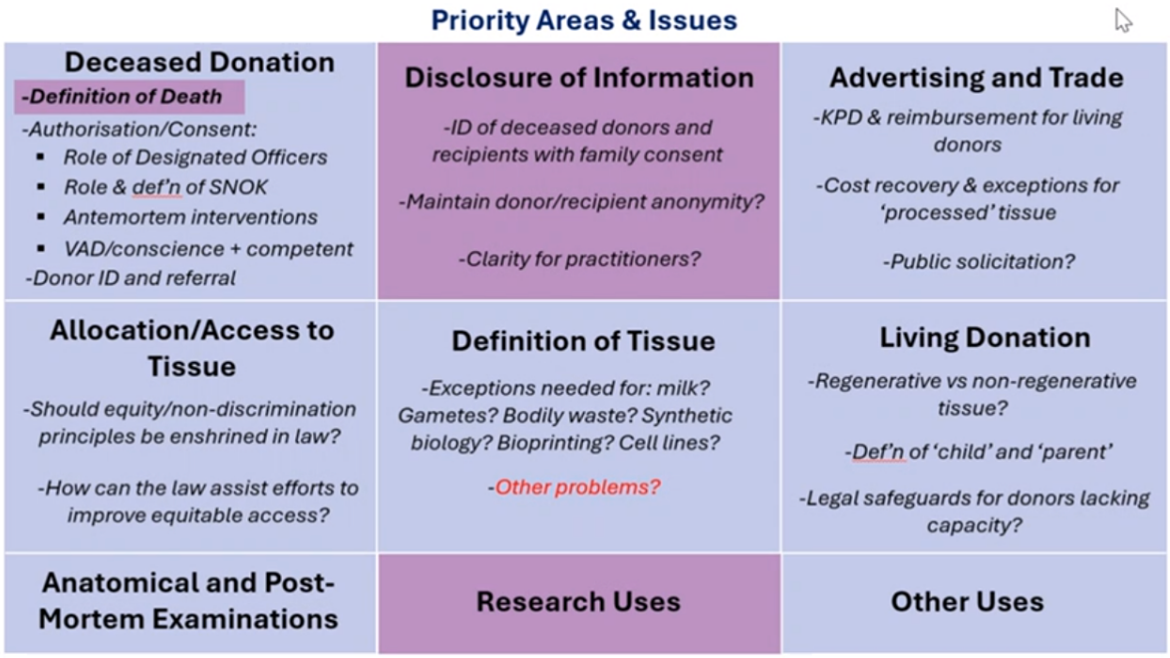
ANZICS is developing an appendix for the Statement on Death and Organ Donation which will set out a framework for the ethical and professional undertaking of antemortem and postmortem procedures in relation to organ donation. The attached draft (*A draft Ethical and Professional Framework for Organ Donation in Australia for ALRC Review*) is guided by the 2022 UK NHS Donation Actions Framework and specifically considers procedures that would be acceptable or not acceptable a) before death and before consent, b) before death and after consent, c) after death and before consent and d) after death and after consent.

Once completed, this appendix would be a working draft pending the outcome of the ALRC review and recommendations.

Therefore, ANZICS recommends that this review of human tissue laws formally recognises DCDD and that consent to antemortem procedures for donation are covered in legislation. It would be ideal for the law to support preserving the opportunity for donation in the end-of-life. This may include the simple investigations to determine the suitability for donation (such as the sampling and testing of blood and urine) before consent is obtained from next-of-kin, irrespective of whether the person has an indicated wish to donate or not. The rationale is

that some of these simple tests (which ordinarily are not regarded as interventional) are time-critical and can provide crucial information regarding organ suitability prior to talking to the next-of-kin about the possibility of donation.

For example, if a potential donor is ventilated in a regional hospital several hours from the capital city in which the organ donation-related blood tests need to be done, legal support to take the blood samples and transport them to the capital city, in preparation for the family discussion, would greatly assist in ensuring that the opportunity for donation is not lost.



5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.

Definition of death

It is now over 50 years since the Ad-hoc Committee of Harvard Medical School published its standard for the neurological determination of death and almost 40 years since the ALRC recommended a statutory definition of death for Australia. In recent it has been recognised that the concept of two different "modes" of death, neurological and circulatory, is no longer a valid concept. International consensus now favours a unified definition of death based on the principle that a person dies only when the brain has ceased to function permanently.

The proposed definition below takes into account the definitions now in place in UK, Canada and USA.

ANZICS recommends that:

1. the definition of death be changed to reflect a unified definition of death. This is consistent with the understanding that a person's circulation can stop for a period of time (eg cardiac arrest, severe hypothermia, medical intervention- during cardiac 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. That the definition of death be in an Act separate from the jurisdictional HTAs in order to signify that the necessity for a definition of death is not linked to organ and tissue donation.

3. That the definition of death be a Commonwealth Act rather than a jurisdictional Act thereby:
   a) ensuring uniformity of practice across the Commonwealth of Australia and
   b) avoiding the previous experience of significant delays in legislating a definition of death after the ALRC recommendation of a definition of death in 1977. This is evidenced by the range of dates of HTAs across Australia. The last jurisdiction to legislate a definition of death was WA in 2008 (section 13C inserted in the Interpretation Act 1984).

      We note that death is already defined in the Criminal Code Act 1995 (Cth), section 4(1), which refers on to the dictionary in Schedule 1 of that Act, where the actual definition is stated. We also note that the definition mirrors that in the states and territories, save for "(including the brain stem)", which is not included in the state and territory provision. This slight but distinct difference in definition puts public confidence at risk. We are also concerned that if the changed definitions were inserted into the transplantation legislation of the states and territories, but the federal legislation was not changed at all, this would add to the impression that the changes to the transplantation legislation were only being made to help facilitate organ transplantation. In any event, we do not want any inconsistencies between federal and state/territory legislation.

4. That the primary intention of changing the definition of death is bring it up to date with current medical understanding of the unified definition and to align with the clinical guidelines and codes of practice of similar respected international medical academies. 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.

Our proposed definition of death

"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."

<u>Explanatory notes:</u>

- This definition consists of 4 sentences
- In sentence 1, "permanent" means will not resume spontaneously and will not be restored through intervention. It is more appropriate than "irreversible".
- Sentence 2 is required for the legislators and the public to understand the link between loss of circulation and brain death

- We recommend the word “circulation” in sentence 2 rather than “perfusion” which would not be acceptable as most would not understand the strict medical meaning of the word
- “Circulation” is defined in Merriam Webster as “orderly movement through a circuit”. It derives from the Latin word “circulatio”, from the Latin root “circulare” meaning to form a circle. So circulation means that the liquid, whether it be blood or water, flows through a circuit in an orderly manner, returning to the same point.
- Thus the movement of a small amount of blood, or the admixture of blood, is not circulation. We already rely on this distinction in the reporting of a 4 vessel angiogram or a CT angiogram[5] in the description of the movement of blood up to the circle of Willis by admixture but not beyond, due to compression of the intracranial vessels. (the term “admixture” refers to the passive mixing of fluids, in this case blood, rather than meaningful flow)
- Furthermore, the word “in” the brain it further distinguishes the absence of meaning blood flow within the brain, as against the term “blood circulation to the brain”, which is in fact an incorrect term given the derivation of the term “circulation” as explained above.
- In sentence 2 we make reference to “devastating brain injury” first, before cessation of circulation. It follows the historic order of the current statute, connotes less deviation from the current statute, and should facilitate easier lay interpretation and acceptance.

<u>The need to ensure greater, accountable and transparent coronial support for donation</u>

In all jurisdictions the HTAs stipulate the need for coronial consent for the removal of tissues for transplantation from a person whose death is subject to a coronial investigation. The requirement for Coronial consent is clearly articulated in the HTA but there is no wording that requires the Coroner to consider the community benefits of organ and tissue donation (amongst other potential competing interests) prior to determining if organs and tissues can be donated in a specific case. The Coroner relies on the on-call forensic pathologist for guidance as to whether the removal of organs for donation will impact on the ability to determine a cause of death.

In some jurisdictions the donation agency staff have built good working relationships and lines of communication with the coronial staff and forensic pathologists to ensure that consent to donation is not impeded. In some jurisdictions, however, the refusal rate can be considerably higher. 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!

We recommend consideration of some form of codification to ensure the support and accountability of coronial staff in consideration of organ donation.

<u>Interaction between VAD and donation</u>

Organ donation after voluntary assisted dying (VAD) is estimated to be possible in around 10% of VAD cases. The possibility of donation after VAD is mainly limited by the illness

[5] Page 21 of ANZICS Statement on Death and Organ Donation Edition 4.1, 2021

permitting the VAD, most likely cancer. It has occurred in about 6 cases across Australia since 2019 (less than 1% of total donors), mainly in the setting of motor neuron disease.

In some countries, such as Canada, some jurisdictions have rates of donation after VAD of 14%, partly due to legislation allowing VAD to be performed in a way that supports a patient-centred approach to facilitate organ donation[6].

Two specific legislative hurdles that are present in some Australian jurisdictions are:

- The inability for the patient to choose an intravenous (iv) route of administration. In at least 2 jurisdictions (Victoria and South Australia), iv administration is only permitted if a medical assessment confirms the patient's inability to swallow. Administration of the VAD medication by the oral route results in a slower and unpredictable progression to death thus leading to a much greater likelihood that the patient will not become a donor. Apart from the lost opportunity for donation, this has been identified by the families of deceased VAD patients as distressing that the patient's strongly held wishes to be donors has not been realised. Furthermore, if only oral administration has been authorised, and the patient's condition has deteriorated such that they can no longer self-administer the oral VAD medication, it is extremely difficult to achieve a change to iv administration.
- Organ donation following VAD is only possible if the VAD medication is administered in the hospital setting. For those VAD patients wishing to commence VAD at home this is a deterrent to donation because the VAD legislation in Australia requires the patient to confirm their wish for VAD immediately prior to substance administration. By contrast, in Canada the legislation allows the patient to say goodbye to their family then be put into a medically induced coma, placed on a ventilator and then be transported to the hospital for the administration of the VAD medication and then proceed to organ donation[7]. Allowing confirmation of their VAD wish prior to the medically induced coma and transport would enable VAD patients to become donors, as per their wishes.

[6] Organ donation after medical assistance in dying: a descriptive study from 2018 to 2022 in Quebec. Matthew J. Weiss, Mathilde Dupras-Langlais, Marie Josée Lavigne, Sylvain Lavigne, Annie-Carole Martel, Prosanto Chaudhury CMAJ Jan 2024, 196 (3) E79-E84; **DOI:** 10.1503/cmaj.230883

[7] Mulder J, Sonneveld JPC. Organ donation after medical assistance in dying at home. CMAJ. 2018 Nov 5;190(44):E1305-E1306. doi: 10.1503/cmaj.170517. PMID: 30397157; PMCID: PMC6217602

An Ethical and Professional Framework for Organ Donation after Death in Australia

1.0 Introduction

This document is intended to provide guidance and advice to healthcare professionals involved in the care of patients approaching the end of their lives in hospital who may be suitable to donate solid organs for transplantation after their death. The document provides an ethical and professional framework to guide practice, based principally on published expert opinion amongst donation, transplantation and intensive care practitioners in Australia. It references similar guidance in other countries with developed donation and transplantation programs and considers what is known regarding Australian public opinion from published surveys. The document, however, is not a guide to the law. In Australia, medical practice at end-of-life and regarding organ donation is governed by various items of legislation, principally Human Tissue Acts and Guardianship Acts. These Acts are similar but not the same between the different States and Territories, and it is not the intention nor scope of this document to interpret the law in relation to each of the recommendations that are made. Practitioners must make themselves aware of the relevant laws in the State or Territory in which they work and ensure that their practice complies with all legal requirements. The document is also intended to be complementary to the two documents published by the Australia & New Zealand Intensive Care Society (Australia's prime organisation representing Intensive Care Medicine): *The Statement on Organ and Tissue Donation* [1] and the *ANZICS Statement on Care and Decision-Making at the End-of-life for the Critically Ill* [2], and the Organ & Tissue Authority documents *Best Practice Guideline for Donation after Circulatory Determination of Death (DCDD) in Australia* [3], and *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* [4]; where appropriate, cross-referencing is provided.

In preparing this document we have been guided by the UK document *Donor Actions Framework* [5]. We have taken a similar approach, first in establishing that the ethical and professional approach to deceased donation is founded on the principal to always act in the best interests of the patient. Secondly and thirdly, we have taken the same approach of considering **all** activities or interventions that might be carried out in relation to a potential donor, from matters as simple as checking the Australian Organ Donor Register (AODR) to complex medical investigations such as a coronary angiogram, and have considered how these might meet the best interests standard at different phases of the process from end-of-life care to death and donation: these are before and after death has occurred, and then for each of these before and after consent has been obtained. For simplicity, we have chosen the same term as used in the UK document, "donor actions", to encompass all the activities or interventions that may be carried out in relation to a potential organ donor for the purpose of exploring donation eligibility, facilitating deceased donation, increasing donor organ utilisation and optimising transplant outcomes.

Considering donor actions in a perspective of best interests means balancing the benefit of the action to the patient against any risks of the action. This is different from substituted judgement in decision making which is the more common approach taken in

law in Australia. Substituted judgement involves making a decision which is consistent with what the person would have decided if they had the capacity to do so. Considering actions using a best interests standard is likely more useful in relation to organ donation as in this situation relying on substituted judgement may make decision-making difficult as there may not be any clear evidence regarding what a person might have decided in relation to certain actions around the time of their death. Furthermore, use of a best interests standard is in keeping with the ANZICS statement on decision-making at end-of-life which uses this approach throughout [2]. For further discussion regarding best interests and the law see also below, section 4.0.

2.0 Structure of the Guidance / Advice

The guidance / advice is provided depending on two variables in time:

1. Whether the patient is deceased
2. Whether consent for organ donation has been obtained.

Consequently, there are four different clinical scenarios where donation actions may occur, in which the ethical and professional standards regarding the potential donor's best interests may differ:

1. Before death and before consent
2. Before death and after consent
3. After death and before consent
4. After death and after consent.

Each individual donor action has been considered (where appropriate) when it might arise in each of these four scenarios as to whether it might be in the potential donor's best interests by balancing potential benefits against potential harms in that scenario. So, for example, the balance between benefit and harm of a particular action may change depending on whether the patient is alive or deceased with consent obtained or not yet requested. Professional and ethical guidance is provided for each action as either:

1. Acceptable actions
   - Actions that are likely to be in the patient's best interests
2. Unacceptable actions
   - Actions that are unlikely to be in the patient's best interests
3. Actions against current professional, ethical or legal guidance in Australia.

In each case (except for the last) the document is providing guidance and advice only, it is not mandating what should or should not be done. That remains a decision for the patient's treating healthcare team and deciding should involve integration of this guidance / advice with the patient's known wishes regarding donation and their family's opinions on the patient's likely wishes. Australian practitioners should feel confident however to proceed with actions that are listed as acceptable. Actions against currently professional, ethical or legal guidance are actions which are likely to contravene fundamental professional and ethical norms or the law. Whilst some of these actions

may be allowed in other countries, they are not currently considered to be in keeping with contemporary Australian medical practice or unlikely to be legally permitted in Australia.

3.0 Organ Donation in Australia in Perspective

The Australian Government in 2008 announced the National Reform Program for Organ and Tissue Donation, a 9-point reform template designed to embed international best practices regarding organ and tissue donation for transplantation with an aim of significantly increasing the availability of organs and tissues for transplantation such that more Australians would benefit from the life saving / life changing effects of transplantation. The National Reform included the embedding of dedicated donation specialists – medical and nursing – in major hospitals across the country, with a remit to ensure that potential donation opportunities were identified and not missed, that potential donor management was optimised such that opportunities to consider donation were preserved during the transition to end-of-life care / death, and that family donation conversations were conducted by trained donation professionals in order to optimise the opportunity for families to consent to donation. The National Reform has continued to be a priority for Commonwealth governments in the intervening years. In the community, support for deceased organ donation is high, with a survey reporting over 80% of the adult Australian population stating that they would have no objection to themselves becoming a donor [6]. Australian society is therefore highly supportive of organ donation, and Australians would in general expect that the opportunity for donation is considered in all appropriate end-of-life situations, and that efforts are made to ensure that donation can be considered in such situations. Of course, it is to be recognised that all individuals may not share the same general expectations as the majority, for example, due to cultural or religious reasons. Nonetheless, it is an accepted principle in general consent and privacy regulations that where actions are being taken in healthcare for a related secondary purpose this can be appropriate without specific information or consent if this is what an average lay person would reasonably expect to happen in the situation [7]. Ensuring that donation can be considered is termed “preserving the opportunity for donation”, and we will use this terminology in this document when we refer to certain donation actions, such as maintaining a patient on life support to enable their opinions regarding donation to be sought and considered.

Deceased organ donation in Australia occurs by two pathways: Donation after neurological determination of death (DND) and donation after circulatory determination of death (DCD). It is a fundamental ethical principle in deceased organ donation that donation must not occur until after the patient has died, and that the donation process itself must not cause the death of the patient (the so-called “dead donor rule” [8]). Furthermore, to prevent any actual or apparent conflict of interest, it is important that consideration of organ donation only occurs after medical consensus has been reached that active treatment is no longer in the patient’s best interests.

Diagnosis of death in the context of organ donation in Australia is described in detail in *The Statement on Organ and Tissue Donation* [1] and will not be covered in this

document, however procedures that might be considered that could have implications regarding the diagnosis of death will be covered[1].

4.0 Consent to Organ Donation

Patients who are potential deceased organ donors will almost always lack the capacity to make their own contemporaneous treatment (and therefore organ donation) decisions as the vast majority are unconscious due to their illness or injury. In this situation, decisions are made by the treating team in discussions with the patient's family / next-of-kin. In Australia, the State and Territory-based Human Tissue Acts outline the hierarchy of next-of-kin that can give assent / consent for organ donation to go ahead. In general, this hierarchy is different to that which applies when a substitute decision maker is needed to consent to medical treatment for a living person that lacks capacity (generally governed by Guardianship Acts or similar Acts). This can pose some difficulties regarding donor actions that are being contemplated in patients before death. Practitioners need to be cognisant of the legislation prevailing at the time that they are requesting consent for any action in a patient from a substitute decision maker. Occasionally, patients may be conscious and also have the capacity to make their own decisions regarding donation as their death approaches, for example, patients with terminal respiratory failure dependent on non-invasive ventilation and those with high spinal cord injuries receiving mechanical ventilation. Persons approved for voluntary assisted dying may also sometimes be medically suitable to donate organs after death and able to provide informed consent for this and associated procedures. Patients providing their own consent just prior to death is termed "**first person consent**" and navigating donor actions with first person consent is ethically simpler than with a substitute decision maker. Important differences in how donor actions may be managed where a patient provides first person consent are discussed in detail in section 9.0.

As previously mentioned, State and Territory Guardianship legislation vary, but most refer both to best interests of a patient and his or her wishes, if known (substituted judgement) [9]. It could be argued, therefore, that where a patient's wishes in relation to donation actions are unknown, and the action is intended to advance the interests of a potential organ recipient rather than those of the patient themselves (for example promoting their health and wellbeing (i.e. NSW Guardianship Act 1987 [10])) then a substitute decision maker cannot give consent. Problems caused by the Guardianship Acts in Victoria and NSW that prevented next-of-kin providing consent for certain procedures in DCD donation have therefore required legislative amendments. Best interests, however, are not necessarily limited to the management of a patient's medical condition. In the UK, courts have established that best interests are wider, and include a person's social, emotional, cultural and religious interests, and can include altruistic sentiments of concern for others. Moreover, best interests do not cease at the moment of death, so around the time of death a clinician needs to consult the next-of-kin to take full account of the person's previously expressed wishes, their general preferences and their beliefs including how they might wish to act altruistically to others and how they might wish to be remembered. In Australia, ANZICS comments in the *ANZICS Statement on Care and*

[1] Normothermic regional perfusion – see section 8.4

Decision-Making at the End-of-life for the Critically Ill that employing a best interests standard is especially useful when a patient has not expressed a preference. Finally, it is important to note that organ donation in Australia is based on the principles of altruism and community solidarity. The community therefore also has interests in what happens to individuals after death, and this should also be considered.

At end-of-life it is essential to establish a patient's wishes, views and beliefs regarding organ donation by checking if they have registered on the Australian Organ Donor Register (AODR) or if they have made any statement regarding donation in an Advance Care Directive, or by talking with their family. Whilst written confirmation of donation decisions may be considered legal, it is current practice that all families are consulted in every case and appropriate donation information shared with them. Regardless of any written form of consent, if the next-of-kin object to donation occurring it will not occur.

Consent registration does not imply that the potential donor has consented to *all* the possible donor actions that may be contemplated, however, and there may still be the need for specific consent to be provided by next-of-kin (see "antemortem procedures" below). Nonetheless, the presence of registration on the AODR would be important evidence of a patient's willingness to donate and can be useful guidance in determining best interests regarding various donor actions. In prescribed circumstances, some State and Territory legislation permits the hospital Designated Officer to authorise donation even where there is no available senior next-of-kin to provide consent.

3.1 Antemortem procedures:

To be an organ donor after death, adjustments are *always* needed to end-of-life care and specific donor actions will also be needed. Stating that end-of-life care should not or cannot be changed to facilitate organ donation is impractical and incorrect. However, every attempt should be made to ensure that any changes to standard end-of-life practices are of the minimum degree that is needed to make donation possible and successful. Medical donor actions carried out on a potential organ donor before their death are termed "antemortem procedures". These procedures may be required before or after consent for donation has occurred. Navigating the requirements to undertake antemortem procedures is principally an issue in patients likely to donate following circulatory death but will also apply in neurological death cases prior to the determination of neurological death. There is no internationally agreed definition of an antemortem procedure in the donation context. so for the purposes of this document we will take a broad approach and define antemortem procedures as any procedure or test that is performed before death for the purpose of organ donation and transplantation, which would not occur in the absence of consideration of donation. This could include remote actions such as screening patients in an ICU for characteristics that suggest they might soon be considered for donation, routine notification of patients to the DonateLife agency, checking the AODR prior to any discussion about donation with the family, then actions such as maintaining intensive care treatments and management after a decision has been made that ongoing active treatment of the patient's illness is not going to benefit them. After consent for donation, more intrusive actions such as the taking of blood for testing, performing x-rays and scans, administration of medications and/or

blood products may be indicated. It is very likely that most people in the community would know that certain tests are required to assess someone's suitability to donate and to "match" donor organs with recipients. Furthermore, it would be understood that ongoing supportive care in the ICU will need to be continued up to the time of donation. These actions can, therefore, be considered an integral part of the donation process and therefore consented for within the overall consent to donate. Beyond these, the donation consent may not be adequate as consent for antemortem procedures. Incompetent patients, even if registered on the AODR, are unlikely to have knowledge of, or have considered, all the antemortem procedures that may be required. In deciding whether any proposed donor action / antemortem procedure is in the best interests of the patient the clinical team need to consider the balance between the potential benefits of that action / procedure and any potential harms that cannot be prevented or alleviated. Efforts should always be made to ensure that only the minimum level of intervention on the donor is used as required to facilitate optimal transplant and recipient outcomes. In assessing the balance between potential benefit and potential harm, especially prior to consent, knowledge of the strength of the donor's willingness to donate can be important. The stronger the evidence of the donor's desire to donate, the greater the weight should be given to the assessment of any particular donor action as being in the patient's best interests.

In some jurisdictions in Australia it is necessary to obtain specific consent for the undertaking of antemortem procedures, so it is important that practitioners are fully aware of the legal requirements where they are practicing. As a more general guide to obtaining consent from next-of-kin for antemortem procedures it is useful to consider what is normal practice in non-competent patients in your hospital. Procedures that you would routinely perform in the ICU without specific discussion or written consent probably do not need specific consent in the donation setting. Where a substitute decision maker would routinely be asked to give consent for a procedure, it is likely that specific consent will also be needed in the donation setting. Competent patients providing first-person consent to donation can in general provide their own consent to antemortem procedures.

5.0 Donor Actions Before Death and Before Consent

These actions are those that are contemplated / carried out after it has been determined that the patient is to be transitioned to end-of-life care but before any discussion regarding organ donation has occurred with the next-of-kin. It applies both to patients who may progress along the DND pathway, where determination of neurological death has not yet occurred, and the DCD pathway.

5.1 <u>Acceptable actions:</u>

a) Ceasing treatments that are in place to manage the patient's clinical condition and transition of care to palliation including, where appropriate, the introduction and / or adjustment of palliative medications
b) Actions to determine a person's willingness and initial suitability to be a donor:

i. **Routine notification** to the DonateLife agency of patients commencing planned end-of-life care
ii. Accessing the AODR
iii. Gathering and sharing clinical information about the patient that is available to the clinical team with DonateLife teams[2] and allowing the DonateLife team to access the patient's electronic medical record

c) Actions to preserve the opportunity for donation:
   i. Actions to temporarily maintain life in order to establish if donation is possible and is in the best interests of the patient
      - Clinical stabilisation of a patient in an appropriate critical care setting
      - Continuation of intensive care treatments currently in place
      - Delaying the withdrawal or limitation of life-sustaining treatments until the patient's donation wishes and suitability have been assessed
   ii. The **introduction** of **routine** intensive care treatment to temporarily maintain life and physiological stability, to preserve the opportunity for donation (e.g. inotrope / vasopressor support, insertion of central venous and arterial lines)[3]
d) Involvement of a Donation Specialist Nurse in all conversations with next-of-kin where there is the potential that organ donation may be discussed
e) Holding a Planning Meeting involving treating clinicians and a Donation Specialist Nurse before any conversation with next-of-kin regarding a transition to end-of-life care or examination to determine death by neurological criteria
f) Determination of death by neurological criteria, including the conducting of ancillary tests where necessary

<u>Rationale</u>

Once it has been established that the patient is to be transitioned to end-of-life care it is appropriate that treatments that are in place solely to manage the patient's clinical condition are ceased. An important example is brain protective treatment in cases of intracranial hypertension. It is appropriate in such cases to stop controlled mild hyperventilation and to allow the patient to breath spontaneously if possible, to normalise serum electrolytes and stop CSF drainage, even if doing this may make the possibility of brain death occurring more likely. Some patients with significant brain injury may take time to develop brain death, and determination of a patient as deceased by neurological criteria is a more certain outcome for a family. Where organ donation is possible, donation after brain death results in more recipients benefiting from a donation decision. Please see below however regarding the maintenance of the opportunity for donation and advice regarding the timing of limitation or withdrawal of life-sustaining therapies.

[2] This includes "in principle" discussion of the patient's case, deidentified, with transplant team clinicians where deemed necessary to **exclude** the possibility of donation.
[3] Not including elective intubation for the purposes of facilitating donation – see below sections 5.4 & 9.0.

As previously discussed, Australian society is overwhelmingly supportive of organ donation therefore it would be generally expected that reasonable efforts are made to preserve the opportunity for donation, to allow time for the patient's likely wishes at end-of-life to be fully explored with next-of-kin and to establish in principle donor suitability for transplantation. Intensive Care specialists in Australia should consider this an appropriate and standard approach to end-of-life care management.

In Australia, the AODR is the main repository of information regarding individuals' donation decisions. To plan next-of-kin approaches at end-of-life, seeking knowledge of patients' preferences, when available, is vital. Early routine notification and routine AODR checking is recommended by ANZICS (*The Statement on Death and Organ Donation* [1] – section 4.3; *ANZICS Statement on Care and Decision Making at the End-of-life for the Critically Ill* [2] – Chapter 10) and is a key element in the *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* [4]. ANZICS recommends that AODR status is communicated to the family during end-of-life conversations.

End-of-life and organ donation conversations are often difficult and may come at a very stressful time for next-of-kin. Where organ donation is *clearly* not a possibility, it is best that treating clinicians and organ donation specialists discussing organ donation with families of patients transitioning to end-of-life care are as fully informed as possible regarding the medical suitability and logistic feasibility of organ donation. This will require the collection / transmission of some information regarding the patient's current illness and past medical history to the DonateLife team. Information contained within the patient's hospital clinical record should therefore be made available to the DonateLife team. Where on the assessment of the DonateLife team it appears highly likely that the patient is not suitable for organ donation, but there is some doubt regarding an individual organ, it is appropriate for the DonateLife team to have an "in principle" discussion about the patient's medical history with a transplant physician, but no potentially identifying material should be shared.

Preserving the opportunity for donation will generally mean that the patient will need to be supported in an appropriate critical care environment for the time taken to establish if donation is possible and to organise a family approach for donation. Regardless of the possibility of organ donation, however, not rushing end-of-life care is very likely to be in a patient's best interests. Taking time over end-of-life care allows family to gather at the hospital and better allows families to come to terms with the situation. Slowing the end-of-life care process in brain injury patients has also been shown to be associated with better prognostication [11]. While continuing current intensive care treatments and not withdrawing or limiting life-sustaining treatments are highly likely to be in a patient's best interests, in some situations it may be necessary to **introduce** new treatments after a decision that active treatment is no longer in the patient's best interests if the opportunity for donation is to be preserved. It is likely that routine intensive care treatments – that is, treatments that are generally provided to patients in intensive care without recourse to specific consent / discussion with next-of-kin – such as the insertion of arterial and central venous lines, the administration of fluid resuscitation, the introduction of vasopressors to defend blood pressure, are likely to be in the patient's best interests in this situation. More invasive supportive treatments might also be considered, however

the use of these would need to include an assessment of potential benefit versus potential harm, and the likelihood that an average person might expect that such interventions were or were not discussed with substitute decision makers.

The Statement on Death and Organ Donation recommends that neurological death is always formally diagnosed when it is suspected to have occurred [1]. In Australia it is accepted that the determination of death is the responsibility of healthcare professionals, and that this responsibility cannot be subject to a requirement to obtain consent from next-of-kin, for example before an examination to determine death is performed.

Given the complexity of end-of-life conversations it is important that there is planning conducted prior to the first conversation. This should involve a Donation Specialist Nurse, as these clinicians are highly trained to navigate these conversations. Even if it is not planned to introduce organ donation in the first end-of-life conversation, it cannot be predicted that donation will not be raised by the family in this conversation, or that the conversation may move unavoidably to a donation discussion. It is essential that there is a clear plan how such eventualities will be managed. The involvement of a Donation Specialist Nurse in all family organ donation conversations is a key element of the *Best Practice Guideline for Offering Organ and Tissue Donation in Australia* [4] and is accepted as a standard of care by ANZICS and the College of Intensive Care Medicine (CICM).

5.3 Unacceptable action:

a) Performance of investigations or initiation of treatments purely intended to assess or enhance the prospects of successful organ transplantation
b) The taking of blood or other samples for the purposes of transplantation (but see also note below)

Rationale

Donor actions that are solely for the purposes of facilitating donation and assessing and enhancing the prospects of successful transplantation are unlikely to be in a patient's best interests prior to obtaining consent for donation.

The taking of blood for tissue typing and serology *may* be in a patient's best interests in a limited circumstance where the patient has a registered donor wish on the AODR and where due to logistical reasons (such as in a remote / rural location) there is an imperative to obtain bloods prior to consent to prevent an inordinate delay to the process after likely family assent. Over 80% of families provide assent to donation in this situation.

5.4 Actions against current professional, ethical or legal guidance in Australia:

a) Approaching clinicians outside of the treating hospital for clinical information about the patient
b) Elective ventilation for the purposes of organ donation (in the absence of first-person consent – see 9.0 below)

Rationale

Pre-consent it is not appropriate for the DonateLife team to contact General Practitioners or other external healthcare professionals about the patient's medical history due to privacy regulations and potential reputational risks.

Prior to death and prior to consent elective ventilation for the purposes of organ donation in non-competent persons cannot be consented to by substitute decision makers in Australia. In the situation where a patient is registered on the AODR, it is unlikely that they will have considered elective ventilation in the setting of potential organ donation as this has received little media or community attention, so the donation registration has little weight. Rarely, a patient may have competed an Advance Care Directive that provides in detail advice regarding their donation wishes and if this is considered to adequately cover the risk / benefit equation for elective ventilation then proceeding may be justified.

6.0 Donor Actions Before Death and After Consent

This clinical scenario applies principally in cases likely to donate by the DCD pathway, although sometimes donation consent is obtained in DND pathway patients before the diagnosis of neurological death has been finalised. "Antemortem procedures" fall within this scenario. It is likely that most ethical and professional concerns occur in this scenario, as there can be the implication of a conflict between duty of care to the patient and duty of care to ensure best transplantation outcomes for recipients. Best interests of the patient will include ensuring that every effort is made to mitigate potential harm or distress to the patient that might be caused by donor actions. In addition, the risk of causing distress to the patient's family must be borne in mind.

6.1 Acceptable actions:

a) Ceasing treatments that are in place to manage the patient's clinical condition and transition of care to palliation including, where appropriate, the introduction and / or adjustment of palliative medications (see (e))
b) Discussing acceptability of (+/- obtaining consent for) particular donation actions / antemortem procedures with a patient's next-of-kin
c) Determining a person's suitability to donate:
    i. Conducting a donor risk assessment interview with next-of-kin
    ii. Carrying out a detailed review of the patient's medical records and where necessary contacting other healthcare professionals / checking healthcare databases[4] for information about the patient
    iii. Discussion with the Coroner, where the patient's death will be a reportable death under State and Territory Coroner's Acts
    iv. Taking, storage and testing of blood for virology and microbiology screening, blood group and tissue typing analysis
    v. Sampling and testing of urine

[4] Such as cancer registries.

vi. Minimally invasive investigations such as performing a physical examination, obtaining a chest x-ray, bedside transthoracic echocardiogram, bedside ultrasonography

d) Actions to continue to temporarily maintain life:
    i. Continuance of intensive care supportive treatments and planning for time of withdrawal to coincide with an appropriate time for organ retrieval
    ii. Management of haemodynamic and ventilatory instability by adjusting existing treatments
    iii. Introduction of routine intensive care treatments (such as inotropes, anti-arrhythmic medications, the siting of venous and arterial cannulae including central lines) to maintain physiologic stability and facilitate organ donation
e) Palliative care:
    i. Administration of adequate treatment to alleviate pain and distress in the period prior to and during the withdrawal of life sustaining treatment
    ii. Extubation as a form of treatment withdrawal, at a timing agreed with the next-of-kin. This is appropriate whether or not organ donation is part of the end-of-life care for the patient
f) Determination of death by neurological criteria, including the conducting of ancillary tests where necessary, as in 5.1 (d) above.
g) Actions with respect to the timing and / or location of withdrawal of life sustaining treatment
h) Pharmacological treatments (e.g. antibiotics, heparin at withdrawal of cardiorespiratory support[5]) with low risk of harm, where the sole intention of which is to enhance the prospects of a successful organ transplant.
i) Administration of blood, blood components and blood products
j) Moderately invasive organ-specific investigations to determine or exclude suitability for donation (e.g. bronchoscopy, superficial (skin, lymph node, gland) biopsy, CT imaging (requiring patient transfer to the radiology department), transoesophageal echocardiography, coronary angiography)

<u>Rationale</u>

As discussed in 5.1, if it has not already occurred, it is appropriate that treatments that are in place solely to manage the patient's clinical condition (such as brain protective management) are ceased.

Possible donor actions / antemortem procedures which may be indicated during the donation suitability work-up should be discussed in general terms with next-of-kin, however care should be taken to ensure that the level of detail provided to next-of-kin is tailored to their specific desire to receive this information, legal requirements for consent, and the risk of overburdening them with unnecessary information. Sometimes

[5] In patients not at a significant risk of haemorrhage. Where there is a risk of haemorrhage, heparin administration can be delayed to the time of onset of apnoea.

more invasive procedures may be necessary to evaluate the suitability of individual organs (for example a coronary angiogram to assess heart suitability). Procedures such as these will always need specific discussion and consent from next-of-kin. A general rule is that any procedure where it would be normal practice to approach a substitute decision maker for consent will need specific discussion and consent. Discussing these matters and establishing the strength of patient's willingness to donate and thus the acceptability of proposed procedures to them is very likely to be in their best interests. Note however that laws and policies relevant to antemortem procedures are not uniform in Australia. Not all jurisdictional legislation and policies clearly specify that antemortem interventions are permissible and/or which interventions can be undertaken, and the consent arrangements for those interventions. Clinicians must ensure that antemortem procedures and the necessary consents comply with jurisdictional, policies, and hospital protocols in their State or Territory.

Some donor actions are essential requirements if donation is to proceed and therefore are included in the overall consent for donation, such as continuing routine intensive care treatments, assessing donor risk and medical history to determine suitability, the routine blood sampling for donation and minimally invasive investigations necessary for organ suitability assessment.

Donor work-up and the logistics of mobilising retrieval teams and organising operating theatre time always takes time, and it is necessary to maintain the patient's clinical stability until the time set for withdrawal of cardiorespiratory support. This mandates the continuation of current intensive care therapies and their titration, as would be done for a patient receiving ongoing treatment. It may involve the introduction of new routine treatments. If a patient is becoming increasingly unstable, the extent to which supportive therapy is increased, or whether new therapies are introduced, should be determined by the treating clinical team taking into account the strength of the patient's willingness to donate, the opinions of the next-of-kin, and the balance between the likely benefit and likely harm of any action. At all times the focus should remain on the best interests of the patient.

It is the responsibility of the treating team to ensure that sedatives and opioids are administered in the same way that they would be used for a patient in a similar end-of-life situation who was not donating organs, however as discussed above, it is important to recognise that a decision to donate always leads to a change in end-of-life care planning. The transition from ongoing treatment to withdrawal of treatment is prolonged, and as discussed above sometimes active treatment will need to be increased to maintain stability during this period. Treating teams should be focussed on ensuring that there is no chance that the patient may be suffering pain, anxiety or distress during this period by administering adequate doses of analgesic and sedative medications. Providing guidance to bedside nursing staff on the titration of analgesic and sedative medications based on a level of responsiveness and physiological parameter targets is a useful method of ensuring the adequacy of dosing.

Where it appears that neurological death has occurred this should be determined by clinical examination +/- ancillary tests, reasoning as outlined in 5.1 above.

Shorter warm ischaemic times are important determinants of outcome from transplantation of organs from donors following circulatory death. This is of particular importance for the liver and heart. Warm ischaemia occurs both before and after death in circulatory death donors. Before death, functional warm ischaemia starts at an arbitrary time following withdrawal of cardiorespiratory support – often taken as when systolic blood pressure falls below 50mmHg (90mmHg for heart). Following death, warm ischaemia continues until cold organ perfusion. This post-mortem period can be modified by ensuring that any action that could delay the onset of cold perfusion is minimised. Arranging that withdrawal of cardiorespiratory support occurs in the operating theatre suite, either in an anaesthetic bay or within an operating theatre itself can significantly reduce the time from death to cold perfusion. In a consented donor, actions that ensure best outcomes for transplanted organs are likely to be in the donor's best interests, and this is supported by public opinion [6]. Practice in Australia varies regarding the preferred location of withdrawal of life support – ICU versus operating theatre suite, however anecdotal experience from jurisdictions where operating theatre suite withdrawal is the norm shows that families are no more distressed in this situation compared to when withdrawal has occurred in the ICU. Timing of withdrawal of life support will always have to be adjusted when donation is occurring compared to when it is not, as it will be necessary to consider factors such as organ retrieval team availability, timing issues pertaining to recipient surgery, operating theatre availability etc. Attempts should always be made to set a withdrawal time that is acceptable to the family, however the importance of donation and recipient factors will need to be explained in a considerate and respectful manner.

The introduction of any new pharmacological treatment, or the performance of any new investigation, purely to optimise donor organ outcomes on transplantation will always have some risk of an adverse outcome for the donor / patient. Again, most Australians would expect that efforts are made to ensure that transplantation outcomes are as good as possible in all donor situations. As previously outlined, decisions on therapies and investigations are the responsibility of the treating clinical team and should be made with consideration of the strength of the patient's willingness to donate, the opinions of the next-of-kin, and the balance between the likely benefit and likely harm of any action. In most cases, items such as those in (b) – (d) above would have minimal risk to a patient and would therefore be likely in a patient's best interests.

6.2 Unacceptable actions:

a) Highly invasive / complex investigations, such as invasive (body compartment) biopsies
b) Instituting actions against the wishes of the family

Rationale

Some investigations can be considered to carry sufficient risk or to be inappropriate in a living person even following organ donation consent, such as a surgical procedure involving entering a body cavity to biopsy or remove a lesion. All actions for which it would

be normal clinical practice to seek consent / assent from a substitute decision maker should be discussed with the next-of-kin and consent or assent obtained, as appropriate. Where the next-of-kin do not provide consent for a donor action it should not be performed. See also below section 9.0 regarding first-person consent.

6.3 Actions against current professional, ethical or legal guidance in Australia:

a) Institution of highly intrusive actions to temporarily maintain life, such as cardiopulmonary resuscitation or extra-corporeal membrane oxygenation
b) Elective ventilation for the purposes of organ donation (without first-person consent)
c) Actions known to be against the wishes of the patient
d) Actions likely to have ongoing deleterious effect on the patient if death does not occur promptly following planned withdrawal of life sustaining treatment (such as the placement of cannulae for post-mortem regional normothermic perfusion circuits)

Rationale

Patients in this clinical scenario will be those in whom discussion and agreement has occurred with a substitute decision maker / family that ongoing treatment is no longer of benefit to them and that either life-sustaining treatment should be withdrawn or that neurological death will be diagnosed. While, for the reasons previously outlined, continuing current therapies and potentially starting routine intensive care therapies is in the patient's best interests in order to facilitate their wish to donate, highly intrusive actions (as exampled above) are not appropriate. Regarding elective ventilation please see section 5.4 & 8.0.

Noting that about 25% of patients planned for donation after circulatory death do not die following withdrawal of life-sustaining therapy in a warm ischaemia timeframe that permits organ donation to occur, these patients will then have ongoing palliative cares, usually continuing in the intensive care unit. Actions which may adversely impact on the patient should they not die in a timeframe for donation are not appropriate. Obviously, nothing should be done where it is known that the patient themselves would not have agreed to it.

7.0 Donor Actions After Death and Before Consent

This section applies to patients in the period between the determination of death by neurological criteria before a donation discussion has been held with the next-of-kin. The priority in this period is care of the family, while the patient's willingness to donate is established. As the patient is now deceased, the concept of causing physical harm to the patient is no longer relevant. However, as previously discussed, other potential harms remain which may include concerns about the treatment of a person's body after death, not respecting values, beliefs and wishes held in life, and causing distress to those close to the deceased.

7.1 Acceptable actions:

a) Actions to establish a person's willingness and initial suitability to be a donor – as listed in 5.1 (a) above: Routine notification to the DonateLife agency, checking the patient's registration status on the AODR and gathering and sharing relevant clinical information
b) Discussion with the Coroner, when the patient's death is a reportable death, prior to speaking to the next-of-kin about organ donation to determine that organ donation can proceed
c) Maintaining intensive care support and stabilising the physiology of the potential donor – including the introduction and titration of inotropic and antiarrhythmic drugs – while a decision regarding donation is made. Furthermore, the following may also be appropriate in individual circumstances:
    i. Initiating more invasive intensive but routine intensive care therapies to temporarily maintain physiological stability
    ii. Short duration attempt(s) at cardiopulmonary resuscitation
    iii. Administration of medications, such as methylprednisolone to achieve physiological stability
d) Conducting a collaborative family donation conversation with the patient's next-of-kin involving the treating team and a Donation Specialist Nurse
e) For patients known to be willing to donate the taking, storage and testing of blood or other samples

Rationale

For (a), as per section 5.1 above.

Discussing reportable deaths with the Coroner prior to approaching the next-of-kin is appropriate as if the Coroner has restrictions on organs and / or tissues that can be retrieved for transplantation, or will not permit donation to proceed, knowing this will inform any conversation with the next-of-kin about donation.

The development of neurological death is frequently associated with marked haemodynamic instability. Although this is most common around the time of tentorial herniation, that is prior to the formal diagnosis of brain death, it may persist post death. Maintaining and stabilising the physiology of the donor during this period is very likely to be in the patient's best interests as it provides the time necessary for family discussions, the family's own end-of-life processes, and to determine wishes regarding organ donation. Patients should be provided with the same expert treatment as is provided to all patients in intensive care following the general principles of critical care management, and appropriate management of physiological derangement will require the insertion of arterial and central venous catheters. Similarly, delaying the withdrawal of cardiorespiratory support is also appropriate for the same reasons, however it is important to set a reasonable duration for support to be continued if donation is not an option or not desired. Depending on the stage of conversations with the family and any information regarding the strength of the patient's wishes to donate it may be also appropriate to temporarily introduce more invasive but routine intensive care therapies

such as dialysis. In the event of a sudden cardiopulmonary arrest, the chance of circulatory resuscitation with appropriate treatment is generally good in such patients and a short duration attempt at CPR may also be appropriate. Medications shown to improve physiological stability are similarly appropriate in this situation.

A Donation Specialist Nurse should be involved in any conversation where organ donation is to be or is likely to be discussed as per the rationale outlined in 5.2 above.

In general, the taking and testing of blood solely for the purposes of donation should only occur after consent to donation has been obtained, however in certain circumstances it can be in a patient's best interests before next-of-kin assent / consent. This would be, for example, where the patient has a known wish to donate (i.e. registered on the AODR) and there are logistical reasons to expedite the taking and transport of blood, for example a potential donor in a remote / regional location.

7.3 Unacceptable actions:

a) Actions that present a significant risk of harm to the patient
b) Instituting actions against the wishes of the next-of-kin

Rationale

Although the patient is deceased, it is still possible to cause non-physical harm to the patient or their next-of-kin. It is important to use conversations with the next-of-kin to establish the patient's beliefs regarding death and wishes after death, to avoid performing actions that would not have been acceptable to the patient. Even though a person may have a legally valid wish to donate, in Australia it would not be considered acceptable to go ahead with this against the express wishes of the next-of-kin.

7.4 Actions against current professional, ethical or legal guidance in Australia:

a) Actions initiated where the known wish of the patient is not to donate
b) Cannulation for, and the initiation of, extracorporeal circuits for normothermic regional perfusion

Rationale

Acting against the known wishes of a person, even after death, is never appropriate.

Cannulation for the purposes of initiating normothermic regional perfusion would not be permissible before consent to donation has been obtained. Please refer to section 8.0 for general comments regarding the implementation of normothermic regional perfusion in Australia.

8.0 Donor Actions After Death and After Consent

A far wider range of donation actions are likely to be in a patient's best interests after death and after consent for organ donation has been established. Donation actions must, however, still be evaluated individually and must be carried out as respectfully as possible, as the risks of failing to respectfully treat a deceased body and to cause distress to those close to the deceased remain. The minimum level of intervention on the donor should be used that is required to facilitate optimal transplant and recipient outcomes.

8.1 Acceptable actions:

a) Discussing proposed investigations / tests / procedures with the family to ascertain the acceptability of the proposed action to the patient
b) Actions to establish a person's suitability to be a donor, such as:
    i. Conducting a donor risk assessment interview with next-of-kin
    ii. Carrying out a detailed review of the patient's medical records and where necessary contacting other healthcare professionals / checking healthcare databases[6] for information about the patient
    iii. Discussion with the Coroner, where the patient's death will be a reportable death under State and Territory Coroner's Acts
    iv. Taking, storage and testing of blood for virology and microbiology screening, blood group and tissue typing analysis
    v. Sampling and testing of urine
    vi. Minimally invasive investigations such as performing a physical examination, obtaining a chest x-ray, bedside transthoracic echocardiogram, bedside ultrasonography
c) Biopsy of organs or tissues during the organ retrieval surgery for the purpose of establishing the safety or suitability for transplantation
d) Administration of blood, blood components and blood products
e) Invasive / more complex actions which may be used to assess a patient's suitability to be a donor, optimise organ quality for transplantation or to identify contraindications that may exclude donation. Possible examples are:
    i. Bronchoscopy
    ii. Biopsy or small excision of a suspicious skin lesion
    iii. Transoesophageal echocardiography (neurological death patients)
    iv. MRI imaging
    v. Coronary angiography
    vi. Lumbar puncture
    vii. Biopsy of organs or tissues prior to organ retrieval
f) Maintenance of mechanical ventilation and physiological stability to allow organ donation to proceed, including the use of additional monitoring or medications.
g) Short duration attempts at cardiopulmonary resuscitation
h) Adjusting goals of care from management of the patient's clinical conditions toward maximising the quality of consented organs, following organ optimisation national protocols, including recommended physical, physiological and pharmacological actions.

[6] Such as cancer registries.

i) In potential DCD lung donors:
    i. Reintubation after the declaration of death and, no earlier than 10 minutes after death, the administration of a single vital capacity breath

Rationale

Once assent / consent for donation has been obtained from the next-of-kin the focus of management for the patient changes to acting to ensure the best quality of organs destined for transplantation and thus the best outcomes from any transplant in a recipient. Donor management is the responsibility of the treating intensive care team and requires as diligent an approach as for any living intensive care patient. It is appropriate for the treating clinicians to discuss aspects of donor management with the DonateLife agency and / or with donation medical specialists when necessary, and also where required with members of transplant teams. Any discussion between treating teams and transplant teams must be conducted in a manner that ensures the patient's identity is not divulged.

As discussed in Section 7.0, as the patient has died, the risk of physical harm to the patient no longer exists, however decisions about actions need to consider the wishes of the patient in life and the possibility of causing distress to the family. The location and the duration of any action will be a key consideration. Additional investigations that may be invasive and/or time consuming may be in the patient's best interests if they lead to more organs being deemed suitable for transplantation or lead to improved transplant outcomes. Such investigations should be discussed with the patient's family and will need careful balancing as to the benefits and potential harms. Balancing the strength of the patient's willingness to donate, the ability of clinical team to minimise potential harms to the family and the justification of the need for the investigation to ensure successful donation will play determining roles.

See section 7.2 regarding CPR.

For potential DCD lung donors, the airway should be re-intubated after death has been confirmed in order to prevent soiling with stomach contents. No earlier than 10 minutes after death, a single vital capacity breath of oxygen-enriched air is administered to reduce lung ischaemia.

8.3 Unacceptable actions:

a) Actions against the wishes of, or the strong objections of the family, irrespective of whether there is legal consent for donation

Rationale

Whilst once legal consent for donation is obtained it would be legal to proceed even if family raise a subsequent objection to any action associated with donation, this is unlikely to lead to a situation that is in the best interests of the patient.

8.4 Actions against current professional, ethical or legal guidance in Australia:

a) Actions against the known wishes of the patient
b) Normothermic regional perfusion
c) Actions with the potential to restore cerebral perfusion after a diagnosis of death using circulatory criteria

Rationale

Normothermic regional perfusion (NRP) is now widely used in many countries in donation after circulatory determination of death. NRP has been demonstrated to result in improved liver and kidney outcomes following transplantation from circulatory death donors, and NRP is an alternative approach compared with ex-vivo perfusion for heart donation following circulatory death where it is significantly less costly. NRP can be instituted just in the abdomen ("Abdominal NRP"), where the thoracic aorta is occluded to prevent thoracic organ perfusion, or in the thorax and abdomen ("Thoraco-abdominal NRP"). There are two main concerns with NRP which at the current time mean that it is not ethically or professionally acceptable in Australia. The first is the risk of restoring intracranial circulation, and thus restoring cerebral function. This risk is likely very low with abdominal NRP but significant with thoraco-abdominal NRP unless very stringent efforts are made to exclude the cerebral circulation involving the clamping +/- venting of the great arteries and veins supplying the cranium. It is not known whether any of the described strategies are wholly effective in guaranteeing that there is no possibility of restoration of intracranial blood flow via collateral circulatory channels. Research is currently underway to document intracranial flow patterns in NRP and once the results of are known this may allow a better assessment of the applicability of NRP in clinical practice, both abdominal and thoraco-abdominal. The second concern is somewhat more specific to Australia, where in all State and Territory Human Tissue Acts it is stated that for the purposes of law a person has died when there has occurred irreversible cessation of circulation of blood in the person's body. It is unclear therefore if the institution of even a limited circulation, such as in abdominal NRP, after the determination of death would then violate the requirement that the cessation of circulation within the body was irreversible.

Regardless of the issues discussed above relating to NRP, any action that has the potential to restore cerebral perfusion after the determination of death by circulatory criteria is not in keeping with professional and ethical practice.

9.0 Implications of first-person consent for organ donation

Occasionally patients may be in a situation where they are competent and able to provide their own consent to organ donation shortly before their death. In the past this has happened, for example, in cases of patients who are ventilator dependent with high spinal cord injury, or in patients dependent on non-invasive ventilation with end-stage neuromuscular or respiratory diseases. More recently, patients that have been approved for Voluntary Assisted Dying have provided first-person consent for organ donation prior to accessing the substance to die. First-person consent allows all matters associated

with organ donation to be discussed with the patient directly and to obtain consent for individual donation actions from the patient. This means that there should be no uncertainty about what the patient would wish, and it should be possible to be certain that one is always acting in the best interests of the patient.

It is important to note, however, that persons do not have a right to demand that things be done to them that will cause them serious harm, and healthcare professionals do not have to do something to a person just because they have asked for it. There are some actions that would not be legal, even if a person clearly asks for them. For example, it is not legal to remove organs from a patient under anaesthesia which then results in their death. Clearly, any medical intervention will have some risk of harm, but many interventions may be justified if the risk of harm is low and this is balanced by the benefit to the patient in undergoing the intervention – this could be simply enabling them to fulfill their wish to donate, or by ensuring for them that their donation will be as successful as possible. The donation team should ensure that they do not propose overly onerous interventions to a patient that have the risk to cause them significant harm, and that they only consider the absolute minimum degree of intervention needed in any situation, and keep in mind the balance between the risk and the likely benefit of any intervention.

Competent individuals may be able to consent to elective mechanical ventilation purely for the purposes of facilitating organ donation. The validity of consent would depend on the information the patient is given as to the risks and benefits of the intervention and being sure that the patient fully understands this.

Patients may provide first-person consent in the form of a written Advance Care Directive. This is likely to provide less certainty compared with the situation where the patient can be spoken to directly. For an Advance Care Directive to be taken as consenting to specific donation actions it is necessary that the document clearly outlines each action that the patient is providing consent for, and for more complex or risky actions there would need to be some indication that the patient understood the complexity or risk when documenting their consent. Taking elective ventilation as an example, it would be necessary to know that the patient clearly understood what this entailed if they had simply documented that they wished to be intubated for organ donation before their death.

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	BEFORE Death and BEFORE Consent	BEFORE Death and AFTER Consent	AFTER Death and BEFORE Consent	AFTER Death and AFTER Consent
Acceptable Actions	a) Ceasing treatments that are in place to manage the patient's clinical condition and transition of care to palliation including, where appropriate, the introduction and / or adjustment of palliative medications b) Actions to determine a person's willingness and initial suitability to be a donor: I. **Routine notification** to the DonateLife agency of patients commencing planned end-of-life care II. Accessing the AODR III. Gathering and sharing clinical information about the patient that is available to the clinical team with DonateLife teams and allowing the DonateLife team to access the patient's electronic medical record c) Actions to preserve the opportunity for donation: I. Actions to temporarily maintain life in order to establish if donation is possible and is in the best interests of the patient	a) Ceasing treatments that are in place to manage the patient's clinical condition and transition of care to palliation including, where appropriate, the introduction and / or adjustment of palliative medications (see (e)) b) Discussing acceptability of (+/- obtaining consent for) particular donation actions / antemortem procedures with a patient's next-of-kin c) Determining a person's suitability to donate: i. Conducting a donor risk assessment interview with next-of-kin ii. Carrying out a detailed review of the patient's medical records and where necessary contacting other healthcare professionals / checking healthcare databases for information about the patient iii. Discussion with the Coroner, where the patient's death will be a reportable death under State	a) Actions to establish a person's willingness and initial suitability to be a donor – as listed in 5.1 (a) above: Routine notification to the DonateLife agency, checking the patient's registration status on the AODR and gathering and sharing relevant clinical information b) Discussion with the Coroner, when the patient's death is a reportable death, prior to speaking to the next-of-kin about organ donation to determine that organ donation can proceed c) Maintaining intensive care support and stabilising the physiology of the potential donor – including the introduction and titration of inotropic and antiarrhythmic drugs – while a decision regarding donation is made. Furthermore, the following may also be appropriate in individual circumstances: i. Initiating more invasive intensive but routine intensive care therapies to temporarily maintain physiological stability ii. Short duration attempt(s) at cardiopulmonary resuscitation d) Administration of medications, such as methylprednisolone to achieve physiological stability	a) Discussing proposed investigations / tests / procedures with the family to ascertain the acceptability of the proposed action to the patient b) Actions to establish a person's suitability to be a donor, such as: i. Conducting a donor risk assessment interview with next-of-kin ii. Carrying out a detailed review of the patient's medical records and where necessary contacting other healthcare professionals / checking healthcare databases for information about the patient iii. Discussion with the Coroner, where the patient's death will be a reportable death under State and Territory Coroner's Acts iv. Taking, storage and testing of blood for virology and microbiology screening, blood group and tissue typing analysis

	II. Clinical stabilisation of a patient in an appropriate critical care setting III. Continuation of intensive care treatments currently in place IV. Delaying the withdrawal or limitation of life-sustaining treatments until the patient's donation wishes and suitability have been assessed V. The **introduction** of **routine** intensive care treatment to temporarily maintain life and physiological stability, to preserve the opportunity for donation (e.g. inotrope / vasopressor support, insertion of central venous and arterial lines) d) Involvement of a Donation Specialist Nurse in all conversations with next-of-kin where there is the potential that organ donation may be discussed e) Holding a Planning Meeting involving treating clinicians and a Donation Specialist Nurse before any conversation with next-of-kin regarding a transition to end-of-life care or	and Territory Coroner's Acts iv. Taking, storage and testing of blood for virology and microbiology screening, blood group and tissue typing analysis v. Sampling and testing of urine vi. Minimally invasive investigations such as performing a physical examination, obtaining a chest x-ray, bedside transthoracic echocardiogram, bedside ultrasonography d) Actions to continue to temporarily maintain life: i. Continuance of intensive care supportive treatments and planning for time of withdrawal to coincide with an appropriate time for organ retrieval ii. Management of haemodynamic and ventilatory instability by adjusting existing treatments iii. Introduction of routine intensive care	e) Conducting a collaborative family donation conversation with the patient's next-of-kin involving the treating team and a Donation Specialist Nurse f) For patients known to be willing to donate the taking, storage and testing of blood or other samples	v. Sampling and testing of urine vi. Minimally invasive investigations such as performing a physical examination, obtaining a chest x-ray, bedside transthoracic echocardiogram, bedside ultrasonography c) Biopsy of organs or tissues during the organ retrieval surgery for the purpose of establishing the safety or suitability for transplantation d) Administration of blood, blood components and blood products e) Invasive / more complex actions which may be used to assess a patient's suitability to be a donor, optimise organ quality for transplantation or to identify contraindications that may exclude donation. Possible examples are: i. Bronchoscopy ii. Biopsy or small excision of a suspicious skin lesion iii. Transoesophageal echocardiography (neurological death patients) iv. MRI imaging v. Coronary angiography vi. Lumbar puncture

	examination to determine death by neurological criteria f) Determination of death by neurological criteria, including the conducting of ancillary tests where necessary	treatments (such as inotropes, anti-arrhythmic medications, the siting of venous and arterial cannulae including central lines) to maintain physiologic stability and facilitate organ donation e) Palliative care: i. Administration of adequate treatment to alleviate pain and distress in the period prior to and during the withdrawal of life sustaining treatment ii. Extubation as a form of treatment withdrawal, at a timing agreed with the next-of-kin. This is appropriate whether or not organ donation is part of the end-of-life care for the patient iii. Determination of death by neurological criteria, including the conducting of ancillary tests where necessary, as in 5.1 (d) above.		vii. Biopsy of organs or tissues prior to organ retrieval f) Maintenance of mechanical ventilation and physiological stability to allow organ donation to proceed, including the use of additional monitoring or medications. g) Short duration attempts at cardiopulmonary resuscitation h) Adjusting goals of care from management of the patient's clinical conditions toward maximising the quality of consented organs, following organ optimisation national protocols, including recommended physical, physiological and pharmacological actions. i) In potential DCD lung donors: i. Reintubation after the declaration of death and, no earlier than 10 minutes after death, the administration of a single vital capacity breath

		f) Actions with respect to the timing and / or location of withdrawal of life sustaining treatment g) Pharmacological treatments (e.g. antibiotics, heparin at withdrawal of cardiorespiratory support) with low risk of harm, where the sole intention of which is to enhance the prospects of a successful organ transplant. h) Administration of blood, blood components and blood products i) Moderately invasive organ-specific investigations to determine or exclude suitability for donation (e.g. bronchoscopy, superficial (skin, lymph node, gland) biopsy, CT imaging (requiring patient transfer to the radiology department), transoesophageal echocardiography, coronary angiography)		
Unacceptable Actions	a) Performance of investigations or initiation of treatments purely intended to assess or enhance the prospects of successful organ transplantation b) The taking of blood or other samples for the purposes of transplantation (but see also note below)	a) Highly invasive / complex investigations, such as invasive (body compartment) biopsies b) Instituting actions against the wishes of the family	a) Actions that present a significant risk of harm to the patient b) Instituting actions against the wishes of the next-of-kin	a) Actions against the wishes of, or the strong objections of the family, irrespective of whether there is legal consent for donation

Actions against current professional, ethical or legal guidance in Australia	a) Approaching clinicians outside of the treating hospital for clinical information about the patient b) Elective ventilation for the purposes of organ donation (in the absence of first-person consent	a) Institution of highly intrusive actions to temporarily maintain life, such as cardiopulmonary resuscitation or extra-corporeal membrane oxygenation b) Elective ventilation for the purposes of organ donation (without first-person consent) c) Actions known to be against the wishes of the patient d) Actions likely to have ongoing deleterious effect on the patient if death does not occur promptly following planned withdrawal of life sustaining treatment (such as the placement of cannulae for post-mortem regional normothermic perfusion circuits)	a) Actions initiated where the known wish of the patient is not to donate b) Cannulation for, and the initiation of, extracorporeal circuits for normothermic regional perfusion	a) Actions against the known wishes of the patient b) Normothermic regional perfusion c) Actions with the potential to restore cerebral perfusion after a diagnosis of death using circulatory criteria