

HEART TRANSPLANTATION AFTER CIRCULATORY DEATH: IT IS TIME TO REDEFINE DEATH ACCORDING TO IRREVERSIBLE CESSATION OF THE CIRCULATION AND RECONCILE IT WITH IRREVERSIBLE CESSATION OF BRAIN FUNCTION

NEERA BHATIA* AND JAMES TIBBALLS**

In this article, we examine whether organ procurement of the heart and transplantation contravenes the dead donor rule and Australian legislative definitions of death as an irreversible cessation of the circulation. We contend that this practice upholds a long-held belief that donors of any organs after cessation of the circulation are not actually dead at the time of procurement – principally because of insufficient time lapse between cessation of the circulation and procurement of organs. Moreover, the fact that the transplanted heart functions in a recipient proves the donor’s circulation had never actually ceased irreversibly. Nonetheless, we suggest that this practice may be legitimised by amending legislation to redefine death as an irreversible cessation of brain function preceded by cessation of the circulation and requiring medical proof that the donor’s cortical brain function has ceased function before organ procurement.

I INTRODUCTION

For over 50 years there has been concern that a person donating organs after circulatory death (‘DCD’) is not actually dead and that organ procurement contravenes the dead donor rule (‘DDR’). The practice of DCD commenced on a systematic basis with a protocol developed at the Pittsburgh Medical Centre in 1992.¹ It has enabled the procurement of many organs, but not hearts for

* Associate Professor, School of Law, Deakin University, Melbourne, Australia, neera.bhatia@deakin.edu.au.

** Associate Professor, Departments of Paediatrics and of Pharmacology, University of Melbourne, and Senior Intensive Care Physician, The Royal Children’s Hospital, Melbourne, Australia, tibballsjames@gmail.com. We thank the anonymous reviewers whose comments helped us refine our arguments.

1 Michael A DeVita and James V Snyder, ‘Development of the University of Pittsburgh Medical Center Policy for the Care of Terminally Ill Patients Who May Become Organ Donors after Death Following the Removal of Life Support’ (1993) 3(2) *Kennedy Institute of Ethics Journal* 131 <<https://doi.org/10.1353/ken.0.0175>>.

transplantation. Although the first heart transplantation, carried out in 1967, was from a donor whose heart had stopped functioning, the donor also had absent respiration and neurological reflexes,² that is, some identifiable elements of brain death. The recipient of the heart survived only 18 days.³ In the following several years, over 100 recipients received hearts from DCD, but the practice declined due to chronic immunological rejection and limited long-term recipient survival.⁴

Since then, and until recently, heart transplantation has been performed with hearts preferably procured from brain dead donors with better outcomes.⁵ However, a paucity of hearts is currently evident because DCD as a practice is increasing while donations after brain death ('DBD') is declining or remaining static. Consequently, this has stimulated a renewed interest in heart transplantation from DCD. In recent times, hearts procured during DCD have been successfully transplanted into recipients in only four countries: the United Kingdom, Australia, Belgium, and the United States ('US'), while Canada is taking a keen interest in the implementation of this practice.⁶

Heart transplantation from DCD raises additional important ethical and legal questions, indeed one was raised by Albert Rosenfeld in 1968, soon after the first heart transplant. He posed the question: 'If you can start this heart going again in a new body, why couldn't you have kept it going in the old one?'⁷ That poignant ethical question remains unresolved.⁸ The practice has never been legally justified and it has been suggested that it contravenes the legal definition of death.⁹ Especially pertinent is how this practice, still in its infancy, contributes to the long-running debate over whether a donor subjected to any organ procurement during DCD is actually dead and whether or not it conforms to legislation defining death, in particular whether it conforms to Australian legislation defining circulatory death and the DDR.

2 C N Barnard, 'A Human Cardiac Transplant: An Interim Report of a Successful Operation Performed at Groote Schuur Hospital, Cape Town' (1967) 41(48) *South African Medical Journal* 1271, 1271.

3 Ibid.

4 Michael A DeVita, James V Snyder and Ake Grenvik, 'History of Organ Donation by Patients with Cardiac Death' 1993 3(2) *Kennedy Institute of Ethics Journal* 113, 119 <<https://doi.org/10.1353/ken.0.0147>>.

5 Peter L Abt, Carol A Fisher and Arun K Singhal, 'Donation after Cardiac Death in the US: History and Use' (2006) 203(2) *Journal of the American College of Surgeons* 208 <<https://doi.org/10.1016/j.jamcollsurg.2006.03.014>>.

6 See, eg, Ian M Ball et al, 'Heart Recovery after Circulatory Determination of Death: Time for Public Engagement' (2019) 66(10) *Canadian Journal of Anaesthesia* 1147 <<https://doi.org/10.1007/s12630-019-01386-9>>; Oliver K Jawitz and Carmelo Milano, 'Is It Time for the United States to Engage in Heart Transplantation Using Donation after Circulatory Death?' (2020) 159(2) *Journal of Thoracic and Cardiovascular Surgery* 512 <<https://doi.org/10.1016/j.jtcvs.2019.07.147>>; Arjun Iyer and Kumud Dhital, 'Cardiac Donation after Circulatory Death' (2020) 25(3) *Current Opinion in Organ Transplantation* 241 <<https://doi.org/10.1097/MOT.0000000000000758>>.

7 Albert Rosenfeld, 'Heart Transplant: Search for an Ethic' (1968) 64(14) *Life* 75, 79.

8 See Shayan Marsia et al, 'Heart Transplantation after the Circulatory Death: The Ethical Dilemma' (2018) 70(3) *Indian Heart Journal* S442 <<https://doi.org/10.1016/j.ihj.2018.08.010>>.

9 Jerry Menikoff, 'The Importance of Being Dead: Non-Heart-Beating Organ Donation' (2002) 18(1) *Issues in Law and Medicine* 3 ('The Importance of Being Dead').

A Aims and Structure of Article

In this article, we examine the legal and ethical issues and status pertaining to DCD with an emphasis on heart transplantation. We suggest how an amendment to the current Australian legislation and existing clinical practice may legitimise heart transplantation during DCD while enabling conformation to the DDR. The principal concerns that we highlight in this article are that the critical interval period between the formal declaration of death from the potential donor and the procurement of organs for transplantation into the potential recipient is too short to be certain that the donor is actually brain dead, and there is insufficient medical proof of this requirement. In the following Part II of this article, for context, we consider the clinical and legal definitions of death and how it is determined. In Part III we discuss the long-standing contentious legal, medical, and ethical debate as to whether organ donors with cessation of circulation are really considered to be dead. We engage in a broad range of perspectives in our examination of this controversial issue, including pragmatic considerations such as whether there is a prospect of resuscitation of the donor and importantly, we examine the legal and ethical nuances of the definition of irreversible for the purposes of determining death to procure the heart for transplantation in another person. We also review and consider the arguments surrounding procurement of organs before the resurgence of heart transplantation after DCD. All the principles derived in this Part apply to the subject in Part IV where we consider more contemporary debate, specifically as to whether heart donors with cessation of circulation are considered to be dead. In Part V of this article, we consider three proposals for reform, namely (i) abandoning the DDR; (ii) abandoning the practice of DCD and (iii) amending the Australian legislation that defines death. We make our closing remarks in Part VI.

II DETERMINATION AND DEFINITION OF DEATH: CLINICAL AND LEGAL

In this part of the article, we consider the background issues pertaining to DCD including the DDR, the determination of death, moment of death and the legal definition of death before describing controlled organ donation after circulatory death.

A The Dead Donor Rule

The procurement of vital organs has always been conducted after the death of the donor, under what is known as the DDR.¹⁰ This term was coined by Robertson in 1999¹¹ but originated from principles developed independently in the 1960s by

10 The rule applies only to procurement of organs from deceased persons. The donation of non-vital tissues or to one of a pair or part of a vital organ from a living donor is not relevant to this discussion.

11 John A Robertson, 'The Dead Donor Rule' (1999) 29(6) *Hastings Center Report* 6, 6 <<https://doi.org/10.2307/3527865>>.

the French National Council of the Order of Physicians, the Ad Hoc Committee of the Harvard Medical School and the World Medical Assembly in Sydney.¹² According to the DDR, organ procurement should not occur until the patient is dead and the procurement of organs should *never* of itself be the proximate cause of a person's death.¹³ Originally, it appeared that the purpose of the DDR had little to do with protecting donors from harm, but rather was a mechanism for avoiding legal consequences, circumventing controversy and a means to persuade the medical profession and the public that organ procurement was morally acceptable and legally safe.¹⁴ Fundamental and well-established laws forbid the intentional killing of one individual by another. This includes circumstances where a person is close to death and seriously medically compromised. The DDR has been noted as 'a centerpiece of the social order's commitment to respect for persons and human life'.¹⁵ Further, 'it is also the ethical linchpin of a voluntary system of organ donation, and helps maintain public trust in the organ procurement system'.¹⁶

B Scientific and Biological Determination of Death

Until the 1950s when mechanical ventilation was invented, differentiating between the states of life and death was relatively uncomplicated. The loss of spontaneous respiration, apnoea, or loss of circulation predicted death with certainty because all organs die when deprived of an oxygenated blood supply. The brain is the most vulnerable organ and ceases to function rapidly after deprivation of blood supply and is dead after minutes, a state which is recognised clinically as permanent loss of consciousness. Thus, death was clinically regarded as a unitary state of absent respiration, absent circulation, and unresponsiveness. However, mechanical ventilation applied during apnoea was able to maintain oxygenation and therefore of a circulation (powered by the heart) even when the brain had ceased function. This state was regarded as a separate brain death and quickly became accepted in medical and legal practice when mechanical ventilation was being used. Such a person appeared to be alive with breathing (albeit artificial), a circulation and ongoing other organ function but was unresponsive, could not move and had no brain stem reflexes. However, other 'higher-brain' functions are untestable. It was uncertain which of the brain functions of a live person should be extinguished to meet the definition of death under the term 'brain death'.

Of the many concepts of death, Bernat regards death as 'fundamentally a biological phenomenon ... an immutable and objective biological fact and not fundamentally a social contrivance'.¹⁷ Others too have rejected the idea of death as

12 David Rodríguez-Arias, 'The Dead Donor Rule as Policy Indoctrination' (2018) 48(S4) *Hastings Center Report* S39, S40–1 <<https://doi.org/10.1002/hast.952>>.

13 Robert M Arnold and Stuart J Youngner, 'The Dead Donor Rule: Should We Stretch It, Bend It or Abandon It?' (1993) 3(2) *Kennedy Institute of Ethics Journal* 263 <<https://doi.org/10.1353/ken.0.0153>>.

14 Rodríguez-Arias (n 12).

15 Robertson (n 11) 6.

16 Ibid.

17 James L Bernat, 'The Whole-Brain Concept of Death Remains Optimum Public Policy' (2006) 34(1) *Journal of Law, Medicine and Ethics* 35, 36–7 <<https://doi.org/10.1111/j.1748-720X.2006.00006.x>> ('Whole-Brain Concept of Death').

a social or legal construct, instead, regarding death as a ‘biological reality’,¹⁸ and ‘first and foremost, a biological process’,¹⁹ but as Youngner, Arnold and DeVita draw attention to, ‘death is both a biologically based and socially constructed notion about which there is little prospect for social consensus’.²⁰ It is only the biological determination of death that is considered here in the procurement of organs for transplantation. It is the biological determination of death which is the basis of the DDR as it relates to organ procurement and transplantation. For these purposes, death should be an event and not a process which separates it from life, it should be irreversible and death should mean death of the whole brain.²¹

C The Moment of Death

Pursuant to the DDR, procurement of organs for the purpose of their transplantation must only occur after withdrawal of life-sustaining treatment when the donor is ‘dead’ but pursuant to physiological factors, when the donor’s organs are still capable of recovering function in the recipient. That interval, in the case of DCD, is very short since with passing minutes of withdrawal of life-sustaining treatment, the viability of the organs deteriorates rapidly and they have become unusable for the purpose of transplantation. Further, various human organs have different survival times during ischaemia (lack of blood supply) after withdrawal of treatment. Ultimately, dying is a process culminating in the event of death – it is not an easily identifiable clinical moment,²² although the law requires a demarcation.²³ After the heart ceases function, the other organs also cease to function but irreversibility in increasing time order: brain, liver, kidneys, lungs and finally skin. Dalle Ave, Shaw and Bernat comment that in DCD, ‘the functions of organs have not been lost irreversibly because organs regain function once transplanted’.²⁴ We observe that if this serves as a definition of ‘reversibility’ of loss of functions of other organs, it ought to apply to the function of the heart as well, but an exception is made by these authors regarding heart transplantation in DCD (vide infra).²⁵

18 The President’s Council on Bioethics, *Controversies in the Determination of Death: A White Paper by the President’s Council on Bioethics* (Research Report, December 2008) 49–50 (‘*Controversies in the Determination of Death*’).

19 Sam David Shemie and Dale Gardiner, ‘Circulatory Arrest, Brain Arrest and Death Determination’ (2018) 5(15) *Frontiers in Cardiovascular Medicine* 1, 1 <<https://doi.org/10.3389/fcvm.2018.00015>>.

20 Stuart J Youngner, Robert M Arnold and Michael A DeVita, ‘When Is “Dead”?’ (1999) 29(6) *Hastings Center Report* 14, 20 <<https://doi.org/10.2307/3527866>>.

21 Bernat, ‘Whole-Brain Concept of Death’ (n 17).

22 President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (Report, July 1981) 37, 77 (‘*Defining Death*’).

23 Menikoff, ‘The Importance of Being Dead’ (n 9) 9.

24 Anne Laure Dalle Ave, David Shaw and James L Bernat, ‘An Analysis of Heart Donation after Circulatory Determination of Death’ (2016) 42(5) *Journal of Medical Ethics* 312, 313.

25 Ibid 314.

D Development of Legal Determination of Death

The legal definition of circulatory death ('cessation of the circulation') began with attempts to define brain death and culminated in two definitions of death, 'brain death' and 'circulatory death', a bifurcated definition (vide infra). Prior to the codification of the definition of death in legal statutes, the determination of death was made by the medical profession at the discretion of each physician's ethical judgment. The creation of a legal bifurcated definition of death has been claimed by some to be 'ethical gerrymandering' designed to facilitate organ procurement or alternatively the legal definition is unnecessarily confused due to interests in organ procurement.²⁶

Medical tests for brain death were first considered in Australia in 1968 at the 22nd World Medical Assembly in Sydney. The WMA Declaration of Sydney on the Determination of Death and the Procurement of Organs provided advice on the determination of death and its timing.²⁷ It was noted that the determination of death should be based on clinical judgment²⁸ but supplemented where necessary by diagnostic aids of which the electroencephalograph ('EEG') was stated at that time as the most helpful. However, caution was issued on the reliance²⁹ upon technological methods in place of the judgment of the physician. In 1977, the Australian Law Reform Commission ('ALRC') addressed the lack of a definition of death in Australian statute law and suggested that one be introduced.³⁰ It foreshadowed what would eventually be adopted, a bifurcated definition. The ALRC draft legislative definition of death stated: 'A person has died when there has occurred – (a) irreversible cessation of all function of the brain of the person; or (b) irreversible cessation of circulation of blood in the body of the person'.³¹

The ALRC stated that 'creation and prescription of techniques of diagnosis should be the responsibility of the medical profession'.³² The ALRC specified that, although it appeared in the context of transplantation, the determination of death should have general application whether or not organ and tissue donation and subsequent transplantation were to follow, and the definition of death should not be governed by the practice or requirements of transplantation.³³ However, none of these recommendations were legislated and irreversible was not defined.

The ALRC proposal was adopted almost verbatim by all Australian jurisdictions (except Western Australia). For example, section 41 of the *Human Tissue Act 1982* (Vic) states:

A person has died when there has occurred

26 James M Dubois, 'Non-Heart-Beating Organ Donation: A Defense of the Required Determination of Death' (1999) 27(2) *Journal of Law, Medicine and Ethics* 126, 127 <<https://doi.org/10.1111/j.1748-720X.1999.tb01445.x>>.

27 'WMA Declaration of Sydney on the Determination of Death and the Procurement of Organs' (Declaration, World Medical Association, August 1968).

28 Ibid.

29 Ibid.

30 Australian Law Reform Commission, *Human Tissue Transplants* (Report No 7, June 1977).

31 Ibid app IV s 42.

32 Ibid 63 [137].

33 Ibid 59 [127].

- (a) irreversible cessation of circulation of blood in the body of the person; or
- (b) irreversible cessation of all function of the brain of the person.

Other Australian states and territories have defined death as occurring in the legislation as follows:

Table 1: Definition of death in Australian statute law per jurisdiction

Jurisdiction	Act/Legislation	Provision
New South Wales	<i>Human Tissue Act 1983</i> (NSW)	Section 33
Queensland	<i>Transplantation and Anatomy Act 1979</i> (Qld)	Section 45(1)
South Australia	<i>Death (Definition) Act 1983</i> (SA)	Section 2
Tasmania	<i>Human Tissue Act 1985</i> (Tas)	Section 27A
Victoria	<i>Human Tissue Act 1982</i> (Vic)	Section 41
Western Australia	<i>Human Tissue and Transplant Act 1982</i> (WA)*	Section 24(2)
Australian Capital Territory	<i>Transplantation and Anatomy Act 1978</i> (ACT)	Section 45
Northern Territory	<i>Transplantation and Anatomy Act 1979</i> (NT)	Section 23
* Note: circulatory death is not defined in Western Australian legislation.		

Similarly, in the US, in 1981 a President's Commission presented a proposal, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* ('*Defining Death*'), for a uniform statute.³⁴ Subsequently, it was codified as the *Uniform Determination of Death Act* ('*UDDA*').³⁵ The *UDDA* was promptly adopted by most US states. The relevant clauses of the *UDDA* are:

An individual who has sustained either

- (1) irreversible cessation of circulatory and respiratory functions, or
- (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.³⁶

Irreversible was not defined except by a few state jurisdictions. For example, in Oklahoma, 'a determination of death must be made in accordance with accepted medical standards; provided however all reasonable attempts to restore spontaneous circulatory or respiratory functions shall first be made, prior to such declaration'³⁷ while in Virginia the relevant statute states 'a person shall be medically and legally deemed dead if ... attempts at resuscitation would not ... be successful in restoring spontaneous life-sustaining functions'.³⁸

34 *Defining Death* (n 22).

35 *Uniform Determination of Death Act* (Uniform Law Commission, 1981) ('*UDDA*').

36 *Ibid* § 1.

37 63 Okla Stat § 63-3122 (2021).

38 Va Code Ann § 54.1-2972(A)(1) (2021).

Although similar in that a bifurcated definition of death is given in both Australian and American jurisdictions, they differ in two important aspects. Firstly, in Australian legislation, the definition of circulatory death contains no additional requirement other than cessation of the circulation whereas the American *UDDA* contains the additional stipulation that respiration must also have ceased irreversibly.³⁹ Secondly, the Australian legislation is silent on how death should be determined whereas the American *UDDA* requires that it be determined according to ‘accepted medical standards’⁴⁰ although such standards are not specified. The mode of determining brain death and circulatory death is not stipulated by law in any state jurisdiction except that in Nevada where the mode of determining brain death in adults is that published in 2010 by the American Academy of Neurology and, in children, is that published in 2012 by the Pediatric Section of the Society of Critical Care Medicine.⁴¹ This is not a feature of any Australian state or territory legislation.

Soon after the *UDDA* was promulgated, Bernat, Culver and Gert criticised the President’s Commission for recommending the bifurcated definition of death.⁴² They point out that the definition fails to reconcile the medical understanding of death as being brain death with the practical recognition of death as being cessation of cardiorespiratory function in the majority of cases.⁴³ The authors noted that detection of cessation of cardiopulmonary function is a test, not a definition of death, and that ‘permanent cessation of spontaneous cardiopulmonary functioning works as a test of death only in the absence of artificial cardiopulmonary support because only there does it produce the true standard of death – the irreversible cessation of all brain function’.⁴⁴ While this is true for all other organ procurement, it does not apply in the context of heart transplantation during DCD because heart function does *not* cease irreversibly. Compared to the single traditional method of diagnosing death (unresponsiveness plus cardiorespiratory failure), the bifurcated legal definition of death has created ‘[t]wo [k]inds of [d]eath’ and has added unintended complexity to the declaration of death in the DCD scenario, and decades of debate about whether organ donors are really dead.⁴⁵

In 1983, Smith proposed that in Australian jurisdictions death should be defined only in terms of brain function – permanent and irreversible unconsciousness with the physiological standard to be irreversible cessation of brain stem function without reference to cessation of respiration and circulation.⁴⁶ Obviously, this is a conflicted proposal in that brain stem function and respiration are functionally linked, but the proposal to avoid cessation of the circulation is admirable.

39 *UDDA* § 1.

40 *Ibid.*

41 Nev Rev Stat § 451.007 (2019).

42 James L Bernat, Charles M Culver and Bernard Gert, ‘Defining Death in Theory and Practice’ (1982) 12(1) *Hastings Center Report* 5 <<https://doi.org/10.2307/3560613>>.

43 *Ibid* 7.

44 *Ibid* 8.

45 Youngner, Arnold and DeVita (n 20) 17.

46 Russell Gordon Smith, ‘Refining the Definition of Death for Australian Legislation’ (1983) 14(2) *Melbourne University Law Review* 199.

Thus, there was a loss of the intended link between the two modes of death as stated by the President's Commission: 'irreversible cessation of respiration and circulation as an alternative standard ... are surrogates for the loss of brain functions'.⁴⁷ Although it may have been the intention of the Commission to connect the two definitions of death, the statement is two distinct bifurcated ways of defining death. With circulatory death there is some, but inadequate, connection with brain function in requiring irreversible cessation of respiration but, in the Australian legal definition of death, this connection is absent.

Negative publicity concerning DCD focused on the perception that the practice was used to procure organs from donors who were not dead, and that the practice of DCD was being used to hasten the death of donors.⁴⁸ In response, in 1997 the Institute of Medicine ('IOM') was tasked with investigating whether 'interventions undertaken in these donors to enhance the supply and quality of solid organs for transplantation were in the best interests of the donor patient or were, in fact, hastening death' and to investigate 'alternative medical approaches that can be used to maximize the availability of organs from that donor without violating prevailing ethical norms regarding the rights and welfare of donors'.⁴⁹ The conclusion of the IOM that the existence of brain function is irrelevant in declaring a person dead under the cardiopulmonary criteria drew strong criticism.⁵⁰

The bifurcated legal definition of death resulting in two distinct pathways to diagnose death has created two pathways for organ procurement – donation after brain death and donation after circulatory death. In the brain death pathway, mechanical ventilation is provided and the circulation may also be supported, such that the organs on procurement have been sustained with adequate blood supply and oxygenation. Until procurement, all the vital organs, including the heart, lungs, kidneys, liver, and others have not sustained any ischaemia or hypoxaemia (loss of blood and oxygen supply). In contrast, in the circulatory death pathway, organs are subjected to a variable amount of ischaemia and lack of oxygenation. For this reason, the number of organs procured during DCD is less than in procurement after brain death. In particular, the heart has not been traditionally procured because it is more susceptible to ischaemia and hypoxia and would not be expected to perform well as a transplanted organ. Since inception in the early 1990s,⁵¹ DCD programmes have steadily been adopted in lieu of DBD programmes thus limiting the supply of donated hearts. However, hearts have recently been procured after DCD, reinvigorating the debate over whether the organ donor is truly dead when the cessation of the circulation is the criterion on which death is diagnosed.

47 *Defining Death* (n 22) 37.

48 Jerry Menikoff, 'Doubts about Death: The Silence of the Institute of Medicine' (1998) 26(2) *Journal of Law, Medicine and Ethics* 157 ('Doubts about Death') <<https://doi.org/10.1111/j.1748-720X.1998.tb01671>>; Youngner, Arnold and DeVita (n 20) 19.

49 Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* (Report, 1997) v <<https://doi.org/10.17226/6036>>.

50 Menikoff, 'Doubts about Death' (n 48).

51 DeVita, Snyder and Grenvik (n 4) 113.

E Donation of Organs after Circulatory Death

The scenario of organ procurement (donation) after circulatory death, alternatively known as donation from ‘non-heart-beating death’, is usually strictly controlled in that ‘life-sustaining treatment’ is only withdrawn when surgeons are ready to procure organs immediately on certification of death.⁵² Typically the patient has sustained a traumatic brain injury or a global lack of oxygen and blood supply (hypoxic-ischaemia) so severe that although some neurological activity may remain, brain recovery is deemed impossible and further life-sustaining treatment deemed futile thus justifying its withdrawal, allowing death to occur. Organs are procured after a set interval (stand-off time) from cessation of the circulation, usually after two to five minutes, to ensure that the heart will not spontaneously recommence functioning (autoresuscitation) to re-establish a circulation. However, there is academic debate and controversy about the duration of the necessary stand-off time. Although organs cease to function on cessation of the circulation of the donor, they recover on transplantation into a recipient. The cessation of their function is therefore *reversible*. The critical question then is – why is not the function of the heart also classed as reversible since it too recovers function after transplantation?

III THE OLD DEBATE: ARE ORGAN DONORS WITH CESSATION OF CIRCULATION REALLY DEAD?

Shortly after the inception of the Pittsburgh protocol, Lynn questioned whether patients who become organ donors are really dead.⁵³ She concluded that the protocol does not satisfy the criteria to justly conclude that the circulation has ceased irreversibly before organ procurement. Her argument was largely based on the prospect of autoresuscitation.⁵⁴ Numerous commentators have since conceded or have argued that a person is not actually dead at the time of organ procurement during DCD.⁵⁵ Further, legal opinion also supports the view that organs are procured

52 Cf uncontrolled DCD occurs in more sudden circumstances where death is not anticipated. A typical example is when a patient presents in an emergency department of a hospital with an unexpected cardiac arrest. A prompt decision must be made whether cardiopulmonary resuscitation should be initiated, or if instituted when to stop. Procurement of organs from the recently deceased patient must be performed as quickly as possible to limit damage to them.

53 Joanne Lynn, ‘Are Patients Who Become Organ Donors under the Pittsburgh Protocol for “Non-Heart-Beating Donors” Really Dead?’ (1993) 3(2) *Kennedy Institute of Ethics Journal* 167 <<https://doi.org/10.1353/ken.0.0081>>.

54 Ibid 170–2.

55 See especially Joseph L Verheijde, Mohamed Y Rady and Joan McGregor, ‘Recovery of Transplantable Organs after Cardiac or Circulatory Death: Transforming the Paradigm for the Ethics of Organ Donation’ (2007) 2(8) *Philosophy, Ethics, and Humanities in Medicine* 1 <<https://doi.org/10.1186/1747-5341-2-8>>; Franklin G Miller and Robert D Truog, ‘Rethinking the Ethics of Vital Organ Donations’ (2008) 38(6) *Hastings Center Report* 38 <<https://doi.org/10.1353/hcr.0.0085>>; Seema K Shah and Franklin G Miller, ‘Can We Handle the Truth? Legal Fictions in the Determination of Death’ (2010) 36(4) *American Journal of Law and Medicine* 540 <<https://doi.org/10.1177/009885881003600402>>; Scott D Halpern and Robert D Truog, ‘Organ Donors after Circulatory Determination of Death: Not Necessarily Dead,

from persons prior to them being dead.⁵⁶ The arguments for stating that the donor is dead at the time of organ procurement are contingent upon the improbability of spontaneous resumption of circulatory function (autoresuscitation) after a defined interval (usually two to five minutes) and the medical intention not to attempt resuscitation. Organ procurement is undertaken on the basis that there is irreversible cessation of the circulation, but this pretext has been challenged.

As noted above, several authors have pondered the matter of whether an organ donor at the time of DCD is really dead. To answer the question 'is the organ donor really dead', whether it pertains to DBD or DCD, depends on the definition of death and how that is determined. In bygone eras, the diagnosis of death was straightforward – when a person became unresponsive, was not breathing, had no heartbeat and no pulse they were deemed dead. However, with the application of artificially supplied breathing (mechanical ventilation) and artificially supplied circulation with extracorporeal devices, the diagnosis of death became obfuscated. Of note is that when death is diagnosed by traditional clinical assessment, and when no attempt is made to resuscitate the person, this constitutes no attempt to determine if the cessation of circulation is reversible. If the heart does not restart by itself (autoresuscitation), the circulatory arrest (and brain arrest) is permanent and with the passing of minutes becomes irreversible.

Fundamental questions such as 'what is death' and 'when is a person dead' are of paramount importance to the practice of organ procurement. Generally, it has been agreed in western civilisations that organ procurement will only be undertaken under the DDR. It is an ethical concept which if not followed, will have legal consequences. However, some ethicists have called for the abandonment of the DDR given that it is not complied with,⁵⁷ in that organ donors under both DBD and DCD circumstances are not actually dead but may be 'dead enough'.⁵⁸ However, most societies are unlikely to ever explicitly agree to this practice since it is universally considered on an ethical basis that no person should be harmed even if it is for the benefit of another, and such practice is patently wrong.

According to Truog and Miller, a deduction that DCD donors are dead is wrong because of the difference between 'dying' and 'dead'.⁵⁹ Under circumstances in which organ procurement is not planned, when physicians are confronted with a dying patient whose circulation has just ceased, it may be reversible if treatment is applied but since no treatment is intended, the patient will soon be dead, which is irreversible. However, that circumstance is quite different to the situation of

and It Does Not Necessarily Matter' (2010) 38(3) *Critical Care Medicine* 1011 <<https://doi.org/10.1097/CCM.0b013e3181cc1228>>; Robert M Sade, 'Brain Death, Cardiac Death, and the Dead Donor Rule' (2011) 107(4) *Journal of the South Carolina Medical Association* 146; Michael Nair-Collins and Franklin G Miller, 'Is Heart Transplantation after Circulatory Death Compatible with the Dead Donor Rule?' (2016) 42(5) *Journal of Medical Ethics* 319 <<https://doi.org/10.1136/medethics-2016-103464>>; Ari Joffe, 'DCDD Donors Are Not Dead' (2018) 48(6) *Hastings Center Report* S29 <<https://doi.org/10.1002/hast.949>>.

56 Menikoff, 'The Importance of Being Dead' (n 9).

57 Sade (n 55); Nair-Collins and Miller (n 55).

58 Sade (n 55).

59 Robert D Truog and Franklin G Miller, 'Counterpoint: Are Donors after Circulatory Death Really Dead, and Does It Matter? No and Not Really' (2010) 138(1) *Chest* 16 <<https://doi.org/10.1378/chest.10-0657>>.

intended organ procurement. When the circulation ceases in controlled withdrawal of life support, the patient is dying and will only become dead when their organs are excised. It is thus a mistake to substitute permanent which pertains to dying, for irreversible which pertains to dead. It can be noted that if DCD is performed in this circumstance, the cessation of the circulation does indeed become irreversible, but it cannot be known whether the irreversibility is a function of the passage of time. We state that in successful DCD situations, the circulation has ceased irreversibly only because the vital organs of the donor have been excised.

A The Prospect of Resuscitation

It is well known that a person who has a sudden cardiac (circulatory) arrest may regain a circulation and may survive if given cardiopulmonary resuscitation ('CPR'), especially if bystanders or ambulance officers out-of-hospital give CPR quickly, or if physicians and nurses in-hospital give CPR or extracorporeal CPR. The arrested heart, resulting in cessation of blood flow (circulatory arrest), can be restarted even after several minutes. That is, cessation of the circulation can be reversed. In the scenario of intended organ procurement, when life-sustaining treatment is withdrawn and circulatory arrest occurs, treatment is withheld and eventually the circulatory arrest becomes permanent and then irreversible. The likelihood of being able to restart the suddenly arrested heart diminishes with each passing minute. The chance of being able to resuscitate the arrested heart diminishes by 5.5% with each passing minute of delay in commencing resuscitation.⁶⁰ If CPR is withheld from a recently arrested heart, the chance of successful resuscitation at two and five minutes after the arrest is thus substantial. However, there is a paucity in data related to this scenario. In the case however of intended procurement of organs, the possibility of resuscitation of the heart is less because the heart of the person has been exposed to prolonged ischaemia and hypoxaemia after withdrawal of life-sustaining treatment and before actual cardiac arrest, implying that the chance of resuscitation if undertaken would be less than for sudden cardiac arrest. Nevertheless, the point is that in the scenario of intended organ procurement, there is no guarantee that the circulation has ceased irreversibly when organs are to be procured, that is two to five minutes after its cessation. Moreover, many patients are supported by extracorporeal circulation when their own circulation has ceased, and such support is discontinued when their own circulation recovers. Thus, to suggest that such patients are dead during artificial circulatory support is an absurdity.

B The Prospect of Autoresuscitation

The important question arises: what period of waiting time after the cessation of the circulation is required to be sure that autoresuscitation, meaning spontaneous re-establishment of a circulation, will not occur? The answer to this question is not clear. The Australian national DCD protocol recommends it should be not less

60 Mary P Larsen et al, 'Predicting Survival from Out-of-Hospital Cardiac Arrest: A Graphic Model' (1993) 22(11) *Annals of Emergency Medicine* 1652.

than three minutes and not more than five minutes.⁶¹ That suggestion does not relate well to presently known data on when autoresuscitation may occur after cessation of CPR for cardiac arrest or following cardiac arrest after withdrawal of life-sustaining treatment. In a systematic review of 162 cases of autoresuscitation in adults and children, Hornby, Dhanani and Shemie observed that the longest interval was 10 minutes in adults and 2 minutes in children.⁶² In a previous analysis, Hornby et al had reported that among 32 cases, autoresuscitation did not occur beyond 7 minutes after cessation of CPR and there were no cases in the absence of CPR.⁶³ In a smaller study of only 12 patients, DeVita et al observed that none had autoresuscitated after more than 1 minute after cessation of the circulation, prompting them to suggest that 2 minutes of absent circulation was sufficient to certify death.⁶⁴ That data prompted Halpern and Truog to calculate that 0 cases of autoresuscitation would be needed among 10,516 cases to rule out an autoresuscitation rate of 1 in 1000 using the conventional statistical metrics of 95% confidence interval and an 80% statistical power.⁶⁵ As testament to the uncertainty of the required stand-off time to exclude autoresuscitation, in Australia it was stated by the Organ and Tissue Authority to be 1 to 5 minutes in 2010,⁶⁶ as a minimum of 2 minutes by the Australian and New Zealand Intensive Care Society ('ANZICS') in 2013,⁶⁷ but lengthened to 3 to 5 minutes in 2019,⁶⁸ and set at 5 minutes in 2021.⁶⁹ In the latest and most extensive data, Dhanani et al observed that among 631 patients from whom life-sustaining treatment was withdrawn, transient resumption of cardiac activity with pulsatility of at least 5 mmHg, occurred in 14% within 4 minutes 20 seconds but only 1% of such resumptions were detected clinically.⁷⁰ Based on this data, a stand-off period of a minimum of 5 minutes appears warranted, as was recommended originally by the American Institute of Medicine in 1997.⁷¹

61 Organ and Tissue Authority, 'National Protocol for Donation after Cardiac Death' (Protocol, Australian Government, July 2010) 48.

62 Laura Hornby, Sonny Dhanani and Sam D Shemie, 'Update of a Systematic Review of Autoresuscitation after Cardiac Arrest' (2018) 46(3) *Critical Care Medicine* e268, e268 <<https://doi.org/10.1097/CCM.0000000000002920>>.

63 Karen Hornby, Laura Hornby and Sam D Shemie, 'A Systematic Review of Autoresuscitation after Cardiac Arrest' (2010) 38(5) *Critical Care Medicine* 1246, 1246 <<https://doi.org/10.1097/CCM.0b013e3181d8caaa>>.

64 Michael A DeVita et al, 'Observations of Withdrawal of Life-Sustaining Treatment from Patients Who Became Non-Heart-Beating Organ Donors' (2000) 28(6) *Critical Care Medicine* 1709 <<https://doi.org/10.1097/00003246-200006000-00002>>.

65 Halpern and Truog (n 55) 1011.

66 Organ and Tissue Authority (n 61) 22 [3.8].

67 Australian and New Zealand Intensive Care Society, *The ANZICS Statement on Death and Organ Donation* (Report No 3.2, 2013) 52 [5.8] ('2013 ANZICS Statement').

68 Australian and New Zealand Intensive Care Society, *The Statement on Death and Organ Donation* (Report No 4, 2019) 23 [1.3.1].

69 Australian and New Zealand Intensive Care Society, *The Statement on Death and Organ Donation* (Report No 4.1, 2021) 23 [1.3.1] ('2021 ANZICS Statement').

70 Sonny Dhanani et al, 'Resumption of Cardiac Activity after Withdrawal of Life-Sustaining Measures' (2021) 384(4) *New England Journal of Medicine* 345 <<https://doi.org/10.1056/NEJMoa2022713>>.

71 Institute of Medicine (n 48) 59.

Although important, the focus on the interval during which autoresuscitation may occur should not be the determining question when deciding at what time after cessation of the circulation can organ procurement proceed. Of course, if autoresuscitation does occur, organ procurement should be abandoned. Surely the quiddity of this matter is that organ procurement should not commence until the brain of the prospective donor is dead. The salient question then becomes: when after cessation of the circulation is the brain of the prospective donor dead? The answer to this question is difficult but it probably relates to a prospective donor's individual circumstances. Around the world, the stand-off time varies from 75 seconds to 20 minutes.⁷² Specifying a time requires consideration of the train of events which precede and follow cessation of the circulation. For example, the brain might be dead at five minutes, or at two minutes or even before that if cessation of the circulation had been preceded by a long interval of very low blood pressure or it might be considerably longer if cessation of the circulation ceases suddenly but had been preceded by adequate brain perfusing blood pressure.⁷³

The only practical measure of brain function on cessation of its blood supply is its electrical activity. Although cerebral neurons can tolerate at least 20 minutes of normothermic ischaemic hypoxia,⁷⁴ the duration of such an insult beyond which brain function irreversibly ceases are not known, and limited data is available. In a series of only 4 patients undergoing withdrawal of life-sustaining treatment, loss of EEG activity (using scalp electrodes) preceded loss of ECG activity and total loss of blood pressure in 3 patients, but in 1 patient single delta wave bursts persisted and in all patients there was significant difference in EEG amplitude at 5 and at 30 minutes after cessation of the circulation.⁷⁵ In a study of 9 patients using either subdural or intraparenchymal electrodes during withdrawal of life-sustaining treatment, silence (absence) of EEG activity commenced when the brain tissue partial pressure of oxygen fell to 11 (interquartile range 7–14) mmHg and a critical mean arterial blood pressure 25 (interquartile range 23–37) mmHg, followed by depolarisation of neurons (loss of function) occurred at a mean of 3.9 (interquartile range 2.6–6.3) minutes after onset of electrical silence

72 Sonny Dhanani et al, 'Variability in the Determination of Death after Cardiac Arrest: A Review of Guidelines and Statements' (2012) 27(4) *Journal of Intensive Care Medicine* 238, 242, 245 <<https://doi.org/10.1177/0885066610396993>>.

73 Studies of outcomes after cardiac arrest show that some patients may survive with good neurological outcomes after no cerebral blood flow for up to 30 minutes. See, eg, Terence D Valenzuela et al, 'Estimating Effectiveness of Cardiac Arrest Interventions: A Logistic Regression Survival Model' (1997) 96(10) *Circulation* 3308 <<https://doi.org/10.1161/01.CIR.96.10.3308>>; Jesús López-Herce et al, 'Characteristics and Outcome of Cardiorespiratory Arrest in Children' (2004) 63(3) *Resuscitation* 311; Christoph Testori et al, 'The Beneficial Effect of Mild Therapeutic Hypothermia Depends on the Time of Complete Circulatory Standstill in Patients with Cardiac Arrest' (2012) 83(5) *Resuscitation* 596 <<https://doi.org/10.1016/j.resuscitation.2011.11.019>>.

74 Peter Safar, 'Cerebral Resuscitation after Cardiac Arrest: A Review' (1986) 74 (Suppl IV) *Circulation* 138, 139.

75 Loretta Norton et al, 'Electroencephalographic Recordings during Withdrawal of Life-Sustaining Therapy until 30 Minutes after Declaration of Death' (2016) 44(2) *Canadian Journal of Neurological Sciences* 139, 139 <<https://doi.org/10.1017/cjn.2016.309>>.

and 0.2–4.4 minutes after critical hypotension.⁷⁶ Thus, brain electrical activity begins to fail when its perfusion is still present but poor, and neurons cease to function at an individually variable time later. Thus, electroencephalographic silence may occur at a variable time according to the individual, perhaps less than or more than five minutes, after cessation of the circulation. In this context when the circulation has ceased, the blood flow to the brain must have also (obviously) ceased thus satisfying a definition of brain death (absent brain blood flow) contained in organ donation guidelines,⁷⁷ but more research is required on residual electrical activity.

From the transplantation perspective shorter stand-off times are sought, but that should not be the principal objective of withdrawing life-sustaining treatment – it should be to allow the person to die and only when they are brain dead after an appropriate stand-off time should organ procurement proceed. Should the duration of stand-off be left to the judgment of the attending physician for each patient, or should that be advised in guidelines or should it be legislated? It has not yet been stipulated in law because the manner of determination of death has been assigned to physicians.

However, straying from usual practice may attract criticism as occurred when physicians permitted organ procurement before 2 minutes had elapsed after cessation of the circulation in 2 infants in the US, where organs were procured after 75 seconds.⁷⁸ Consequently, this resulted in a call for a moratorium on the practice of DCD.⁷⁹ The Chairman of the President's Council on Bioethics considered that the extrapolations (of the stand-off time) based on this report were 'exceedingly perilous and border on the irresponsible'.⁸⁰ The practice was condemned on the grounds that the infants could have been conscious at the time of surgical incision for organ procurement.⁸¹ This is our essential concern with DCD – how long must the stand-off period be to ensure awareness/consciousness is not present?

Whatever is used as the stand-off period to protect against autoresuscitation, it should be regarded only as a surrogate for ensuring that the brain of the intended organ donor is dead before surgical incision. Stand-off time to ensure against autoresuscitation is a 'red herring'.⁸² From a practical clinical viewpoint, there has

76 Jens P Dreier et al, 'Terminal Spreading Depolarization and Electrical Silence in Death of Human Cerebral Cortex' (2018) 83(2) *Annals of Neurology* 295, 295 <<https://doi.org/10.1002/ana.25147>>.

77 See above n 61 and accompanying text.

78 Mark M Boucek et al, 'Pediatric Heart Transplantation after Declaration of Cardiocirculatory Death' (2008) 359(7) *New England Journal of Medicine* 709, 713 <<https://doi.org/10.1056/NEJMoa0800660>>.

79 Joseph A Carcillo et al, 'A Call for Full Public Disclosure and Moratorium on Donation after Cardiac Death in Children' (2010) 11(5) *Pediatric Critical Care Medicine* 641 <<https://doi.org/10.1097/PCC.0b013e3181dd517d>>; Ari R Joffe et al, 'Donation after Cardiocirculatory Death: A Call for a Moratorium Pending Full Public Disclosure and Fully Informed Consent' (2011) 6(17) *Philosophy, Ethics, and Humanities in Medicine* 1, 16 <<https://doi.org/10.1186/1747-5341-6-17>>.

80 Edmund D Pellegrino, 'Personal Statement of Edmund D Pellegrino, MD', quoted in The President's Council on Bioethics (n 18) 122 ('Personal Statement').

81 Carcillo et al (n 79) 641.

82 Ahmeh Ghavam, 'Death Determination and Donation after Circulatory Death: Can Physicians Reconcile Cardiorespiratory Death and Irreversible Loss of Brain Function?' (2021) 16(4) *Clinical Ethics* 307, 310 <<https://doi.org/10.1177/1477750920983573>>.

been no attempt to determine if the brain of the donor is dead before commencing organ procurement. In defence of ANZICS's *The Statement on Death and Organ Donation* ('2021 ANZICS Statement'), it is recommended that circulatory death is not declared until all of the following are present: absence of spontaneous movement, breathing and circulation as evidenced by absent arterial pulsatility (maximum five minutes) as measured by pulse palpation or preferably by monitoring the intra-arterial pressure.⁸³ Thus far, there has been no or little attempt to incorporate aspects of failure of brain function into the legal circulatory definition of death. Arguably, the *2021 ANZICS Statement* could be strengthened by recommending more objective assessments of brain function before organs are procured.

C Attempts to Rationalise Organ Transplantation after DCD

Attempts have been made to rationalise organ procurement for transplantation by changing the definition of death. This has not been without criticism, indeed, one commentator referred to this as the 'gerrymandering of the existing legal definition' of death.⁸⁴ Much of the contention and debate has surrounded the phenomenon of autoresuscitation and/or the meaning of irreversible for the purposes of organ procurement and subsequent transplantation.

1 Irreversible Means Failure to Autoresuscitate

DuBois supports the notion that DCD can be ethically justified and claims that a declaration of death (at five minutes stand-off) is compliant with the *UDDA*.⁸⁵ First, he contends that since any doubts about the necessary time to wait for brain death after cardiorespiratory function ceases have not been adequately addressed, a stand-off time selected by organ procurement agencies is therefore satisfactory.⁸⁶ We argue that this is a non sequitur – just because the required time to be certain of brain death is unknown, does not in any way legitimise a time chosen to suit organ procurement. Second, he concedes, like Cole,⁸⁷ that 'irreversible' means 'cannot be reversed' but since it is not defined in the *UDDA* and moreover since it does not feature in the ordinary concept of death, it thus satisfies an ethical determination of death.⁸⁸ Curiously, DuBois also questions the involvement and intention of policy and lawmakers by speculating that the President's Commission, the initial developers of the *UDDA*, may have had in mind the notion of inability to autoresuscitate as the definition of irreversibility, notwithstanding that no such definition was considered by the President's Commission.⁸⁹ Then, developing this

83 2021 ANZICS Statement (n 69) 24.

84 Menikoff, 'The Importance of Being Dead' (n 9) 19.

85 DuBois (n 26) 127.

86 Ibid.

87 David J Cole, 'The Reversibility of Death' (1992) 18(1) *Journal of Medical Ethics* 26, 27 <<https://doi.org/10.1136/jme.18.1.26>>; David Cole, 'Statutory Definitions of Death and the Management of Terminally Ill Patients Who May Become Organ Donors after Death' (1993) 3(2) *Kennedy Institute of Ethics Journal* 145, 148–50 ('Statutory Definitions of Death') <<https://doi.org/10.1353/ken.0.0025>>.

88 DuBois (n 26) 127.

89 Ibid.

theme, since the Pittsburgh protocol used inability to autoresuscitate to legally justify its practice and since the IOM in 1981 nominated five minutes as the stand-off period in the absence of autoresuscitation, DuBois opined that ‘irreversibility’ is shown by ‘the inability to autoresuscitate’ when further treatment is declined.⁹⁰ We reject that reasoning.

2 Irreversible Means Permanent Loss of Circulation or of Cardiac Function

As noted earlier, only a few American statutes define irreversible and no Australian jurisdiction has done so. It has been suggested that this deficiency may place healthcare providers at risk of civil or criminal liability with current practices.⁹¹ Further, it may ‘discourage potential organ donation, and frustrate the wishes of some individuals to donate their organs’.⁹² Consequently, physicians have tinkered with the definition to remove potential impediment to organ procurement and transplantation, yet it remains the subject of keen ethical debate. For instance, Cole claims that philosophically, ‘irreversible’ is ambiguous in the ordinary context of death.⁹³ We disagree. Moreover, Harrington has drawn attention to US case law on the definition of ‘irreversibility’, which although limited, supports a definition that is at odds with current DCD practice.⁹⁴ In essence, the cases show that circulatory arrest is not a definition of death and whenever a circulation is restored after cardiac arrest it proves that the circulatory arrest was not irreversible in the body of the person. We have observed and noted elsewhere that the definition has not yet been adjudicated in the scenario of organ transplantation.⁹⁵ The meaning of the word irreversible as shown in US cases is the conventional meaning, that is, which *cannot be reversed*, which DCD proponents have chosen to disregard.⁹⁶ Instead, DCD is conducted under a moral, not a physiological basis that promotes organ transplantation.⁹⁷

As noted above, there is a slight but important difference between the *UDDA* and the Australian legislation. The *UDDA* contains a stipulation, that is absent in Australian legislation, that death (whether brain or circulatory death) must

90 Ibid.

91 Jocelyn Downie et al, ‘Eligibility for Organ Donation: A Medico-Legal Perspective on Defining and Determining Death’ (2009) 56(11) *Canadian Journal of Anaesthesia* 851 <<https://doi.org/10.1007/s12630-009-9130-x>>; James Tibballs and Neera Bhatia, ‘Transplantation of the Heart after Circulatory Death of the Donor: Time for a Change in the Law?’ (2015) 203(6) *Medical Journal of Australia* 268 <<https://doi.org/10.5694/mja.15.00295>>.

92 Downie et al (n 91) 851. See also Tibballs and Bhatia (n 91).

93 Cole, ‘The Reversibility of Death’ (n 87) 27.

94 Maxine M Harrington, ‘The Thin Flat Line: Redefining Who Is Legally Dead in Organ Donation after Cardiac Death’ (2009) 25(2) *Issues in Law and Medicine* 95, 116–18. See, eg, the following cases, *People v Selwa*, 543 NW 2d 321, 322–3 (Mich App, 1995); *Jefferson County v Eastern Idaho Regional Medical Center*, 883 P 2d 1084 (Idaho App, 1994); *Finnegan v Finnegan* (Conn Super, No FA074031514, 19 February 2008).

95 Tibballs and Bhatia (n 91).

96 Harrington (n 94) 118.

97 See especially Tom Tomlinson, ‘The Irreversibility of Death: Reply to Cole’ (1993) 3(2) *Kennedy Institute of Ethics Journal* 157 <<https://doi.org/10.1353/ken.0.0053>>; Cole, ‘The Reversibility of Death’ (n 87); Cole, ‘Statutory Definitions of Death’ (n 87); E T Bartlett, ‘Differences between Death and Dying’ (1995) 21(5) *Journal of Medical Ethics* 270 <<https://doi.org/10.1136/jme.21.5.270>>; David Lamb, ‘Reversibility and Death: A Reply to David J Cole’ (1992) 18(1) *Journal of Medical Ethics* 31 <<https://doi.org/10.1136/jme.18.1.31>>.

be determined according to ‘accepted medical practice’.⁹⁸ According to Bernat and others, the *UDDA* permits physicians to substitute ‘permanent’ cessation of circulation for ‘irreversible’ cessation of circulation yet still comply with the *UDDA* and the *DDR*.⁹⁹ Even though it is conceded that the lexical significance of ‘permanent’ is not equivalent to ‘irreversible’, permission for physicians to reinterpret the *UDDA* is claimed on the basis that the qualifying phrase requiring physicians to diagnose death is according to ‘accepted medical practice’.¹⁰⁰ A physician’s usual practice of diagnosing death, when organ donation is not intended, is to check for absence of breathing and circulation in the context that they have no intention of attempting cardiopulmonary resuscitation. In that circumstance, barring autoresuscitation, the cessation of circulation is permanent but within minutes becomes irreversible. Thus, as proposed by Bernat, permanent cessation of the circulation becomes a valid surrogate or proxy for and is the actual meaning of irreversible cessation of the circulation and therefore is claimed to adhere lawfully to the *UDDA* and not contravene the *DDR*.¹⁰¹ We however contend that this is fundamentally erroneous. Sade notes that ‘under the circumstances of DCD, clearly the heart has not irreversibly arrested, as cardiopulmonary resuscitation can restore cardiac function’,¹⁰² further that the only reason for substitution of ‘permanent’ for ‘irreversible’ is a ‘rhetorical device needed to satisfy the *DDR*’.¹⁰³

Moreover, Bernat et al also claim that since the words ‘irreversible’ and ‘permanent’ are used interchangeably in *Defining Death* published by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research as a prelude to the formulation of the *UDDA*, they may be interpreted as equivalent in the legislation.¹⁰⁴ However, close inspection reveals that the two words irreversible and permanent, despite the claim, are never used interchangeably in *Defining Death*. The only phrase that joins the two words is in a description likening the English and British and American criteria for death which is established when ‘all functions of the brain have permanently *and* irreversibly ceased’.¹⁰⁵ Indeed, this description in *Defining Death* implies on the contrary that the meaning of permanent is not

98 *UDDA* § 1.

99 See James L Bernat, ‘Are Organ Donors after Cardiac Death Really Dead?’ (2006) 17(2) *Journal of Clinical Ethics* 122, 130; James L Bernat, ‘Point: Are Donors after Circulatory Death Really Dead, and Does It Matter? Yes and Yes’ (2010) 138(1) *Chest* 13 (‘Are Donors after Circulatory Death Really Dead?’) <<https://doi.org/10.1378/chest.10-0649>>; James L Bernat et al, ‘The Circulatory-Respiratory Determination of Death in Organ Donation’ (2010) 38(3) *Critical Care Medicine* 963 <<https://doi.org/10.1097/CCM.0b013e3181c58916>>; James L Bernat, ‘On Noncongruence between the Concept and Determination of Death’ (2013) 43(6) *Hastings Center Report* 25 <<https://doi.org/10.1002/hast.231>>; James L Bernat, ‘Conceptual Issues in DCDD Donor Death Determination’ (2018) 48(6) *Hastings Center Report* S26 <<https://doi.org/10.1002/hast.948>>; John P Lizza, ‘Why DCD Donors Are Dead’ (2020) 45(1) *Journal of Medicine and Philosophy* 42 <<https://doi.org/10.1093/jmp/jhz030>>.

100 *UDDA* § 1.

101 Bernat, ‘Are Organ Donors after Cardiac Death Really Dead?’ (n 99) 128–9.

102 Sade (n 55) 147.

103 *Ibid*.

104 Bernat et al, ‘The Circulatory-Respiratory Determination of Death in Organ Donation’ (n 99) 964.

105 *Defining Death* (n 22) 28, quoting Conference of Royal Colleges and Faculties of the United Kingdom, ‘Memorandum on the Diagnosis of Death’ in Working Party (ed), *The Removal of Cadaveric Organs for Transplantation: A Code of Practice* (Department of Health and Social Security, 1979) 36 (emphasis added).

the same but is different from irreversible. In short, the use of permanent in place of irreversible is catachresis. In 2008, the President's Council of Bioethics while addressing *Controversies in the Determination of Death: A White Paper by the President's Council on Bioethics* clearly recognised that 'irreversible' in the context of organ procurement is used with its correct etymological meaning.¹⁰⁶ It declared that in DCD in order '[t]o call the loss of functions irreversible, it must be the case that the functions could not possibly return, either on their own or with external help'.¹⁰⁷ Thus, if recovery does occur (as in a transplanted heart) the prior declaration of death based on 'irreversibility' is clearly false.

3 Parsing Irreversible: The Heart Could Not Be Stopped versus the Heart Would Not Be Stopped

Alternatively, to justify permanent cessation of the circulation as being equivalent to irreversible cessation of the circulation, it has been claimed that one may philosophically parse the meaning of irreversible claiming that it is ambiguous and may be construed to mean permanent in the context of diagnosing death.¹⁰⁸ However, such explanation has been dismissed as simply being implausible.¹⁰⁹ We agree. Although the two words have plainly different meanings, Bernat maintains that they are interchangeable because they are connected in a causal and temporal fashion.¹¹⁰ They are not. Permanent has a temporal context, while irreversible has a causal context, but they are neither related nor synonymous. Permanent cessation of the circulation is a preceding and necessary requirement for cessation of the circulation to become irreversible to which it progresses within minutes. We note that an irreversibly ceased circulation is certainly permanent, but a permanent cessation of the circulation is not necessarily irreversible. Curiously elsewhere in self-refutation, Dalle Ave, Shaw and Bernat state that the cessation of function of other organs procured during DCD is reversible because they function in the recipient.¹¹¹ This statement extinguishes his earlier claim that the practice of DCD is undertaken under the guise that the circulation has irreversibly ceased.¹¹² We pose the question: why is the function of the heart also not reversible since it too ceases function in the donor but recovers in the recipient? Dalle Ave, Shaw and Bernat later argue that when death criteria are based on permanency of cessation of the circulation, rather than irreversibility, organ procurement is compatible with the DDR provided that the stand-off period is a minimum of five minutes to ensure autoresuscitation does not occur and that no medical intervention is undertaken which might support brain circulation.¹¹³ These authors analysed DCD protocols from several countries and concluded that only the Australian protocol followed the DDR.¹¹⁴ However,

106 *Controversies in the Determination of Death* (n 18) 83.

107 *Ibid.*

108 Bernat, 'Are Organ Donors after Cardiac Death Really Dead?' (n 99) 124–5.

109 Lamb (n 97) 32.

110 Bernat, 'Conceptual Issues in DCDD Donor Death Determination' (n 99) S27.

111 See Dalle Ave, Shaw and Bernat (n 24) 313.

112 Bernat, 'Are Donors after Circulatory Death Really Dead?' (n 99) 14.

113 Dalle Ave, Shaw and Bernat (n 24) 314.

114 *Ibid* 315.

their conclusion flounders because the law requires the cessation of the circulation to be irreversible, not permanent, and the Australian protocol which was considered did not recommend a stand-off period of five minutes which they had assumed, but quoted as two minutes in New South Wales (where transplantation was undertaken) and erroneously as five minutes in other jurisdictions.¹¹⁵

D Why Irreversible Cannot Be Permanent

Joffe maintains that ‘permanent cessation of the circulation’ is not a diagnosis of death but rather a prognosis of death, and that organ procurement soon after cessation of the circulation removes the ability to confirm irreversibility of cessation of the circulation.¹¹⁶ He gives four reasons why ‘permanent cessation of the circulation’ cannot be equated to death – an irreversible state. Firstly, he asserts that ‘permanent cessation of the circulation’ is not a diagnosis of death, or being dead, but rather a prognosis of death, that is, a state of dying which will culminate in death.¹¹⁷ Secondly, treating (defining) death as a concept, which relies on human action or intent, has unacceptable implications, and leads to absurdity.¹¹⁸ Joffe gives the example borrowed from others, of a man suffering commotio cordis (permanent but reversible cardiac arrest on being struck in the chest with a baseball) – at that moment, according to the substituted phrase ‘permanent cessation of the circulation’, the victim is already dead if a competent bystander intends not to use a nearby defibrillator.¹¹⁹ Thirdly, in the standard medical sense, permanent and irreversible are not equivalent.¹²⁰ Joffe exemplifies this with a hypertensive patient who refuses medication – their hypertensive state is permanent but not considered medically as irreversible.¹²¹ Finally, since it is not true that capacity to regain consciousness and self-awareness is lost at the time of death declaration in the DCD donor, it cannot be true that death has occurred if death is defined as an absent potential to resume consciousness and self-awareness, as claimed by Baker and Shemie.¹²²

There have been other concerns raised about the meaning of irreversible – particularly in situations when a decision has been made to withhold or discontinue CPR.¹²³ Legal statutes refer to irreversibility in terms of stopping circulation, respiration and responsiveness. Yet, this lacks clarity as to whether irreversible

115 Kumad K Dhital et al, ‘Adult Heart Transplantation with Distant Procurement and Ex-Vivo Preservation of Donor Hearts after Circulatory Death: A Case Series’ (2015) 385(9987) *Lancet* 2585, 2586 <[https://doi.org/10.1016/S0140-6736\(15\)60038-1](https://doi.org/10.1016/S0140-6736(15)60038-1)>; 2021 ANZICS Statement (n 69).

116 Joffe (n 54) S29.

117 Ibid.

118 Ibid.

119 Ibid S29–30, citing Nair-Collins and Miller (n 55) 319–20.

120 Joffe (n 55) S30.

121 Ibid.

122 Ibid, quoting Andrew Baker and Sam D Shemie, ‘Biophilosophical Basis for Identifying the Death of a Person’ (2014) 29(4) *Journal of Critical Care* 687, 688 <<https://doi.org/10.1016/j.jcrc.2014.04.013>>.

123 Sam D Shemie and Michael De Vita, ‘Legal, Moral, and Ethical Issues’ in David Talbot and Anthony M D’Alessandro (eds), *Organ Donation and Transplantation after Cardiac Death* (Oxford University Press, 2009) 7, 11.

means the heart ‘could not’ be started, or ‘would not’ be started.¹²⁴ The authors note that the difference is volitional – that is, based on the physician’s will and choice to intervene.

Also of concern, are instances in which spontaneous resumption of the heart has occurred within a range of seconds to minutes and longer. The IOM’s *Non-Heart-Beating Organ Transplantation* report notes that irreversibility is defined by an absence of spontaneous recovery of cardio-respiratory function.¹²⁵ Arguably, it is impossible to know if spontaneous recovery of cardiac function will occur if physicians are determining death by using their discretion, lack of uniformity, and interpreting ‘irreversible’ to serve their own purpose. Further, the report noted issues with timing of events and irreversible cardiac death – ‘lack of adequate safeguards in declaring death could leave transplant programmes open to [scrutiny around the potential for] charges of orchestrating a premature death and retrieval of organs.’¹²⁶

Advocates for DCD have argued that irreversibility of heart function is a moral reality, rather than a physiological one, as it promotes the social objectives of organ transplantation.¹²⁷ We contend that this is simply illogical and hypocritical. This lacks the moral responsibility of protecting the potential donor and ensuring that a physician does not ‘choose’ to reverse the function of the heart in one person to serve their purpose of organ procurement for another. To ‘choose’ when to reverse cardiac function, as opposed to when it is ‘possible’ simply to legitimise organ procurement is unethical and unlawful. If something is irreversible – it means it is not possible to undo, as Shah and Miller state, in contrast to DCD situations where something, cessation of the circulation, would be possible to undo but for the fact that another option was chosen.¹²⁸ Thus, irreversibility becomes a matter of ‘choice’ rather than a ‘physiological’ condition with absolute consequences.

We have argued elsewhere, as have other scholars, that the lexical meaning of irreversible is not open to debate.¹²⁹ If it is not otherwise defined in legislation, the dictionary meaning of the word applies.¹³⁰ Further, it is wholly unethical, of grave concern and should not be open to physicians to impose a new meaning to the term irreversible to suit their purpose of procuring organs. We noted too that physicians do not have the right to reinterpret a statute to suit their practice. We extend that opinion now to organisations. Of concern is that one Australian Health Department (New South Wales Health) has erroneously claimed that the legal diagnosis of death is stated in terms of permanent cessation of the circulation in spite of the actual legislation which stipulates irreversible cessation of the circulation as a criterion for death.¹³¹

124 Ibid.

125 Institute of Medicine, *Non-Heart-Beating Organ Transplantation* (n 49) 58–60.

126 Harrington (n 94) 110, citing Institute of Medicine, *Non-Heart-Beating Organ Transplantation* (n 49) 57.

127 Harrington (n 94) 118.

128 Shah and Miller (n 55) 553–4.

129 Tibballs and Bhatia (n 91).

130 Ibid.

131 ‘Organ Donation after Circulatory Death (DCD)’, *New South Wales Health* (Web Page, 30 June 2021) <<https://www.health.nsw.gov.au/organdonation/Pages/donation-following-circulatory-death.aspx>>.

IV THE NEW DEBATE: ARE HEART DONORS WITH CESSATION OF THE CIRCULATION REALLY DEAD?

Although previous arguments and contentions have centred on whether a donor of other organs from DCD is dead according to law, the renewed practice of heart transplantation has honed the pertinent questions and relevant issues. It has been argued that organ procurement may violate the DDR because irreversible cessation of the circulation is not proven. However, successful heart transplantation does prove that cessation of the circulation in the donor cannot have been irreversible. The reasoning is simple but compelling – death is an irreversible state, but it cannot be certified in law as irreversible cessation of the circulation under DCD because the procured heart restores circulation in another body. It defies logic to claim that cessation of the donor’s circulation was irreversible. Consequently, the donor cannot have been dead at the time of procurement of their heart. The donor’s state must have been one of dying or imminent death, but they were not dead.

Criticism of this conclusion is based on claimed confusion between cessation of heart activity and cessation of circulation in the donor, and that the legislation in the US (*UDDA*) and Australia (*Human Tissue Acts*) do not refer to cessation of heart activity.¹³² In other words, the argument turns on the difference between cessation of the circulation and cessation of heart function. These critics claim that cessation of the heart activity is not the same as cessation of the circulation, and that the reference in legislation to ‘cessation of the circulation’ does not refer to ‘cessation of heart function’, thus permitting heart transplantation during DCD without contravening legislation.¹³³ However, the heart pumping activity is the only driving force for the circulation, thus responsible for the circulation. Although legislation employs the term ‘cessation of circulation’,¹³⁴ it is cessation of the functioning of the heart as a pump which is the physiological meaning, rather than other detectible activity such the electrical activity of the cardiac as detected by electrocardiography. Moreover, we note that in recently published ANZICS clinical guidelines for DCD when the patient does not have an arterial line in place: ‘Electrical asystole should be observed for a minimum of 3 minutes 5 minutes on the electrocardiogram and confirmed by clinical examination’.¹³⁵ This is contrary to the previous recommendation by ANZICS that ‘the ECG is not monitored, as electrical activity may persist for many minutes following the cessation of circulation, which is the basis for the declaration of death’.¹³⁶ Thus, currently it is recognised in Australian organ procurement guidelines that cessation of the circulation is equivalent to cessation of electrical activity (asystole) but we observe that the latter does not align with the statutory definition.

132 D Gardiner and A McGee, ‘Death, Permanence and Current Practice in Donation after Circulatory Death’ (2017) 110(4) *Quarterly Journal of Medicine* 199, 200 <<https://doi.org/10.1093/qjmed/hcw184>>.

133 *Ibid.*

134 *Human Tissue Act 1983* (NSW) s 33(b).

135 2021 ANZICS Statement (n 69) 24.

136 2013 ANZICS Statement (n 67) 52.

It may be argued that DCD does not violate the law, as the law pertains to ‘irreversible cessation of the circulation *in the body of the person*’, that is, in the donor, but not irreversible in the recipient’s body.¹³⁷ This argument also founders because no attempt was made to prove that the circulation could not be restored in the donor’s body – bringing us back to the poignant question posed over 50 years ago by Albert Rosenfeld: ‘If you can start this heart going again in a new body, why couldn’t you have kept it going in the old one?’¹³⁸

Given that the heart is the only driving force for existence of the circulation of blood, if the circulation is deemed irreversibly ceased in one body, the heart would be useless as a driving force to generate a circulation when transplanted into another body. If it does generate a circulation in the recipient, the inevitable and unpalatable conclusion is that the circulation had not irreversibly ceased in the donor. The only condition for a donor heart to be able to function in a recipient is that the donor’s circulation had not ceased irreversibly and hence the donor was not dead at the time when their heart was procured. Unambiguously, a heart cannot both be non-functional and serve as the cause of death in one body and yet be functional and sustain life in another.

Veatch observes that ‘any successfully transplanted heart cannot have come from a person who was declared dead on the basis of irreversible stoppage of the heart’.¹³⁹ We agree. Veatch puts the poignant question lucidly – how can there be an irreversible cessation of cardiac function, when it can be later reversed?¹⁴⁰ Dalle Ave, Shaw and Bernat assert that the term irreversible implies that no amount of technology or intervention can restore the function of the heart – thus all function is irreversibly lost.¹⁴¹ If this is the case, then logically there is no possibility that the heart could ever function in another person and its transplantation would not be successful. If the heart ceases to work in one person, how can it ever work in another? If the heart can successfully function in another, this is an explicit violation of the DDR. The common sense, logical and lexical approach to the word irreversible is that it *cannot* be reversed. Interpreting its meaning otherwise to enable heart transplantation after DCD is deliberate distortion.

V THREE PROPOSALS FOR REFORM

Three possible solutions to the challenges posed by heart transplantation during DCD – that is whether a person is dead or needs to be dead at the time of heart procurement during DCD – include to: (1) abandon the practice of DCD, (2) abandon the DDR or (3) alter the legal definition of death.

137 *Human Tissue Act 1983* (NSW) s 33(b) (emphasis added).

138 Rosenfeld (n 7).

139 Robert M Veatch, ‘Donating Hearts after Cardiac Death: Reversing the Irreversible’ (2008) 359(7) *New England Journal of Medicine* 672, 673 <<https://doi.org/10.1056/NEJMp0805451>>.

140 *Ibid.*

141 Dalle Ave, Shaw and Bernat (n 24) 110.

We will explore all three below, while our preference leans towards the third reform suggestion – an alteration to the legal definition of death. Other scholars and physicians have attempted to resolve this long-standing issue by taking a very modest and narrow approach, by making the least amount of alteration to the legal current definition of death. They have either reinterpreted the meaning or wording of legislation or have devised substitute phrases for the legislation which favour procurement of organs.¹⁴² In particular, attempts have been made to reinterpret the meaning of ‘irreversible cessation of circulation’ or to have the ‘permanent cessation of circulation’ substituted for ‘irreversible cessation of circulation’.¹⁴³ As we have argued previously, it is the role of policy makers and law reformers, not physicians and health officials, to reformulate legislation. Physicians cannot make assumptions about the lexical significance of a statute, they cannot apply an alternative meaning to irreversible other than the lexical meaning contained in authoritative dictionaries nor can they substitute words into legislation that best accommodate their practice of organ procurement.¹⁴⁴

A Abandon the Dead Donor Rule

Numerous scholars have advocated for the abandonment of the DDR on ethical grounds.¹⁴⁵ The contention of Arnold and Younger is that although DCD donors are not dead, they are dying and a legitimate decision has been made to stop life-sustaining treatment before procurement of organs.¹⁴⁶ The patient will be dead within a short interval of time as a result of stopping treatment despite organ procurement. It is posited that the absence of harm in addition to appropriate informed consent legitimises organ procurement without relying on the DDR.¹⁴⁷

Nair-Collins and Miller¹⁴⁸ and Ghavam¹⁴⁹ concede that heart transplantation after ‘circulatory death’ is not compatible with the DDR, but rather than formulating new ad hoc criteria for death so that organ procurement after circulatory death can satisfy the rule, they suggest that the rule be abandoned entirely. They propose that organs be procured under general anaesthesia prior to withdrawal of life-sustaining treatment from suitable donors who have (previously) consented or where the next

142 Cole, ‘The Reversibility of Death’ (n 87); Cole, ‘Statutory Definitions of Death’ (n 87); Dalle Ave, Shaw and Bernat (n 24).

143 See Dalle Ave, Shaw and Bernat (n 24).

144 Tibballs and Bhatia (n 91).

145 Arnold and Younger (n 13); Robert D Truog and Walter M Robinson, ‘Role of Brain Death and the Dead-Donor Rule in the Ethics of Organ Transplantation’ (2003) 31(9) *Critical Care Medicine* 2391 <<https://doi.org/10.1097/01.CCM.0000090869.19410.3C>>; Norman Fost, ‘Reconsidering the Dead Donor Rule: Is It Important That Organ Donors Be Dead?’ (2004) 14(3) *Kennedy Institute of Ethics Journal* 249 <<https://doi.org/10.1353/ken.2004.0030>>; Robert D Truog and Thomas I Cochrane, ‘The Truth about “Donation after Cardiac Death”’ (2006) 17(2) *Journal of Clinical Ethics* 133; Verheijde, Rady and McGregor (n 54) 2; Miller and Truog, ‘Rethinking’ (n 55); Truog and Miller, ‘Counterpoint’ (n 59).

146 Arnold and Younger (n 13).

147 Elysa R Koppelman, ‘The Dead Donor Rule and the Concept of Death: Severing the Ties That Bind Them’ (2003) 3(1) *American Journal of Bioethics* 1 <<https://doi.org/10.1162/152651603321611782>>.

148 Nair-Collins and Miller (n 55).

149 Ghavam (n 82).

of kin have provided consent.¹⁵⁰ Namely, they claim that since the rule is neither adhered to in a moral or legal sense, there is little need to manipulate the definition of death to allow organ procurement.¹⁵¹ This is indeed a radical stance. It would clearly be the procurement of organs which caused death, which we believe is unacceptable.

Truog argues that the rule is an impediment to good ethics for organ donors and recipients alike. Indeed, that adherence to good ethics is thwarted by this rule.¹⁵² He argues that it is impossible to define when a patient is dying as distinct from dead for the purpose of ensuring that procuring organs is only performed under the DDR. He argues that the distinction between dead and dying is an illusion and the separation between withdrawing life-sustaining treatment and the surgical procurement of organs is a myth.¹⁵³ He also asserts that it is a myth that organ procurement is unethical if it does not comply with the rule.¹⁵⁴ According to him, the ethical management of organ procurement is simply that the patient is dying, the patient is kept free from pain and suffering, and that their organs should be procured from those who desire it, in a way that maximises both the quality and the number of organs.¹⁵⁵ He also suggests that organ procurement be conducted under anaesthesia as part of withdrawal of life support.¹⁵⁶ We do not consider this to be an appropriate solution, but we opine that it may be appropriate in the circumstance of voluntary assisted dying (euthanasia by anaesthetic medications) provided that the patient has died before organ procurement and has not died by the organ procurement process itself.

Conversely, Magnus has argued that the DDR should not be abandoned, rather patients (most likely their guardians) should have the choice of defining the conditions in which they (the patient) would want to be considered dead to allow for organ removal.¹⁵⁷ Abandonment of the DDR might be considered in order to deflect suspicion that it is contravened by organ procurement and transplantation.¹⁵⁸ If donors cannot be diagnosed as really dead, there is a dilemma as to whether to abandon organ procurement or abandon the DDR. However, he has argued that if we accept the current neurological criteria for death then there is no reason to abandon the DDR.¹⁵⁹ The problem in relation to DCD is to specify what clinical criteria satisfy the legal criteria for brain death. We doubt that the procurement of organs from persons not legally dead will ever be a practical solution in a democratic

150 Nair-Collins and Miller (n 55) 320; Ghavam (n 82) 310.

151 Nair-Collins and Miller (n 55) 319; Ghavam (n 82) 312.

152 Robert Truog, 'The Price of Our Illusions and Myths about the Dead Donor Rule' (2016) 42(5) *Journal of Medical Ethics* 318 <<https://doi.org/10.1136/medethics-2015-103361>>.

153 *Ibid.*

154 *Ibid.*

155 *Ibid.*

156 *Ibid.*

157 David Magnus, 'A Defense of the Dead Donor Rule' (2018) 48(S4) *Hastings Center Report* S36 <<https://doi.org/10.1002/hast.951>>. See also Osamu Muramoto, 'Informed Consent for the Diagnosis of Brain Death: A Conceptual Argument' (2016) 11(8) *Philosophy, Ethics, and Humanities in Medicine* 1 <<https://doi.org/10.1186/s13010-016-0042-4>>.

158 Magnus (n 157) S36.

159 *Ibid.*

society which abhors the deliberate and purposive killing of individuals to procure their organs.

B Abandon DCD

We do not argue for the abandonment of the practice of DCD. Rather, this article is a call for action to improve the current system. We do not envisage any impediment to procuring organs from persons who are indeed truly dead, however we must ensure that they are indeed, truly dead before organ procurement to enable the practice to be ethically, legally, and morally viable. We also fear public and professional mistrust in the medical profession if the practice continues in its current state. Although the first heart transplantation carried out in 1967 has been widely considered as under the guise of DCD, it was in fact performed in conjunction with elements of requirement for DBD which we argue below warrant a reconsideration in legal and medical terms.

C Amend the Legislation Defining Death as Irreversible Cessation of the Circulation

Our strongest recommendation is to amend the sections of legislation across all Australian jurisdictions that state irreversible cessation of the circulation as a definition of death. However, we do not accept that by proposing an amendment to the legislation that we are involving ourselves in ‘resolving moral and social dilemmas by playing with the definition of death’ as others have asserted.¹⁶⁰ Instead, we contend that we are attempting to resolve a long-standing medico-legal controversy – are organ donors really dead, especially in the case of heart transplantation after circulatory death? We consider that the current law is misdirected in its definition of death. Since there is no universal consensus in the context of organ procurement on what death actually is, any legal definition may be regarded as a ‘legal fiction’ – a legal device which solves an ethical dilemma, in this case of adjudicating between the two competing goals of requiring death to be proven thus protecting the potential organ donor (DDR) and the utilitarian goal of achieving maximum organ procurement.¹⁶¹

The Australian bifurcated definition of death without a link between the two has created a problem in determining death in the context of DCD. This is partially solved in the Australian clinical context by the ANZICS guidelines requiring observation of apnoea and lack of neurological reflexes,¹⁶² but this is insufficient to prove brain death. It is also partially resolved in the American legal context by the requirement of cessation of not only cardiac function but also of respiratory function, but likewise this too is insufficient.¹⁶³ The problem of a bifurcated definition of death

160 Koppelman (n 147) 2.

161 Shah and Miller (n 55); Seema K Shah, ‘Rethinking Brain Death as a Legal Fiction: Is the Terminology the Problem?’ (2018) 48(S4) *Hastings Center Report* S49 <<https://doi.org/10.1002/hast.955>>.

162 2021 ANZICS Statement (n 69) 15.

163 UDDA § 1.

has been highlighted within the *UDDA* by Bernat, Culver and Gert who criticised the President's Commission for not articulating a single brain standard which it had proposed in *Defining Death*.¹⁶⁴ The Commission had reasoned that the brain standard could be tested in either of two ways, with irreversible cessation of the circulation and respiratory functions being adequate only because they inevitably lead to irreversible cessation of all brain functions, but as Cole remarked, '[i]n the extreme case, the definition allows the possibility of someone who had at least some upper-brain activity despite cardiopulmonary failure to be counted dead and be the subject of organ removal'¹⁶⁵ and 'the UPMC protocol [which specified two minutes stand-off time] invites the charge that it countenances certifying as dead and removing organs from living humans – vivisection'.¹⁶⁶ Worse in this context, in Australia, any link between circulatory death and brain death sections of the legislation is non-existent.

We suggest that the sections of legislation referring to irreversible cessation of the circulation be amended. This may indeed require the removal of some provisions, for instance, removal of section 41(a) of the *Human Tissue Act 1982* (Vic). In this case, reliance would only be placed on (the current) section 41(b) of the *Human Tissue Act 1982* (Vic) as the definition of death – that is 'cessation of all function of the brain'. It has been remarked that (loss of) 'cardiopulmonary function is merely a proxy for [loss of] of brain function, the one that really matters'.¹⁶⁷ Our proposal is neither entirely new nor radical but previous proposals require further refinement in the context of heart transplantation after DCD. Smith had argued for a redefinition of death in the *Melbourne University Law Review* in 1983,¹⁶⁸ before heart transplantation from DCD commenced. We contend that the need is now more urgent. Others have also argued for a transition to a definition of death based entirely on loss of brain functions.¹⁶⁹ On the other hand, Dalle Ave and Bernat contend that brain function criteria are unnecessary to determine death in DCD, arguing that cessation of the circulation inevitably leads to cessation of brain function, but that a stand-off period of 5 to 10 minutes is insufficient to achieve the irreversibility requirement of brain death, and that the absence of reversible causes such as toxic or metabolic causes cannot be excluded.¹⁷⁰ We would obviously agree that the lack of circulation leads to brain death and that 5 to 10 minutes of lack of circulation may not satisfy the irreversibility required for brain death, but disagree that such time would not ensure lack of cortical brain function and that other causes of apparent brain death (toxins and metabolites) could not be excluded. We

164 Bernat, Culver and Gert (n 42).

165 Cole, 'Statutory Definitions of Death' (n 87) 153.

166 Ibid.

167 Youngner, Arnold and De Vita (n 20) 17.

168 Smith (n 46).

169 Veatch (n 139).

170 Anne L Dalle Ave and James L Bernat, 'Using the Brain Criterion in Organ Donation after the Circulatory Determination of Death' (2016) 33 *Journal of Critical Care* 114 <<https://doi.org/10.1016/j.jcrc.2016.01.005>>.

maintain that it is necessary to show that cortical brain function has at least ceased before organ procurement in DCD.

We hasten to add that this reliance on cessation of all brain functions would not preclude procurement of organs after cessation of the circulation. However, a physician would be required to certify death as being brain death on cessation of the circulation. In the DBD situation where the patient's circulation is ongoing and not expected to cease, cessation of brain circulation function (brain death) can be diagnosed either by showing clinical absence of brain function or by showing complete absence of brain blood flow. The latter ought to be sufficient and mandatory to satisfy the criterion for whole brain death¹⁷¹ and can be demonstrated by radionuclide scanning of the brain blood flow.¹⁷² However, in the situation where organ procurement is planned after cessation of the circulation (DCD), any investigation which relies upon blood flow to the brain to determine its function/lack of function obviously cannot be performed. Other means of detecting brain function (electrical activity) upon cessation of the circulation, such as electroencephalography, would be useful in that by showing absence of activity could at least show lack of awareness and loss of function but cannot prove irreversible loss of function. Although brain electrical activity is suppressed rapidly (within seconds) by ischaemia and returns with restoration of brain blood flow,¹⁷³ and it is practical to perform scalp electroencephalography in this situation, it would not be reliable to diagnose whole brain death because the EEG records only information from surface cortical brain areas, not all brain areas, but it could at least show lack of awareness.

Physicians could simply fall back on their traditional usual way of diagnosing death – that is of determining cessation of circulation and breathing with unresponsiveness and use that as a surrogate for brain death which quickly follows the former within minutes. If this is used, that is diagnosing brain death by simple cessation of the circulation and breathing with unresponsiveness in the situation where the circulation is not supported, it would enable procurement of all organs, including the heart, under the umbrella of brain death with no contravention of legislation. This course is open to jurisdictions which specifically state that death should be diagnosed by the usual means. This course would also be open to physicians in Australian jurisdictions because it is not stated in law how brain death should be diagnosed, that is, physicians ought to be able to diagnose brain death according to their usual practices, despite the fact that Australian legislation does not specify this practice. The issue then becomes how to define and demonstrate

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- 171 Bernat, 'Whole-Brain Concept of Death' (n 17) 39–40; Anne L Dalle Ave and James L Bernat 'Inconsistencies between the Criterion and Tests for Brain Death' (2020) 35(8) *Journal of Intensive Care Medicine* 722 <<https://doi.org/10.1177/0885066618784268>>.
- 172 James Tibballs, Sainath Raman and Peter Francis, 'Effects on Organ Donation of Transition from Apnoeic-Oxygenation to Radioisotope Brain Scanning to Diagnose Brain Death in Children' (2021) 6(1) *Archives of Organ Transplantation* 1 <<https://dx.doi.org/10.17352/2640-7973.000017>>.
- 173 Thomas J Losasso et al, 'Electroencephalographic Monitoring of Cerebral Function during Asystole and Successful Cardiopulmonary Resuscitation' (1992) 75(6) *Anesthesiology and Analgesia* 1021 <<https://doi.org/10.1213/00000539-199212000-00025>>.

cessation of all brain function in the context of DCD? We concede that this is impossible at present to show cessation of all brain function in the context when decisions have to be made within minutes to proceed to organ procurement or not. However, we could show that cortical brain function has ceased.

A change to legislation is required to accomplish this practice, since death may be diagnosed by irreversible cessation of all function of the brain but it infers, for example, that section 41(a) of the *Human Tissue Act 1982* (Vic) is redundant. It is impossible to prove that the circulation has irreversibly ceased in the context of organ procurement within minutes of its cessation in DCD.

Although changes in the *UDDA* in the US are being presently debated,¹⁷⁴ they do not relate to circulatory death but to the medical standards required to diagnose brain death and whether consent should be required for brain death testing. Almost 40 years ago, in 1982, Bernat, Culver and Gert proposed that the *UDDA* be replaced with the following:

An individual who has sustained irreversible cessation of all functions of the entire brain, including the brainstem, is dead

- (a) In the absence of artificial means of cardiopulmonary support, death (the irreversible cessation of all brain functions) may be determined by the prolonged absence of spontaneous circulatory and respiratory functions.
- (b) In the presence of artificial means of cardiopulmonary support, death (the irreversible cessation of all brain functions) must be determined by tests of brain function.

In both situations, the determination of death must be made in accordance with accepted medical standards.¹⁷⁵

This definition is acceptable; however, the problems remain of what constitutes ‘prolonged absence of spontaneous and respiratory functions’ in subsection (a) and how to prove brain death by testing in subsection (b). It appropriately removes irreversible cessation of the circulation as a definition of death which is in any case a test and not a diagnosis of death – it is a prognosis, not a diagnosis. This definition would not legally impede heart transplantation during DCD conducted under subsection (a) because cardiorespiratory support has been withdrawn. The term DCD would fall into abeyance since there would be no cardiac/circulatory death. However, it would be necessary for physicians to specify the duration of absence of spontaneous circulatory and respiratory functions, and the accepted medical standards to ensure brain death which may involve clinical and investigational testing.

Lastly, we add that the determination of brain death as equivalent to death of the person has been problematic for decades and is currently under renewed debate in the US. There have been calls for a revision of the definition of brain death in the *UDDA* and specification of its medical determination principally because some

174 Ariane Lewis, Richard J Bonnie and Thaddeus Pope, ‘It’s Time to Revise the Uniform Determination of Death Act’ (2020) 172(2) *Annals of Internal Medicine* 143 <<https://doi.org/10.7326/M19-2731>>; Doyen Nguyen ‘Does the Uniform Determination of Death Act Need to Be Revised?’ (2020) 87(3) *Linacre Quarterly* 317 <<https://doi.org/10.1177/0024363920926018>>.

175 Bernat, Culver and Gert (n 42) 8.

patients diagnosed as brain dead have regained some vestigial brain function when mechanical ventilation had been continued. Fundamentally, the calls have been to dispense with the need to obtain consent for apnoeic-oxygenation testing and to exclude ongoing neuroendocrine function as a sign of continued brain function.¹⁷⁶ Conversely, it has also been argued that it is not appropriate to forego consent for brain function testing nor to exclude neuroendocrine function.¹⁷⁷ It has been argued too that determining brain death should involve a reliable test of brain blood flow with abandonment of apnoeic-oxygenation because it is both unreliable and may be harmful by exacerbating brain injury causing death.¹⁷⁸

VI CONCLUSION

The renewed practice of heart transplantation to a recipient after the current legal definition of death as irreversible cessation of the circulation of the donor is *proof positive* that the donor was not dead at the time of heart procurement – it functions in the recipient. There is no possible reinterpretation of the meaning of irreversible that justifies the adoption of permanent cessation or of failure to autoresuscitate. Employing the term permanent cessation in place of irreversible cessation of the circulation is simply catachrestic. Even if this were permissible in relation to other organs, the concept cannot operate for heart transplantation because the transplanted heart functions in the recipient. The donor's heart in this circumstance *has not* ceased function either irreversibly or permanently. Notwithstanding, physicians cannot invent meanings of common place words in legislation to accommodate their purpose.

In answer to a leading question – what does the practice of heart transplantation during DCD tell us about that the legislation for defining death, such as section 41(a) of the *Human Tissue Act 1982* (Vic) for example, that defines death as irreversible cessation of circulation? The answer must be that it is failing to control organ procurement in the medical practice of DCD. Accordingly, the practice is not adhering to the legal definition of death and we believe it is fictitious to claim that it is adhering to the DDR.

We contend that death should only be defined in terms of cessation of brain function, thus defusing all arguments about stand-off times to ensure against autoresuscitation and defuse spurious arguments about the definition of death arising from irreversibility of circulatory cessation. Moreover, brain death is the foremost requirement for the donor's benefit before any organ procurement and the only acceptable meaning of death in the clinical context. Cessation of the circulation, and therefore cessation of brain blood flow, and cessation of respiration should be used as supportive tests for cessation of brain function, but they cannot diagnose

176 Lewis, Bonnie and Pope (n 174).

177 Nguyen (n 174).

178 James Tibballs and Neera Bhatia, 'New Challenges to the Legal Definition and Medical Determination of Brain Death: A Multi-Jurisdictional Approach' (2021) 28(3) *Journal of Law and Medicine* 831.

biological brain death in the context of DCD. We propose that the bifurcated legal definitions of death be simplified by removing the cessation of the circulation as a definition, and reliance be placed on a single definition related to cessation of brain function, but that physicians be required to prove the patient's brain has at least ceased cortical function before procurement of their organs. We suggest this be accomplished by surveillance of electroencephalographic recordings.