THE CASE FOR REFORM OF THE SO-CALLED SYSTEM OF CADAVERIC PROCUREMENT OF SOLID ORGANS FOR TRANSPLANTATION

A PhD Thesis

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Abstract

The purpose of this doctoral thesis is to critically scrutinise contemporary systems allowing for the removal of essential to health/life organs for transplantation and the case for their reform. Central to this scrutiny is a sociological, political, and ethical critique of current approaches to defining and determining death. I argue that the objective of securing more transplantable organs has been allowed to drive modern approaches to definition and determination at the cost of their credibility. Indeed, I argue that these modern brain and/or circulatory-based approaches make a mockery of the dead donor rule (DDR). Their reform is imperative and must be grounded on an appropriate approach to ethics.

The thesis makes three key original and significant contributions to the field. Firstly, whilst criticism of modern approaches to defining and determining death is nothing new, it develops a novel approach to their substantive critique. Secondly, it dovetails this critique with a more complete analysis of the process by which contemporary approaches have (from a sociological and political perspective) established and maintained themselves. This analysis advances the case that their existence is not only substantively problematic but the product of the reification of an inappropriate use of medical power, critical to which has been the normalisation of the idea that death is a medical matter rather than a spiritual or metaphysical one and resultant investment of modern medical approaches to death with an almost mystical level of authority. Thirdly, when it comes to the specific question of how contemporary approaches to death should be reformed, the thesis is the first piece of work that goes beyond the fairly limited use of different approaches to ethics to forge a comprehensive analysis of the comparative merits of key specific approaches. The significance of the thesis naturally flows from these three points of originality given that the credibility of so-called cadaveric organ procurement systems and of approaches taken to determining death are both of high societal importance.

In terms of its methodology, the thesis is not merely critical, but also multi-disciplinary, comparative, and broad-ranging in the materials it draws on. Specifically, its critical focus centres not just on relevant law relating to death and organ procurement but also governance and practice and the discourses that swirl around and intersect with them. As

well as law, the thesis draws heavily on ethics, medical science, sociology, and politics. It employs both a case study-based and comparative approach when addressing relevant law, governance, and practice to provide an accurate picture of key differences and commonalities in their process of evolution and maintenance as well as substantive nature.

The case for reform of the so-called system of cadaveric procurement of solid organs for transplantation

1.1 Aim

This doctoral thesis aims to critically explore contemporary systems allowing for the removal of essential to health/life organs for transplantation and the case for their reform.

1.2 Background, rationale, objectives, and significant original contribution

How we conceive of death, define it, and test for it has always been socially, culturally, and practically important and has long been contested. However, throughout the modern era that importance has grown, and the contestation has become more intense.

Two particularly critical happenings in the 20th century were the development of the capacity to assist/take over respiratory function via ventilation and the development of the capacity to transplant essential to health/life organs from one human being to another. In an era where death standards were based on the absence of circulatory function, the advent of ventilation was necessarily both something one could positively couch as the development of a life-extending therapy but also perhaps negatively couch as one that could keep patients alive for an indefinite time even in circumstances where all but the vitalist would disapprove of doing so. Determining the circumstances in which it is ethically acceptable to remove ventilatory support necessarily entailed, and continues to entail, tackling tricky ethical and legal issues around what is and isn't legitimate withdrawal of treatment and, relatedly, what is and is not killing. The idea of dispensing with a circulatory-based approach to death in favour of a brain-based approach held out the prospect of bypassing those issues in whatever circumstances the brain-based approach could be used to define the ventilated individual as dead. By enabling some brain-injured patients to be defined as dead even when they maintained (via ventilatory support or otherwise) circulatory function, the idea of a brain-based approach to death also held an attraction for those who wanted to procure essential to health/life organs for transplantation and/or

other otherwise normally legal medical purposes without fear of being subject to successful civil and/or criminal law action, all the way up to potential criminal prosecution for homicide. A key practical catalyst for turning this idea of a shift in approach into a broad reality in medical practice, governance, and the law was the 1968 report by a committee at Harvard Medical School that was entitled "A Definition of Irreversible Coma". The report concluded that it should be possible to define death not just by reference to loss of cardiorespiratory (i.e., circulatory) function but also by reference to loss of brain function.[1]

With this change in landscape in the medical field, there became a shift in how people perceived the human body and its uses. Most pertinently to the immediate context one can point to the fact that humans across nearly all societies have, over time, increased the extent to which they do things to those that are defined as dead that have come to be generally accepted but would generally be regarded as transgressing body related functional interests were they done to the living. These are not just death-related rituals like embalming and cremation, but also certain uses of the body and parts taken from it for the ends of others, in contexts such as public display, medical education, research, and transplantation.

This thesis is situated immediately in the context of these uses and the fact that the desire to promulgate them to an ever-greater extent has been allowed to be a driver of further formalisation around the definition and determination of death and its specific character. With members of the Harvard Medical Committee involved with transplantation it can legitimately be asked whether the introduction of brain death has from its outset been predicated on vested interests the same can be asked with reference to subsequent changes in various jurisdictions. The direction of travel has been to further expand who is being defined as dead in a manner that has extended opportunities for procurement of essential to health/life organs for the end of transplantation. In particular, certain jurisdictions have allowed people to be defined as dead in certain circumstances after their

[1] Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, *A definition of irreversible coma*, Journal of the American Medical Association 1968; 205:337-340

circulation has stopped for only a short period of time (such as 10 minutes, 5 minutes, 2 minutes, or even less).

While part of the purpose of this thesis is to critique current approaches to death from an ethical perspective, another is to critique them sociologically and politically. In essence, I argue that the objective of securing more transplantable organs has led to a watering down of the requirements for the definition of death and critically explore how this is linked to formal systems around the determination of death. Specifically, most jurisdictions have such formal systems and nearly all such systems are:

1) Medico centric;

2) Largely supportive of body and body part use;

3) Are promulgated to the public as if they are the product of medical fact rather than as the reflection of a contested ideology and instrumental purpose; and

4) Have become embedded in an orthodoxy that is hostile to their disputation.

The thesis will challenge the legitimacy of current formal systems on all four of these fronts. It focuses on transplantation not merely as a case study but also because it has for some time acted as a principal driver of the formalisation process, including the fact and nature of its radicalness. As stated in the previous paragraph it has been suggested that the desire to remove essential to life organs from a human being for transplantation resulted in the development of brain-based standards criteria for the determination of death. The desire to expand such removals led to such standards and criteria being taken up by most jurisdictions over the decades. Furthermore, whilst the literature continues to be almost evenly divided over the merits of brain-based standards and criteria, there has been considerable hostility around opposition to them, not least consequent upon the concern that if the public were to 'get wind' of just how contentious such standards and criteria were, they might be 'put off' the idea of 'bequeathing' their organs for transplant use.

Meanwhile, some jurisdictions have permitted the use of even more radical standards and criteria, allowing death to also be defined, or, to the same effect, brain death to be imputed in certain contexts by reference to loss of circulatory function.

The stakes are high because not only are contemporary systems officially presented to the public as being robust in character, but they are also specifically presented as consistent with the so-called dead donor rule (DDR). The DDR is an unwritten rule that states that potential donors must be dead before the removal of essential organs and that the removal of said organs must not be the cause of their death. It was first used by John Robertson in 1988. The principle of the DDR and related ethico-legal norms support the protection of human life and can be situated more broadly within an inherent dignity/worth-based approach to ethics. A proper reading of the DDR and related norms would imply that is necessary to go beyond a 'box ticking' exercise of checking whether a person is dead under legal or other regulatory criteria to actually ensure that no one is at material risk of having essential to life or health body materials extracted from them for donation until it is very clear that they are dead according to a conservative/precautionary approach to interpreting what death is and determining practically when it has occurred. Doubts about current legal/regulatory approaches to death largely result from perspectives that they fall short on this front. A significant proportion of thinkers take a whole organism approach to death and thus logically view the removal of essential to life/health materials for donation as per se incompatible with the DDR and related norms. Meanwhile, a much larger group sees such removals as problematic in either certain circumstances or under certain particularised approaches to death standards, usually the more radical ones that are declaring death by reference to loss of circulatory function.

Questions have always been asked about the validity of brain death as a standard due to the fact there is a long association between the development of brain death as a diagnosis of death and the practice of organ donation. Since then, death standards have become more dubious as standards have become stretched to accommodate the fact that organ donation is now heavily relied upon in the medical community. It is routinely used and is a mass-scale

therapy to treat many diseases across the medical sector, which has become its downfall as there is a continuing problem of the imbalance between the supply of solid organs and tissue for transplantation and demand for them. To compensate for this demand, the standards for diagnosing death have become less robust, for example, to satisfy the circulatory definition, in some procurement protocols the no-touch time is two minutes,[2] and there have been reports of this time being as little as seventy-five seconds.[3]

When considering the above paragraph in isolation alarm bells should start to ring but could there be a situation in which the apparent watering down of standards is justified? Contemporary narratives in procurement discourse often treat shortfalls in supply versus demand for many solid organs as a foundation for such a justification. Certainly, there is a shortfall when it comes to some such organs even with respect to geographies within which there are many evolved systems. A good example of this is the position in the UK which at the end of financial year 2022 had 6,269 patients waiting for an organ transplant[4], with a further 3,990 temporarily suspended from the waiting list (10,259 in total). Compare this with actual organ donors during the same time period, where there was a total of 1,397[5] this represents one deceased donor per year for every 4.5 patients on the waiting list (7.3 including temporarily suspended patients). The figures were not that much 'better' before the pandemic. Merely pointing to the fact that something is more demanded than supplied is, however, not a basis on its own for developing more supply, let alone doing so at the cost of further damage to ethical norms. A more considered approach is required.

The first objective of the thesis in light of the foregoing discussion is to build a systematic critique of what may be described as establishment approaches to the definition and

[2] As is the case in the Pittsburgh Protocol.

[3] Rob Stein, 'Infant Transplant Procedure Ignites Debate', *Washington Post*, 14th August 2008 http://articles.washingtonpost.com/2008-08-14/news/36802270_1_transplant-advocates-patient-brain-dead-donation-after-cardiac-death, accessed 31st March 2022; Robert M Veatch, 'Transplanting Hearts after Death Measured by Cardiac Criteria: The Challenge to the Dead Donor Rule', Journal of Medicine and Philosophy 2010 **35**(3): 313-329

[4] Summary of Donor and Transplant Activity https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/27113/section-1-summary-of-donor-and-transplant-activity.pdf (accessed 2nd December 2022)

[5] The number of donors after a neurological death diagnosis increased by 1% to 962, while the number of donors after a cardiorespiratory death increased by 3% to 638

determination of death, both as phenomena that have emerged and maintained themselves and in terms of their substance. On the substantive question, this critique finds considerable fault with both brain and circulatory-based approaches to determining when death has occurred and concludes that we cannot assuredly treat those who are being defined as dead are in fact dead. In light of this finding, and given the need for conservative logic around death, the thesis recommends that we must then treat these donors as alive.

The other objectives of the PhD flow from the question of what, if anything, ought to be done about this. To answer this requires, in the first place, an ethical benchmark. Do we, for example, adopt an approach that centres on respect for human beings and, if so, what does this mean? Or, in the alternative, do we allow that emphasis to be subjugated – and hence potentially diluted – by reference to some other goal, such as utility or justice? Answering these questions is the focus of the second objective of the thesis.

The third objective is to address, in the light of conclusions reached on what approach to ethics is preferable, the question of what substantive reforms to the current system of so-called cadaveric solid organ procurement ought to take place – specifically this includes what approaches should be taken not just to death but also the use of practices designed to facilitate procurement before and after death (as currently determined) and the approach taken to gaining authority for organ transplantation, whether by consent from the subject and/or on an alternative basis. The thesis is not intended to be jurisdiction-specific but, rather, to discuss typical current approaches and their possible reform, though current approaches in England and the UK more broadly are often drawn on as an exemplar/case study.

1.3 Original and significant contribution:

It is well documented that current approaches to death have been analysed extensively in the discourse. The thesis makes three key original and significant contributions to the field.

1. It develops a novel approach to substantive critique of contemporary approaches for defining death and determining its occurrence.

The central concern for contemporary approaches is that they may result in essential-to-wellbeing and essential-life-organs being taken from donors who may actually be alive.[6] Ethico-legal debate on this issue and death standards more generally has become much polarised. On the one hand, authors like DuBois[7] and Caplan[8], have suggested that the issues around diagnosing death have been resolved and that further debate is not just unnecessary but should be stifled to protect donation rates. On the other hand, although the Harvard Medical School Committee published its report defining and endorsing a brain-based approach to determining death over five decades ago and the fact that over time most jurisdictions came to endorse it at least broadly, there are concerns among many experts that brain death standards are not credible. These concerns have been extensively documented before, in, and after the influential 2008 President's Commission report.[5] There are also new dimensions in scientific understanding that need to be further evaluated; for

[6] Alan Shewmon is a neurologist who withdrew his prior support for the concept of brain death after research showed that many patients' who were considered brain dead still retained considerable measurable brain function. Alan Shewmon, (1998) "Brainstem death", "brain death" and death: A critical re-evaluation of the purported equivalence, Issues in Law and Medicine 14(2): 125-45

[7] James M Dubois, 'The Ethics of Creating and Responding to Doubts about Death Criteria', The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine, Volume 35, Issue 3, 1 June 2010, Pages 365–380

[8] Arthur Caplan, 'The case against care for those who are brain dead', *https://www.newsday.com/opinion/oped/caplan-the-case-against-care-for-those-who-are-brain-dead-1.6767446,* January 2014 (Accessed 10th May 2018)

[5] The President's Council on Bioethics. *Controversies in the Determination of Death*, 2008. US Government Printing Office, Washington, DC

example, there is an emergent body of evidence suggesting that Electroencephalography (EEG)[9] silence does not mean that the individual under observation is dead.[7]

Furthermore, the thesis will generate a novel lens for critique of approaches to death more generally specifically making and applying the argument that the way we test for death will be flawed unless it meets the challenge of: (i) being able to prove the 'negative' absence of life and (ii) being properly aligned to a definition of death that is (iii) based on a valid (philosophical or spiritual) conception of death. The thesis illustrates that there are problems with contemporary approaches to death on all three fronts.

2. It develops the first thorough analysis and critique of the process by which establishment approaches to death have arisen and maintained themselves.

Central to my argument is the notion that from the outset of the very first successful organ transplantation, death criteria have continually been set by those who have a vested interest in the outcomes. The underlying principles and mechanisms of defining death have been driven and devised mainly by the medical establishment, to the point, that in certain cases, the law has become almost a rubber stamp. I argue that the situation in most jurisdictions may be characterised as (i) democratically deficient in the sense of a lack of proper wider public involvement and sway in the development and reformation of standards; and (ii) expertise deficient in the sense that the conceptualisation and related definition of death has been handled as if it were a medical question and afforded a 'medical mystique' that has served to cloak the fact that it is ultimately a philosophical or spiritual question.

[9] Electroencephalogram is a test used to investigate problems related to electrical activity of the brain. An EEG tracks and records brain wave patterns.

[7] Jens P Dreier, Sebastian Major, Brandon Foreman, Maren K L Winkler, Eun-Jeung Kang, Denny Milakara, Coline L Lemale, Vince DiNapoli, Jason M Hinzman, Johannes Woitzik, Norberto Andaluz, Andrew Carlson, Jed A Hartings, 2018. 'Terminal spreading depolarization and electrical silence in death of human cerebral cortex'. Annals of Neurology 82(2), 295-310

3. It develops the first thorough analysis of what the ethical lens or framework for reform of the so-called system of cadaveric organ procurement ought to be.

Prior critiques of the system have tended to take a more limited approach to evaluating what approach to ethics should be preferred. Truog and Miller, for example, handle the question perfunctorily in their significant book on this topic.[10] Amongst those who disagree with current approaches taken to death, there is also a conflict over what changes could/should be implemented to organ procurement practice. Some authors, for example, favour keeping the DDR which is a deontic constraint that categorically prohibits causing death by organ removal. This informal rule has guided the practice of organ transplantation since its inception. One such commentator is Bernat who has said, "I believe that … violating the DDR is misguided … and will result in an overall decline in organ donation" (p. 1290).[11] There are others, such as Truog, who are in favour of abandoning the rule in certain circumstances.[12] On this issue, I can relate to both opinions, on Bernat's view I can see that there would be a distinct possibility that the number of organ donations would be reduced if medics went ahead and violated the DDR. It is one of the main principles that patients rely on at the end of their life, it is there to protect vulnerable patients at a time when they may no longer be able to decide for themselves. It offers reassurance that their organ will not be removed until they are dead. With Truog's view, I can see a potential for a system being set up in which potential donors could register their views on the removal of organs before they are declared dead. This of course would only be in circumstances for example where a patient is being removed from life-sustaining treatment it could potentially allow for the removal of organs without waiting for the no-touch period[13] which is required to declare someone dead.

[10] Franklin G Miller, Robert D Truog, 'Death, Dying, and Organ Transplantation; Reconstructing Medical Ethics at the End of Life', 2012, Oxford University Press

[11] James L Bernat, 'Life or death for the dead-donor rule?' The New England Journal of Medicine 2013;**369**(14):1289–91

[12] Robert Truog, Walter Robinson, 'Role of Brain Death, and the Dead-Donor Rule in the Ethics of Organ Transplantation'. Critical Care Medicine. 2003; 31:2391–2396

[13] This no touch time is dependent on which jurisdiction a patient finds themselves in for example, England 5mins, USA between 2-5mins.

Bringing theoretical rigour to this issue enables the thesis to have a more robust foundation for its consideration of reforms in this area. In tackling this issue, the thesis builds upon Garwood-Gowers' argument that organ procurement is a form of medical use of the human being[14] and uses his categorisation of key ethical issues as a starting point. Specifically, I employ his thesis that the key ethical issue is whether this use should be constrained by respect for human beings or whether that orientation might acceptably be wholly rejected or partially diluted to meet the claimed needs of others. In the context of the so-called cadaveric organ procurement system at least, I share his conclusion that such negation or dilution ought to be considered unacceptable. However, when addressing the question of what respect for human worth means, I adopt a somewhat more libertarian or utilitarian approach to his, depending on the situation in which the human body is being utilised.

When considering the use of human tissue in research I have a more utilitarian or social value-based instinct which I have developed through my work within a research laboratory that works with human tissue on a daily basis. Some of the projects that I worked on rely on patients making difficult decisions about donating tissue upon death for research,[15] and although this may not have a direct effect on others like the donation of an organ, without the selfless donation scientific research within certain areas would grind to a halt. These patients go through a consenting process similar to that seen when consenting to surgery. Consent must be given by someone who has capacity, they are fully informed, consent is given freely and voluntarily and the act is not against public policy. So why is this not the case when organs are being considered for organ transplantation? Consent in such cases bears little resemblance to informed consent and even less so now that England has adopted an opt-out approach with the introduction of the Organ Donation (Deemed Consent) Act 2019.

[14] Austen Garwood-Gowers, 'Medical Use of Human Beings: Respect as a Basis for Critique of Discourse, Law and Practice', 2019, Routledge

[15] For example, I work with samples for the PEACE (Posthumous Evaluation of Advanced Cancer Environment) Study, which facilitate tissue donation from multiple tumour sites in the post-mortem setting and enable future research using samples collected at post-mortem within different disciplines related to cancer research.

With regards to organ donation, I have a view of liberty that acts as both a constraint on the exercise of those instincts and a facilitator of them in others I tend to agree with some aspects of Truog's views that a potential organ donor should be able to give informed consent to donate their organs in circumstance before death is declared. My instincts and views are perhaps somewhat less circumscriptive of the extent to which I think it might be acceptable for one person to alienate the interests of another where that other knows of the alienation and is (capacity-wise) able and willing to accept it, and where public policy allows it. This thinking will influence my conclusions as to the specific shape that a reformed system for so-called cadaveric organ procurement ought to take. Whereas Garwood-Gowers takes a traditional approach to what is often called the principle of legality in contrast to those who would like to see it weakened or eliminated either for reasons of expediency in the context of transplantation or medical use more generally or as a matter of fundamental principle.

The significance of the thesis naturally flows from these three points of originality given that the credibility of the so-called cadaveric organ procurement systems is of high societal importance. The spectre of the DDR being breached by current approaches to death begs the question of whether removals of essential to well-being and essential to life organs should be stopped completely or whether, in the alternative, they could potentially be maintained on some modified basis with the DDR, and the dignitarian emphasis which underpins it, being replaced with an alternative guiding principle such as liberty, justice or utility. It is well documented that current approaches to death have been analysed extensively in the discourse. This doctoral thesis aims to bring together all the weaknesses of death diagnoses and carry out a broad analysis of the issues, including legal, ethical, medical, and social aspects. The thesis will challenge the notion that just because something is historical does not necessarily mean it should be continued.

1.4 Methodology

This doctoral thesis adopts a critical approach to the discourse related to organ procurement and related law, governance, and practice. It is necessarily interdisciplinary as a result, with the principal disciplines being employed including law, ethics, medical science, and sociology. It also employs comparative methodology - specifically drawing on the law, governance, and practice of a range of contemporary systems for so-called cadaveric organ procurement in order to build a substantive picture of differences and commonalities in both their substantive character and process of evolution and maintenance.

By carrying out a thorough literature review I aim to show that there is enough evidence within the discourse relating to organ procurement to back my case for the reform of the so-called system of cadaveric procurement of organs for transplantation. The main grounds for the argument will be based on the fact that the politics of the development and reification of establishment approaches to death bely the fact that the nature of what death is and, in turn, how we should define it and set diagnostic criteria are contested issues. I will argue in terms of neurology definitions of death that at the time the definition was developed there were other influencing factors that may have led to the decision to allow it. I will also show that we use a concept based on loss of capacity for awareness as is the case for neurological death; this means that there is a biological reductionistic assumption to link life with the brain. In other words, by using a theoretical approach that aims to explain all social or cultural phenomena in biological terms, removes death from a natural life process, and in doing so denies them any causal autonomy to be used to describe an event such as dying. After all, death as an event is influenced by social and cultural ties, which could be denied by a neurological diagnosis.

For death by circulatory diagnosis, I will argue the fact that this is not a credible definition due to (1) there being no universal standard that all procurement protocols follow;[16] (2)

[16] In the UK, Belgium, France, The Netherlands, Spain and Canada no touch time is five minutes, United States it can range from five minutes down to two minutes and more controversially it has been reported that death was certified and organs were removed after waiting only seventy-five seconds, Austria, Czech Republic and

how 'irreversible'[17] should be defined: there have been cases where hearts have been removed from a so-called dead donor and transplanted in the recipients, which seems to contravene the main requirement – irreversibility of cessation of the circulatory system.

I will state that to carry on with any sort of organ procurement system it ought to be constrained by respect for the human being and not as it appears to be at the moment: a diluted version of this to meet the claimed need for organs. I put forward the notion that any new system will need to be based on a libertarian ethical footing leaning towards a dignitarian/worth principle to protect those individuals who have the inability to decide for themselves. To show that a libertarian approach is the most preferable basis for a procurement system I will consider other potential ethical theories including utilitarian, and justice ethics theory, after which I will justify as to why I have disregarded them.

Having conducted a literature search in this field, it is evident that conflicts of opinion persist with respect to all relevant medico-legal aspects of death - namely how it is conceptualised, defined, and tested for.

1.5 Plan and outline of the thesis

The first part of the thesis is focused on the critical exploration of contemporary systems allowing for the removal of essential to-life organs for transplantation. It is split into two chapters. The first is centred on a critique of the way death is being conceived, defined, and tested for. It will critically reflect on both the substance of historical and modern standards and the structures of power that have fostered and maintained them. I highlight how certain factions of the medical community, have instrumentally approached death to achieve both resource objectives (in the context of ventilation) and transplant ones (i.e., expanding procurement). Whilst this does not invalidate modern approaches to death it

Switzerland have a time ten minutes, in Latvia, the no touch time is fifteen minutes, while in Italy the no touch time is twenty minutes.

[17] In the context of death, the capacity to breathe, maintain a circulation or brain function is described as irreversibly loss.

does provide a reason to critique both their substance and the question of more keenly whether in accepting/embracing the views of these factions medical and legal establishments have been 'captured' and fostered a situation in which law and practice in this field basically reflect that capture rather than being the outcome of vigorously independent and critical reflection on death.

The second chapter builds on this critique of current approaches to death by examining what ethical lens might most validly condition the consideration of systemic reform. This chapter will aim to re-examine the normative grounding for the cadaveric system: I will specifically explore dignitarianism and libertarianism as the key respect for worth approaches and conceptions of utilitarianism and justice that have been used in the transplant context/more generally to achieve greater medical use of the human being at what I will argue is at a cost to respect for worth. Ultimately, I will make the case for a heavy liberty-centred view of respect for worth as the appropriate grounding for critically reflecting on reform. Both political and moral ethics are used to inform this view.

The second part of my thesis will be a reflection on the parameters that I consider to be required to enable a new system to be put in place. This part will consist of three chapters. The first chapter will reflect on how the approaches to death will need to change. If, as this thesis suggests a potential donor on the balance of probabilities is in fact not dead then this asks the question should the organs be removed? This obviously creates a huge dilemma in the transplant community, because it is getting harder for the medical profession to deny they are just paying lip service to the DDR.

Death has been described as the permanent loss of life, but what is life? Should life be a biological concept, where the body is working together as a whole organism, or is it having the ability to interact with your surroundings and being conscious of oneself and others, or a combination of the two? In the case of defining death and the procurement of organs, I will argue that a libertarian approach may be favoured as it supports the person who believes in

the doctrine that human beings possess free will to decide on how they wish to be treated. This chapter will also discuss who should be the driving force for creating and enforcing the reforms, be it legislative, the medical/scientific community, the ethicist, or a combination.

The second chapter in this part will concentrate on the approaches to so-called pre- and post-mortem practices. Potentially, in England, any pre/post-mortem intervention to a patient in order to facilitate organ donation could be seen as a battery under civil law[18] or as a criminal offence[19] as the treatment in most cases is of no direct benefit to the patient medically, the benefit is usually received by the organ recipient. Current guidelines for clinicians state that when considering whether any actions should be taken to facilitate or optimise donation then they must reflect on any risk of harm or distress to their patient. They will need also to have regard for a person's best interests in personal dignity, especially when close to death. Examples of potential harm can include a) worsening of the patient's medical condition; b) shortening of the patient's life; c) pain from an invasive procedure; and d) distress to family and friends. Clinical teams will need to balance these risks against the knowledge that they have regarding a patient's wish to donate.[20] The Department of Health has expressed an opinion on the fact that organ donor registration does not provide consent to pre-mortem intervention to procure organs and that any such intervention is only lawful if believed to be in the best interests of the patient.[21]The remaining element of this chapter will question if a patient has decided to be an organ donor, should they not be allowed to draw up a plan that could potentially include pre-mortem interventions designed to facilitate procurement after death, to enable this to happen.

Finally, the third chapter will critically deploy the preferred framework and the critique of current approaches to death in identifying how so-called cadaveric procurement systems should be reformed in terms of post-mortem approaches to procurement. Should a

[18] Tort of Trespass to the Person
[19] Offences Against the Persons Act 1861
[20] *Legal issues relevant to non-heart beating organ donation,* The Department of Health, November 2009, www.dh.gov.uk/publications
[21] Department of Health-*Legal Issues Relevant to Non-Heart Beating Organ Donation*, London: Department of Health, 2008

procurement system be based on an opt-in or an opt-out model for obtaining patient consent? Even though England, Scotland, and Wales have recently introduced new legislation to allow for an opt-out system to be in place there is still ongoing debate. Another option I will consider is whether a new system should stop the use of donations after circulatory death; after all the UK courts themselves have stated that brain death is the only one true test for death. It was Lord Lane C.J. in *R v Malcherek*[22] who on the subject stated that:

"Modern techniques have undoubtedly resulted in the blurring of many of the conventional and traditional concepts of death... There is, it seems a body of opinion in the medical profession that there is only one true test of death and that is the irreversible death of the brainstem, which controls the basic functions of the body such as breathing. When this occurs, it is said that the body has died, even though by mechanical means the lungs are being caused to operate and some circulation of blood is taking place"

If the above statement from Lord Lane C.J. is correct then how we can possibly allow donation via a circulatory diagnosis, is the medical profession saying that lack of circulation is an indicator of brain death? With all the uncertainty that still surrounds the subject: it is about time for a complete overhaul of the system, with any new proposal put forward to acknowledge the fact that a potential donor may not be dead at the time of removal of organs.

This would require a whole new way of thinking: who would it involve: the medical/scientific community, the ethical community, the legislative community, or a combination of them? At the same time this review could also potentially answer the main controversial viewpoint that is currently being argued, does it matter if potential organ donors are not dead at the time of procurement if it is deemed that no real harm is being done to the potential donor? According to some views, potential donors could have their organs removed because they

[22] [1981] 2 All ER 422

have no prospect of regaining consciousness and continued life cannot benefit them. This was the viewpoint that James Rachel took when he stated that: "while their biological life may continue, their biographical life has ended."[23] Since then, there have been various commentators who hold a similar view on the issue by stating that patients who are not yet dead but have no hope of recovery are beyond harm and, therefore, they cannot be harmed by the removal of their organs.[24] For this type of system to be in place, it would mean that the medical community would have to abandon the DDR, which states that organs cannot be removed from a patient who has not been declared dead.

There is a divided opinion on this suggested system but as Miller and Truog[25] have argued, that the current practices of vital organ donation, although deemed to be consistent with the DDR, do in fact violate it. They have argued that brain-dead donors, though drastically compromised neurologically, remain fully alive while being maintained on life support. Potential donors who fall under donation after circulatory determination of death (DCDD) protocols are not known to be dead, based on the irreversible cessation of circulatory functioning, when organs are procured a very short interval after asystole. In other words, in the view of the biological conception of death adopted in standard medical practice, there is no satisfactory resolution of the paradox.[26]

I will conclude this thesis by answering the question: is there a case for the reform of the so-called system of cadaveric procurement of organs for transplantation? In doing this I will reflect on the outcomes of my research, which suggests that potential organ donors are not yet dead at the time of organ procurement. I will argue that the potential organ donor should have their rights protected in the same way as the conscious person. Therefore, going forward any suggested procurement system should include a universal consensus on the definition of death, which can ethically and morally allow organ donation programmes

[23] James Rachels, *The End of Life: Euthanasia and Morality*. Oxford: Oxford University Press 1986. 24–25
[24] Robert Truog, Walter Robinson, 'Role of Brain Death, and the Dead-Donor Rule in the Ethics of Organ Transplantation'. Critical Care Medicine. 2003; 31:2391–2396
[25] Franklin G Miller, Robert D Truog, *Death, Dying, and Organ Transplantation; Reconstructing Medical Ethics at the End of Life*, Oxford University Press 2012
[26] ibid

to carry on. I will also conclude that the reforms should be based on a libertarian and dignitarian/worth ethical thinking, inclusive of the religious/cultural views of the community that the legislation is meant to serve. To finish off the thesis I will question why, many transplant laws, including England's, have been changing to an opt-out system,[27] seemingly without considering some of the problems highlighted in the literature and focused on in this thesis.

[27] Organ Donation (Deemed Consent) Act 2019, the so called 'Max and Keira's Law

"Why should I fear death? If I am, death is not. If death is, I am not. Why should I fear that which cannot exist when I do?"

- Epicurus[28]

2.1 Introduction

Five decades after the Harvard Medical School Committee published its report on brain death and with the continual use of cardiorespiratory death, there are still persistent criticisms facing the medical/legal profession with respect to the credibility of approaches taken to defining when death has occurred. There are some commentators like Dubois[29] and Caplan[30] who not only suggest that these criticisms are unwarranted but argue that they should be suppressed because of their potential to adversely impact procurement.[31] However, a considerable number of thinkers, including those who wrote the President's Commission report Controversies in the Determination of Death (2008), disagree.[32] Put simply, the philosophical investigation of human death focuses on two overarching questions: (1) What is human death? and (2) Can we determine that it has occurred and, if so, how?

As to the first question, the Oxford Dictionary simply describes death as:

"The action or fact of dying or being killed; the end of the life of a person or organism, the permanent ending of vital processes in a cell or tissue."[33]

[28] "Epicurus." AZQuotes.com. Wind and Fly LTD, 2017. 31 January 2017. http://www.azquotes.com/author/4529-Epicurus

[29] James M Dubois, 'The Ethics of Creating and Responding to Doubts about Death Criteria', The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine, Volume 35, Issue 3, 1 June 2010, Pages 365–380

[30] Arthur Caplan, *The case against care for those who are brain dead, https://www.newsday.com/opinion/oped/caplan-the-case-against-care-for-those-who-are-brain-dead-1.6767446,* January 2014 (Accessed 10th May 2018)

[31] Dubois (n29) 365–380

[32] Controversies in the Determination of Death: A White Paper by the President's Council on Bioethics, The President's Council on Bioethics, Washington, D.C., December 2008

[33] www.oxforddictionaries.com/definition/english/death

This reflects the common conceptualisation of death as an endpoint, i.e., life is permanently lost and cannot be retrieved. It also alludes to the timing being related to a physical process. However, it is the nature of that physical process that has been a key subject of controversy. The Oxford explanation of it being the permanent ending of vital processes in a cell or tissue is clearly satisfactory but there is an ongoing tussle over whether it entails cessation of all vital processes in the body or can be narrowed down to irreversible cessation of a particular part or function of the body.

Notably, most contemporary standards of death require only cessation of brain function, and some allow cessation of circulation to be treated as a proxy for that in certain circumstances or, in the alternative, cessation of circulation to in some circumstances be treated as an alternative basis for death in its own right. The earlier conflict alluded to specifically centres on the fact that whilst many regard contemporary reliance on brain-based standards as unassailable and some regard the move into circulatory approaches as acceptable others regard one or both as questionable in their conception and/or application. Regarding application, there is also a more fundamental question of whether it is actually even possible to viably test for death.

2.2 Historical context prior to the development of a brain-based approach

It has been suggested that questions about death and how it was diagnosed did not come to widespread public attention until well into the twentieth century.[34,35] However, concerns about defined dead when one is not are actually very natural and primal, at least in contexts where the consequence of being defined dead is to be subject to action (such as embalming, burning, or burial) that would be incompatible with the functional interests one has if still alive. In the 18th and 19th century, these concerns were frequently reflected in fictional and

[34] Martin S Pernick, 1999, "Brain Death in a Cultural Context: The Reconstruction of Death, 1967–1981," in Stuart J Youngner, Robert M Arnold, and Renie Shapiro (eds.), *The Definition of Death: Contemporary Controversies*, Baltimore, MD: Johns Hopkins University Press: 3–33.
[35] Arthur M Capron, 1999, "The Bifurcated Legal Standard for Determining Death," in Stuart Youngner, Robert Arnold, and Renie Shapiro (eds.), *The Definition of Death: Contemporary Controversies*, Baltimore, MD: Johns Hopkins University Press: 117–136.

non-fictional works, including Mary Shelley's Frankenstein. They also spawned practices like keeping the grave open and, for graves that were closed, devices like safety coffins of various types that would feature a bell that would stay above the surface but be attached to the inside of the coffin by wire or string in such a way that if the buried person turned out to be alive, they might have some means of ringing it and attracting the attention of a 'watcher' on the surface. The possibility of being defined dead when alive has always had the potential to emanate not just from an inappropriate definition of death being used but also weaknesses in the criteria and tests developed pursuant to a definition. To mitigate against this, many people specified in their wills that special tests were to be carried out before burial. These included using a candle or mirror to detect respiration. Equally, some took extreme steps to make sure they were dead, such as by demanding they were to be decapitated, exsanguinated (drained of blood), or stabbed through the heart. Others required that boiling liquids be applied to their skin, surgical incisions be made, or red-hot irons be touched to their flesh to see if they could be aroused. As a final resort, some people requested a way of killing themselves if they should wake up in their coffin, so they were buried with guns, knives, or poison.[36]

Over time, with the increased understanding of human anatomy and biological function, it was decided that death could be declared after a passing of time, this was then developed further, and death was declared once it was ensured that respiratory failure was permanent, which in turn lead to terminal cardiac arrest. Equally, prolonged cardiopulmonary failure inevitably led to total, irreversible loss of brain function. However, with the invention of mechanical respirators in the 1950s, it became possible for patients who had had such failure to have their cardiopulmonary functioning maintained, and with that, the functioning of their organs sustained The question of whether such a patient was alive or dead started to be asked and debated and the possibility of having a definition, criteria, and tests for death that centred purely on loss of neurological functioning emerged.

[36] Larry Dossey, 'The Undead: Botched Burials, Safety Coffins, and the Fear of the Grave', EXPLORE, Volume 3, Issue 4, 2007, Pages 347-354

The determination of the end of life is important on many levels. It signals the start of the mourning period; various rights and rituals can proceed; legal affairs may be settled; succession can take place. It has always been important in medical law and ethics; this has become even more central and at the forefront in recent decades because of two major advancements in medicine; life-support systems and organ transplantation. With these advancements in medicine come challenges to culture and religious beliefs on death. Life-sustaining treatment can give the impression that a patient is still alive even though they may have been diagnosed as brain dead/ brainstem dead. This can be confusing as the general public associate life with the ability to breathe, but it also questions the diagnosis when you consider the fact that the body can still perform functions even though they are supposedly dead.

2.3 Aim

This chapter aims to carry out a critical exploration and analysis of how the key aspects of death are and should be addressed in terms of the medical/scientific community, legal community, and ethical community. It will consider the backdrop at the time of the original thoughts and discussions during the time period just before the Harvard Committee meeting and there on afterward, as well as who were the participants of the meeting, to see if there were any influences or alternative motives for the decisions made. I will achieve this by firstly addressing and deconstructing the underlying values of the medical/scientific community to see how their views and values may have influenced the current definitions, conception, and criteria/tests, many of which are now nearly fifty years old. I will reflect on the fact that current systems appear to have a heavy reliance on the medical profession, to essentially lead the development of how death was conceived and in the light of this defined and tested for, with the law not being constructed or used in a manner that represents a challenge to the medical establishment in this area, despite the apparent radicalism of many of the developments in death standards.

Ethically speaking many feel the drive to obtain organs has been allowed to unduly influence death standards – such that people are actually having essential to-life organs removed in some or even all cases whilst they should be classed as still alive.

2.4 A critical analysis of the emergence and modern reliance on a brain-based approach

To get an understanding of the current methods used for diagnosing death, firstly I must consider what came before, this will require me to consider the historical events that have led to the current approaches used to diagnosing death. The medical criterion of death has evolved over time with increasing advancements in medicine, firstly with the invention of life-supporting techniques, but arguably one of the driving forces behind the developments of assessing death is down to the advancements of organ transplantation and the need to increase the number of donors.

In the past, the diagnosis of death could take some time and variably involved some strange and somewhat primitive techniques by today's standards. Throughout most of human history, the process used for the determination of death has been straightforward, death was diagnosed when a person was cold, blue, and stiff. For example, the Romans and Greeks who disposed of corpses by burial believed that putrefaction was the only sure index of death, so they waited three or four days to make sure that the decay process had begun before the burial could take place. The ancient Greeks also thought that the heart was the essential organ of life, the first organ to live and the last to die. Therefore, a heartbeat distinguishes the living person from the dead one.[37] Hippocrates believed that the brain had an important role in reason, sensation, and motion, but that the heart held the primary function for life.[38]

[37] Martin S Pernick, (1988) Back from the grave: recurring controversies over defining and diagnosing death in history. In: Richard M Zaner (Ed.), Death: Beyond Whole-Brain Criteria. Kluwer Academic Publishers, Dordrecht, the Netherlands, pp. 17-74

[38] James L Bernat, Ethical and Legal Issues in Neurology**:** Chapter 33. The definition and criterion of death, Elsevier Inc. Jan 2014

Other influential proponents of criteria for human death were the twelfth-century rabbi and physician scholar Moses Maimonides, who is regarded by many as the father of brain death as he was the first to argue that a decapitated person was immediately dead, despite the presence of residual movement in the body.[39,40] William Harvey was an English physician who in the seventeenth century first described the circulation of blood and the function of the heart as a pump and which, under this concept, death was when the heart and circulation stopped.[41] This thinking led to the criteria that a person had died once they had stopped breathing and their heart had stopped beating. As late as the nineteenth century, Europe and the United States used a similar technique waiting for rigor mortis, decomposition, and stench to prove death. The Germans developed 'waiting mortuaries', buildings where bodies were kept above ground in open coffins until unmistakable decay occurred.[42,43] The detection methods used were very primitive and improvised, for example, they were usually household objects, such as a mirror, if it was misted then the person was still living. Feathers and candles were often utilised for a similar purpose, to detect the presence of breath. [44]

Many religions believe the moment of death coincides with the departure of the soul. According to Catholic teaching, the soul is the principle of life, and death is therefore understood as the separation of body and soul. It is defined doctrine that human beings, body, and soul, are good by nature and are created by God, and furthermore that the soul does not pre-exist the body but is created instantly when the body comes to be, forming a unity with the body.[45] During the early twentieth century, Dr Dougal believed the soul contained 'substance'. In 1907, to test this hypothesis, he conducted an experiment to

[39] Fred Rosner. *The definition of death in Jewish Law*, In: Stuart J Youngner, Robert M Arnold, Renie Schapiro, eds. *The Definition of Death: Contemporary Controversies,* Baltimore: Johns Hopkins University Press, 1999; 210–21

[40] James L Bernat, *Brain Death, In: Ethical Issues in Neurology,* Philadelphia: Lippincott Williams & Wilkins, 2008; 253–86

[41] http://www.bbc.co.uk/history/historic_figures/harvey_william.shtml

[42] Norman L Cantor, *After We Die: The Life and Times of the Human Cadaver*, Washington, DC, USA: Georgetown University Press, 2010. p 15

[43]Emily Jackson, *Medical Law: Text, Cases and Materials*, Oxford University Press, 2nd Edition 2010

[44] Cantor (n 42)

[45] On the Ethics of Organ Transplantation: A Catholic Perspective, the report of a working party, The Anscombe Bioethics Centre 2014, 8th April 2014

weigh the soul.[46] He observed closely six terminally ill patients placed on a bed mounted on a platform with sensitive beam scales. Sudden weight loss at the time of death would indicate the soul had departed. A weight loss of 3/4 ounces was observed in the first subject and 3/8 ounces in another. In two patients the balance beam dropped not once but twice. Two other patients were excluded due to 'technical difficulties'. Despite this limited evidence, McDougal reported that the human soul weighed 3/4 ounces (21 grams),[47] and therefore a person could be said to have died once a decrease in weight was shown.

One of the first major factors that affected the diagnosis of death occurred during the majority of the nineteenth century, and early twentieth century, with the introduction of certification of death by a physician, which up until then was not a prerequisite to the disposition of a corpse. Sometimes an undertaker (who might be the same cabinetmaker who had made the coffin) or a lay relative claiming to have experience in assessing death would pronounce death.[48] Consequently, there were times when the supposed corpse was not a corpse at all. This all started to change during the twentieth century once it became common practice for a physician to diagnose and certify death. Misdiagnosis became less frequent as medical advancements allowed for better diagnosis, but while this was happening there were also advancements made in treatment. For example, during the twentieth century, it became possible to revive someone once their heart had stopped, antibiotics were developed and routinely used, which reduced the number of deaths from infections. By the latter part of the twentieth century coinciding with the development of intensive care medicine and organ transplantation, a radically different understanding of death was introduced and took hold, the view that death could be determined entirely in terms of the function of the human brain started to be considered by some within the medical community. Even in its infancy, there were disagreements as to whether or not brain death could equate to the death of a human being, as shown in the next section.

[46] Duncan MacDougall, Hypothesis concerning soul substance, together with experimental evidence of the existence of such substance. The Journal of American Society for Psychical Research 1907; 1: 237– 244.
[47] ibid
[48] Cantor (n 42) 13

2.4.1 The development and normalisation of a brain-based approaches

The phenomenon of a brain-based approach to death can be questioned in a biological sense. Why should death be based on the brain rather than the heart or any other major organ, all of which if failed can lead to death? And why should it not be based on total loss of function in the organism as a whole? As highlighted in the introduction to the thesis part of the genesis of brain-based approaches can be seen as related to some of the nuances of navigating ethics, politics, and law relating to the withdrawal of life-maintaining intervention. When ventilating specifically there are such questions to address as how long to provide it for, whether its removal can be legitimate in terms of protecting the interests of the person it is being removed from, or is justifiable in terms of resource and/or whether in removing it a medical is necessarily or in some circumstances causing death or killing (or even will just be in danger of feeling like they are). To successfully portray some unconscious ventilated patients as dead, is a way of removing these issues from focus in relation to them. Some in the profession used this as a reason to develop brain-based standards. One influential pioneer of this approach was Robert Schwab, a neurologist at Massachusetts General Hospital. In 1954 when evaluating a comatose patient with a massive brain haemorrhage on a respirator he opined. The question was, "Is the patient 'alive or dead?' Without reflexes, breathing, and with total absence of evidence of an electroencephalogram, we considered the patient dead despite the presence of an active heart maintaining circulation. The respirator was therefore turned off and the patient pronounced dead."[49] Several years later, French neurologists Wertheimer and Jouvet[50] came to the same conclusion, they said, "that this kind of severe coma whilst on a respirator was different, and it represented 'death of the nervous system'." However, there were detractors to this approach at the time including Mollaret and Goulon[51] who questioned whether it was possible to rightfully ascribe death to those who still had cardio-respiratory function. "Do we have the right," they asked, "to stop treatment using criteria that pretend to know the boundary between life and death?" They preferred the term *coma*

[49] Gary S Belkin, *Brain death and the historical understanding of bioethics*. Journal of the History of Medicine and Allied Sciences 2003; 58: pp. 325-361

[50] Pierre Wertheimer, Michel Jouvet, J Descotes, *Diagnosis of death of the nervous system in comas with respiratory arrest treated by artificial respiration*. Presse Med 1959; 67: pp. 87-88,

[51] P Mollaret, M Goulon, *The depassed coma (preliminary memoir)*. Rev Neurol (Paris) 1959; 101: pp. 3-15

dépassé or "beyond coma"[17] and that it should be used as a *prognosis* of death but not equal to death.

Schwab persisted, however, and nine years after his initial thinking on neurological testing he proposed the flat electroencephalogram (EEG) criterion of death,[52] stating that "this could provide the necessary reassurance of death of the nervous system." It is significant, of course, that Schwab went on to be a member of the Harvard Ad Hoc Committee. So too did Murray who was influential in supporting a neurological approach in the context of organ procurement for transplantation.[53] In 1966 A CIBA Foundation[54] symposium considered for the first time the ethical issues of organ transplantation and the philosophic issues of the definition of death. It also discussed the utilitarian issues in linking brain death to organ transplantation.[55] The symposium involved not only representatives of the medical community but also judges and legal scholars, a minister, and a science journalist, and they came from a variety of countries including the United States, the United Kingdom, Belgium, France, Holland, Italy, and Sweden.

In 1963, in the backdrop of the medical community discussing the possibility of brain death criteria the Belgian surgeon Guy Alexandre, using neurological criteria, carried out the first transplantation from a heart-beating donor, and in 1967 Christiaan Barnard performed the first heart transplantation. At the time there were no guidelines for the diagnosis of death of beating heart donors, but it was declared that the donor satisfied the criteria for *coma dépassé*.[56] Also during 1967 Henry Beecher a bioethicist at Harvard played a lead role in setting up a review panel to investigate the outcomes of patients who had a profound brain

[52] Roland S Schwab, F Potts, P Mathis, EEG as an aid in determining death in the presence of cardiac activity (ethical, legal, and medical aspects), Electroencephalography and Clinical Neurophysiology 1963 15:147
[53]Joseph Murray, (1964) Moral and ethical reflection of organ transplantation. Linacre Q 31: 54-64
[54] The Ciba Foundation (1949-2008) was created by the Swiss chemical company of CIBA, Ltd "to foster international cooperation among scientists"
[55] Gordon Ethelbert Ward Wolstenholme, Maeve O'Connor, (1966) Ethics in Medical Progress: With Special Reference to Transplantation. Little, Brown, Boston.
[56]James L Bernat, Alexander M Capron, Thomas P Bleck, Sandralee Blosser, Susan L Bratton, James F Childress, Michael A DeVita, Gerard J Fulda, Cynthia J Gries, Mudit Mathur, Thomas A Nakagawa, Cynda Hylton Rushton, Sam D Shemie, Douglas B White, The circulatory–respiratory determination of death in organ donation, *Critical Care Medicine*, 2010, vol.38 (pg.963-70)

injury and irreversible apnoeic coma. He was personally familiar with the development of the hospital intensive care unit and the use of mechanical ventilation to sustain the lives of patients who earlier would have died from cardiac arrest or respiratory failure. In 1968 the United States Harvard Medical School Committee published the report[57] defining irreversible coma and recognising that death could occur as a result of irreversible damage to the brain, including the cortex and the brainstem.

In 1981 a Presidential commission issued a landmark report Defining Death: Medical, Legal, and Ethical Issues in the Determination of Death, which rejected the higher brain approach to death in favour of a whole-brain definition. The definition of whole-brain death has since been endorsed by the American Medical Association and the American Bar Association and is law in forty-six states. Thirty-six of these states have adopted some version of the Uniform Determination of Death Act (UDDA) 1980,[58] which includes whole-brain death as a legal determination of death.

In 2008 the President's Council on Bioethics provided a rational for equating whole-brain death and death, stating that:

"Total brain failure can continue to serve as a criterion for declaring death… because it is a sign that this organism can no longer engage in the essential work that defines living things."[59]

Examples given of essential work included breathing and consciousness, but critics were quick to point out that patients who are in an apnoeic coma, high cervical quadriplegics in a

[57] Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, *A definition of irreversible coma*, JAMA 1968;205:337-340
[58] S1. UDDA 1980
[59] The President's Council on Bioethics. *Controversies in the Determination of Death*, 2008. US Government Printing Office, Washington, DC

vegetative state (VS), and foetuses are all living organisms but satisfy the definition stated by the President's Council.[60]

In the UK, the first statement from the British medical profession was made in 1976 in a paper at the Conference of the Medical Royal Colleges entitled "Diagnosis of brain death".[61] This paper describes the procedures for the diagnosis and asserts that for a diagnosis of brain death what is required is the irreversible loss of all function of the brainstem. It also states that "once it could be shown that all function of the brainstem is irreversibly lost then further artificial support is fruitless and should be withdrawn."[62] However, nowhere in the paper does it say that brain death is equated with the death of the patient. It says that brain death is described as "accepted as being sufficient to distinguish between those patients who retain the functional capacity to have a chance of even partial recovery from those in whom no such possibility exists." Put simply, a diagnosis of brain death should be an indicator that the patient's prognosis is a reduced chance of recovery, not that the patient is dead already.

A second statement was published in 1979, also from the Conference of the Medical Royal Colleges, only this time it was entitled "Diagnosis of death".[63] There was no change to the diagnostic protocol, but now it is stated that: "brain death represented the stage at which a patient becomes truly dead." No clarification was given for this massive leap in interpretation, it just said that brain death is the point at which "all functions of the brain have permanently and irreversibly ceased." Yet, the standard for a neurological death in England seems to have been watered down since this published statement stipulates, that we now have a brainstem death definition since 1995.

[60] ibid
[61] Conference of Medical Royal Colleges and their Faculties in the UK. British Medical Journal 1976, 2:1187–8
[62] ibid
[63] Conference of the Medical Royal Colleges (1979) "Diagnosis of death" British Medical Journal 1:332

In 1995 after a review by a Working Group of the Royal College of Physicians, the Conference of Medical Royal Colleges formally approved the more current term brainstem death. The suggested new definition of death was the irreversible loss of the capacity for consciousness, combined with the irreversible loss of the capacity to breathe. It was stated that the irreversible cessation of brainstem function will produce this state and therefore brainstem death is equivalent to the death of an individual. In 2008 the Academy of Medical Royal Colleges issued a Code of Practice for the Diagnosis and Confirmation of Death in 2008.[64] This revised code built upon their earlier code published in 1998, in which they gave the following definition of human death:

"Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe. The irreversible cessation of brain-stem function whether induced by intra-cranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore irreversible cessation of the integrative function of the brainstem equates with the death of the individual and allows the medical practitioner to diagnose death."[65]

According to the preamble, the document provides clear, scientifically rigorous criteria for confirming death, both in clinical settings where confirmation of death by brain-stem testing is appropriate, and where confirmation of death following cardiac arrest is required. In other words, once it was identified that there was irreversible damage to the brainstem, then the patient in question could be declared dead, whether or not the function of some organs, such as a heartbeat, was still maintained by artificial means.[66] Subsequently, the conference led to the introduction of diagnostic criteria of such rigor that on their fulfilment

[64] Academy of Medical Royal Colleges (2008) "A Code of Practice for the Diagnosis and Confirmation of Death" www.aomrc.org.uk
[65] ibid
[66] Statement issued by the Honorary Secretary of the Conference of Medical Royal Colleges and their Faculties in the United Kingdom, *Diagnosis of Brain Death*, Annal Royal College of Surgeons of England. 1977 March; 59(2): 170–172.

a mechanical ventilator could be switched off, in the secure knowledge that there was no possible chance of recovery.[67] This led to an established method for direct brainstem testing to determine whether or not death had occurred.

Since first being published in 1968[68] and 1976[69] there has been little change in the way brain death/brainstem death is diagnosed. In the most recent guidelines published by The Royal Colleges gave the following list of conditions under which the diagnosis of brainstem death should be considered and then the diagnostic tests for which the confirmation of brainstem death is established. [70] The signs and tests that they suggested to look out for are as follows:

- The patient is deeply comatose, and this is due to irreversible brain damage. There should be no doubt that the patient's condition is due to irreversible brain damage of known aetiology and the disorder, which has caused this, has been fully diagnosed. It should be fully investigated and shown that the patient's condition is not down to reversible causes such as drugs, hypothermia, or metabolic disturbances.

- Exclusion of potentially reversible causes of coma, the patient is deeply comatose, unresponsive, and apnoeic, with his/her lungs being artificially ventilated and that the patient is being maintained by the ventilator because spontaneous respiration was inadequate or had ceased. Relaxants (neuromuscular blocking agents) and other drugs must have been excluded as the cause of respiratory inadequacy or failure.[71]

[67] Conference of Medical Royal Colleges and their Faculties in the UK. British Medical Journal 1979; 1:332
[68] The Harvard Ad Hoc Committee report
[69] Conference of Medical Royal Colleges and their Faculties in the UK. British Medical Journal 1976; 2:1187–8
[70] Academy of Medical Royal Colleges (2008) "A Code of Practice for the Diagnosis and Confirmation of Death" www.aomrc.org.uk
[71] See appendix 1 for the Form for the Diagnosis of Death using Neurological Criteria

As for the tests they suggested that a range of procedures be used to confirm that all brainstem reflexes are absent for example, pupils are non-responsive to light, and there is no corneal reflex. There is an absence of oculo-vestibular reflexes,[72] no eye movements are seen during or following the slow injection of at least 50mls of ice-cold water over one minute into each external auditory meatus[73] in turn. There is no cough reflex response to bronchial stimulation by a suction catheter placed down the trachea to the carina, or gag response to stimulation of the posterior pharynx with a spatula. The absence of respiratory movements when the patient is disconnected from the ventilator is also tested.[74] But how do these tests relate to the areas of the brain, for example, how can the lack of ability of being able to cough relate to irreversible damage to the brainstem? The following section will look at the structure and functions of the brain.

[72] This is an involuntary reflex that stabilizes the visual field and retinal image during head motion by producing eye movements in a counter direction.
[73] Ear canal
[74] *A Code of Practice for the Diagnosis and Confirmation of Death*, Academy of Medical Royal Colleges 2008

The structure of the brain

The brain is part of the central nervous system and within this system, it is responsible for the control of every part of your daily life, from breathing and blinking to creating memories. The brain is made up of three main parts: the forebrain, midbrain, and hindbrain. The forebrain consists of the cerebrum, thalamus, and hypothalamus. The midbrain consists of the tectum and tegmentum. The hindbrain is made of the cerebellum. The midbrain along with the pons, medulla is often referred to together as the brainstem.

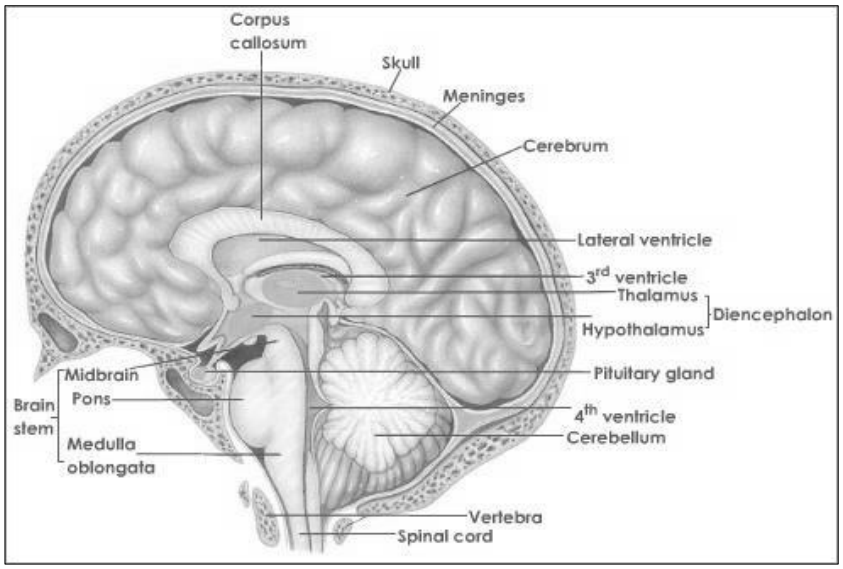

Figure 1: The structure of the human brain[75]

The cerebrum is a major part of the brain and is concerned with higher brain functions such as interpreting sensory impulses and initiating muscle movements. It is divided into four sections called lobes and each lobe is responsible for different functions:

- Frontal Lobe- associated with reasoning, planning, parts of speech, movement, emotions, and problem solving

[75] Figure 1. The structure of the human brain, taken from http://cerebrumfunction.net/cerebrum-function-and-structure/ (visited 7th February 2014)

- Parietal Lobe- associated with movement, orientation, recognition, perception of stimuli
- Occipital Lobe- associated with visual processing
- Temporal Lobe- associated with perception and recognition of auditory stimuli, memory, and speech

There are some advocates of using a higher brain standard for determining death, because patients that have permanently and irreversibly lost the capacity for consciousness and have effectively ended their life as a human being. The reasoning behind this is since consciousness has been thought to be lodged in the higher portion of the brain (cerebral cortex) death of the entire brain, not including brainstem, is necessary for human death.[76] This method for determining death can be regarded as biological reductionistic view, many feel that the consciousness is not bound by space and cannot be located in a specific part of the brain, although it might have a relationship with that part.

[76] Franklin G Miller, Robert D, Death, Dying, and Organ Transplantation: Reconstructing Medical Ethics at the End of Life, Oxford University Press 2012 pg. 87

The Brainstem

The brainstem is a small but most important centre in the brain. It serves as a central relay station between the spinal cord, cerebellum, cerebrum, and the rest of the body it is intricately involved in functions ranging from motor control, sensorimotor integration, and regulation of autonomic functions to consciousness and attention.[77] It comprises of the midbrain, pons, and medulla.

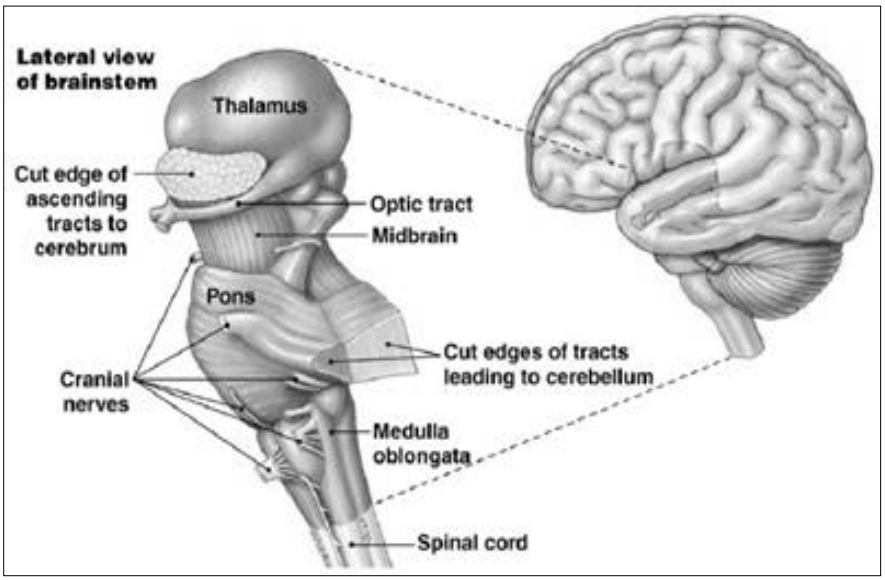

Figure 2: A lateral view of the brainstem[78]

The midbrain controls eye movement, pupil dilatation, and the moves of the human body. It also controls hearing function. The pons is involved with processes like eye movement, facial mimics, and saliva secretion. It also has a role in establishing sleep patterns along with the hypothalamus, which in turn establishes the circadian rhythm. Finally, the medulla, controls the most important autonomic functions, such as breathing, the heartbeat, and the heart rate, but also the blood pressure. Also, the medulla has within the centres for the

[77] John Rothwell, Neurophysiology of the brainstem-structure and function of brainstem circuits, Clinical Neurophysiology, 123:1 Jan 2012 p 2-3

[78] Figure 2. A lateral view of the brainstem, taken from http://cerebrumfunction.net/what-is-the-brainstem (Accessed 6th February 2014)

cardiac functions, for respiratory system, and vasomotor function. The medulla also contains reflex centres for actions like vomiting, sneezing, swallowing, and coughing.[79,80]

Although the concept of brainstem testing is endorsed by the Royal Colleges and the Department of Health, some in the medical profession believe that death should be determined by whole brain death in a similar practice to the one used in the USA. But what is the difference between the brain death criteria that are used?

2.4.2 The different criterion for brain death

Whole-brain death is the criterion to describe the irreversible cessation of all measurable clinical brain functions, including those executed by the brainstem, diencephalon, thalamus, and cerebral hemispheres.[81] This in turn equates to the irreversible cessation of the critical functions of the organism as a whole. In their recent report, the President's Council on Bioethics[82] accepted the coherence of the formulation of whole-brain death. Despite what its name suggests, the whole-brain criterion does not require the irreversible cessation of the functioning of every brain neuron. Some brain cellular activities such as random electroencephalographic (EEG) activity, may remain recordable after brain death.[83]

The brainstem death concept has mainly been argued for in the UK, but it is also used in Canada and India,[84] it is the inverse of higher-brain formulation because it requires only permanent cessation of brainstem functions and is unaffected by the presence or absence

[79] Christopher Pallis, *ABC of Brainstem Death*, 2nd Edition London: British Medical Journal Publishing Group, 1996
[80] Andrew Johnston, Basil Matta, *Brainstem Death*, Surgery (Oxford): Critical Illness and intensive care, 25:3 March 2007. p 134-137
[81] James L Bernat, The definition and criterion of death, Chapter 33, Handbook of Clinical Neurology, Vol. 118 (3rd series) Ethical and Legal Issues in Neurology, JL Bernat and R Beresford, Editors 2013
[82] President's Council on Bioethics (2009) Controversies in the Determination of Death: A White Paper by the President's Council on Bioethics. Washington, DC
[83] Madeleine M. Grigg, Michael A. Kelly, Gastone G. Celesia, Mona W. Ghobrial, Emanuel R. Ross, Electroencephalographic Activity After Brain Death. *Archives of Neurology* 1987;44(9):948–954.
[84] L. Syd M Johnson, *Death by neurological criteria: expert definitions and lay misgivings*, QJM: An International Journal of Medicine, Volume 110, Issue 5, 1 May 2017, Pages 265

of hemispheric functions. It has been described that once the brainstem is destroyed loss of the capacity to breathe or control circulation, and ablated conscious awareness occurs. The late neurologist Christopher Pallis[85] was the leading scholar proposing and defending the use of the brainstem criterion. He advocated the role of brainstem death in brain death and said that "the irreversible cessation of brainstem function implies the death of the brain as a whole."[86] Some have argued that brainstem death entails a lower burden of proof compared to whole-brain death therefore, a patient who is diagnosed via the brainstem criterion could potentially still be alive.[70,87] The Academy of Medical Royal Colleges and the Royal College of Paediatrics and Child Health, now recommend that the terms 'brain death' and 'brainstem death' are not used when physicians talk to families. On the Organ, Donation and Transplantation Clinic (ODT Clinic) website it states that: "We would encourage all healthcare professionals to use the terms 'diagnosis of death using neurological criteria' or 'diagnosis death by neurological criteria' instead, and when talking to families, simply, the 'diagnosis of death'."[88]

The final criterion to be used is the higher-brain criterion of death. This the earliest alternative formulation accepted the concept of brain death but argued that the appropriate criterion should not be cessation of clinical functions of the entire brain but only those of the cerebral hemispheres. This was because these areas controlled the characteristics that distinguish humans from other species. The founder of this criterion Robert Veatch, claimed that death should be defined uniquely for human beings as "irreversible loss of that which is considered to be essentially significant to the nature of man."[89] He denies that death can be defined biologically, and argues that the loss of

[85] Pallis (n 79)
[86] Pallis (n 79)
[87] Michael Souter, Gail Van Norman, *Ethical controversies at end of life after traumatic brain injury: Defining death and organ donation,* Critical Care Medicine, 2010 38:9
[88] Diagnosing death using neurological criteria, An educational tool for healthcare professionals, https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donation-after-brainstem-death/diagnosing-death-using-neurological-criteria/ (visited 16th August 2020)
[89] Robert M Veatch, The whole-brain-oriented concept of death: an outmoded philosophical formulation. *Journal of Thanatol*ogy 1975;3(1):13-30.

personhood is morally relevant for it signals the loss of moral standing, and appropriately precipitates death-related activities.[90]

Despite over three decades of scholarly articles endorsing the higher-brain criterion, it has not received enough support to change or for it to be incorporated into legislation in any jurisdiction. Plus, no physicians or medical societies in any country practice or permit it.[91] An explanation for this is that the higher brain death concept alone could create a serious slippery slope problem, during which the criterion for death becomes indistinct. If patients in persistent vegetative states were considered dead because they fit the criteria for higher brain death, then perhaps so should severely brain-damaged patients because they too lack experiential and social integrating functions.

2.4.3 Problems with the Brain Death Criterion

From when it was first conceptualised brain death has been and to a certain extent still is a very controversial subject. One of the main contentious being how the criterion was developed in the first place, it has been argued that some of the panel on the Ad Hoc Committee had a reason as to why brain death should equate to the death of the patient. Byrne and Weaver are strongly critical of the committee they have said:

"Brain death" was not propagated via a medical scientific method. A committee of experts was convened to deal with the issues that could affect the disposition and/or utilisation of these patients. The first words of the "Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death" … are as follows: "Our primary purpose is to define irreversible coma as a new criterion for death."

[90] Robert Veatch, The death of whole-brain death: the plague of the disaggregators, somaticists, and mentalists, Journal of American Medical Philosophy 2005; 30:353-78

[91] James L Bernat, The definition and criterion of death, Chapter 33, Handbook of Clinical Neurology, Vol. 118 (3rd series) Ethical and Legal Issues in Neurology, James L Bernat and Richard Beresford, Editors 2013

In other words, the primary purpose of the Committee was not to determine 'If' irreversible coma was an appropriate criterion for death but *to see to it* that *'*It was' established as a "new criterion for death." With an agenda like that at the outset, the data could be made to fit the already concluded. It seems that there was a serious lack of scientific methods in this process.[92]

Shewmon who was once a staunch supporter of brain death has a different viewpoint now; he has stated that:

"The integrative functions of the brain, important as they are for health and mental activity, are not strictly necessary for, much less constitute, the life of the organism as a whole. Somatic integration is not localized to any single 'critical' organ but is a holistic phenomenon involving the mutual interaction of all the parts. Under ordinary circumstances, the brain participates intimately and importantly in this mutual interaction, but it is not a sine qua non; the body without brain function is surely very sick and disabled, but not dead." [93]

Another critical point of the brain death criterion is that it has never been open to public debate. At the time, and even now the subject is only debated by a select group of physicians and bioethicists who have then gone onto and still make normative judgments about a fundamental moral issue involving life, death, and the value of biologically living human beings at the end of life. They then go on to present this judgement as a medical fact that no one outside the medical community has the expertise or authority to challenge, [94] as the following statement from a Wijdicks article suggests:

[92] Paul A Byrne, Walt F., "Brain Death' Is not Death," in C. Machado and D.A., Shewmon, eds., *Brain Death and Disorders of Consciousness* (New York: Springer, 2004): 43-49, at 43

[93] Alan Shewmon, *The brain and somatic integration: insights into the standard biological rationale for equating "brain death" with death***,** The Journal of Medicine and Philosophy 2001 26:457–78.

[94] Michael Nair-Collins, Death, Brain Death, and the Limits of Science: Why the Whole-Brain Concept of Death Is a Flawed Public Policy, *Journal of Law Medical Ethics*. 2010;38(3):667-683.

"Generally, the diagnosis of brain death is not a legal, but a medical, matter. For the courts, a person is brain-dead when the physician says so and uses current standards."[95]

These criticisms of the process by which the definition/diagnosis of death was decided are still relevant today, we have a definition/diagnosis defined by a committee that sets out the question and answer with little to no external input. The subject of death is a very public one with many factors that can influence a person's perspective on it, yet the decision on how we define/diagnose death was made by relatively few people who had a vested interest in the outcome. There needs to be a broad interaction making it more morally and democratically accountable. Why is it just medics who make the decisions, why can it not include ethicists, theologists, and lay people to discuss death in its broadest sense to include several concepts, rather than a team to set tests? Medical dominance on how we define death is still seen today with death being defined by medical colleges, not legislation.

The brainstem criterion is not without its critics too, some feel the UK's use of the brainstem criterion has a principal weakness by which not requiring the absence of cerebral hemispheric function, it allows for false-positive determination in those cases in which retained awareness cannot be excluded. The main concern for this is loss of brainstem function only, resulting in irreversible loss of consciousness and irreversible loss of spontaneous breathing, while other brain functions may continue.

From a religious viewpoint, the Catholic Church feels that the UK and the Republic of Ireland's standard for diagnosing death via a neurological criterion (brainstem death) does not meet the standards specified by Pope John Paul II who stated that there should be loss of all brain function. [96] Rady and Verheijde have argued that some religions do not accept brain death as a diagnosis of death, they point out that the Quran explicitly distinguished

[95] Eelco F.M. Wijdicks, Chapter 16 Brain Death, Handbook of Clinical Neurology, vol 118 (3rd series) Ethical and Legal Issues in Neurology, James L Bernat, Richard Beresford.
[96] On the Ethics of Organ Transplantation: A Catholic Perspective- The report of a working party The Anscombe Bioethics Centre 2014

between the dying process and death, with the latter being biological disintegration that occurs after the dying process is complete. This means that by accepting brain death as a diagnosis of death directly conflicts with the Quran.[97] In a later publication Rady, Verheijde, and Potts[98] summarise that "it is well known that empirical knowledge from contemporary neuroscience challenges the validity of death determined with a neurologic criterion". They discuss the philosophical, legal, and religious implications of a faulty death determination in clinical practice and conclude that "Abrahamic faith traditions (Judaism, Christianity, and Islam) acceptability of the concept brain death was conditioned upon (1) equivalency with biological death, (2) clinical determination with scientifically verifiable criteria and tests, and (3) alignment with the theological definition of death, the separation of the soul from the human body. With current standards for brain death determination failing to meet these conditions, it raises serious moral questions for organ donation practice." Therefore, they suggest, like many other critics of the brain death criteria, that new legislation should be enacted ratifying religious exemption to death determination by neurologic criteria.[99]

There are many ethical concerns about the definition of death, testing, and the administration of therapies to the potential organ donor that may hasten death.[100] This is one reason why it has been argued by some commentators that testing for the brain death criterion should require informed consent. The main reason for this suggestion is that current and past literature shows that apnoea testing can be associated with serious complications, including hemodynamic instability, tension pneumothorax, pneumomediastinum, cardiac arrhythmias, and cardiac arrest, among others. These results could suggest that the tests used to diagnose death actually cause or speed up death. Every set of criteria for 'brain death' includes an apnoea test, considered the most important step in the diagnosis of brain death. The apnoea test looks for the absence of breathing in a patient. The ventilator is discontinued then the patient is observed over a

[97] Mohamed Y Rady, Joseph L Verheijde, A *response to the legitimacy of brain death in Islam*, Journal of Religion and Health, 2016

[98] Joseph L Verheijde, Mohamed Y Rady, Michael Potts, Neuroscience and Brain Death Controversies: The Elephant in the Room. Journal Religion and Health. 2018;57(5):1745-1763.

[99] This could be similar to the ones in place in New Jersey and New York State in the USA.

[100] Bethany Speilman, Cynthia Simmons McCarthy, *Beyond Pittsburgh: Protocols for controlled non-heart-beating cadaver organ recovery*, Kennedy Institute of Ethics Journal, 1995 5:323-333

period of time to determine if they can breathe unaided. If they are unable to breathe on their own, then the physician will declare 'brain death'. In addition to the risk of complications that may result in immediate harm to the patient, the apnoea test may confer a more insidious risk, that is, the risk associated with an acute rise in partial pressure of carbon dioxide and consequent cardiovascular changes, which may result in a further rise in intracranial pressure. Roth and colleagues[101] recently studied 16 apnoea tests in 13 patients. The authors found a significant increase in intracranial pressure during the testing. Such elevation is an important marker of secondary brain injury in patients who have suffered neurologic insults. More significantly however, is the fact that changes in the cerebral hemodynamics and hydrodynamics may not result in an immediately recognised complication but could cause secondary injury such that patients who do not meet the criteria for brain death on initial testing might subsequently be made brain dead as a result of the testing. Dr Yoshio Watenabe, a cardiologist from Natoya, Japan, stated that "if patients were not subjected to the apnoea test, they could have a 60 percent chance of recovery to normal life if treated with timely therapeutic hypothermia (cooling of the body)".[102]

With the knowledge that the tests carried out aggravate the patient's condition and are commonly done without the knowledge or consent of family members, and since tests are performed before it is known that the patient is brain dead, there is a genuine argument to suggest informed consent should be sort before carrying out the tests.[103] On the flip side of this argument, because both death by cardiopulmonary criteria and death by neurologic criteria are treated equally under the law, both determinations should be handled the same way by physicians who are making determinations of death.[104] As such, because consent is

[101] Christian Roth, Wolfgang Deinsberger, Jens Kleffmann, Andreas Ferbert, Intracranial pressure, and cerebral perfusion pressure during apnoea testing for the diagnosis of brain death: an observational study, European Journal of Neurology, 22 (8) (2015), pp. 1208-1214

[102] Ari R. Joffe, critical care physician, Stollery Children's Hospital, University of Alberta, e-letter to J.R. Cuo *et al.* Time dependent validity in the diagnosis of brain death using transcranial Doppler. *Journal of. Neurology and Neurosurgery Psychiatry.* 2006; 77: 646-649

[103] Robert D. Truog, Robert C. Tasker, COUNTERPOINT: Should Informed Consent Be Required for Apnoea Testing in Patients with Suspected Brain Death? Yes, Chest, Volume 152, Issue 4, 2017, Pages 702-704

[104] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death*. Washington, D.C.: U.S. Government Publishing Office; 1981.

not required for the determination of cardiopulmonary death, it should not be required for the determination of brain death.

A prominent critic of the use of brain death was Hans Jonas[105] who accused this definition of death of understanding the human body as a mere material object, forgetting that the human body should be seen and understood as the organism of a living person. He has criticised the Harvard Committee's definition of death as motivated by its desire to ensure sufficient organ availability. Jonas does not accept redefining death as brain death to declare a patient dead, while the body is still living, to retrieve the organs for transplant. He challenges the utilitarian principle of using one person to serve a great good, pointing out our lack of knowledge regarding life and death and the boundary between them. He prefers to err on the side of life, keeping respect for individual life as an unwavering principle in the face of the perhaps compelling desire to use the brain-dead patient's body as a living corpse that can provide organs to others in need. Thus, for Jonas, total brain failure does not represent death, but merely a state in which it was thought to be appropriate to let death occur by removing life-sustaining support and allowing the functions of the heart and lungs to cease. He states that:

"Now my point is a very simple one. It is this. We do not know with certainty the borderline between life and death, and a definition cannot substitute for knowledge. Moreover, we have sufficient grounds for suspecting that the artificially supported condition of the comatose patient may still be one of life, however reduced- i.e., for doubting that, even with the brain function gone, he is completely dead. In this marginal ignorance and doubt the only course to take is to lean over backward toward the side of possible life. It follows that interventions, as I described, should be performed on a par with vivisection and on no account be performed on a human body equivocal or threshold condition. And the definition that allows them, by stamping as unequivocal what at best is equivocal, must be rejected. But mere rejection in discourse is not enough. Given the pressure of the – very

[105] Hans Jonas, *Philosophical essays: from ancient creed to technological man*. Englewood Cliffs, NJ: Prentice-Hall; 1974.

real and very worthy- medical interests, it can be predicted that the permission it implies in theory will be irresistible in practice, once the definition is installed in official authority. It's becoming so installed must therefore be resisted at all costs."[106]

Jonas's views highlight the uncertainty between the advancements in medical technology and the knowledge we have about life and death. He questions what is meant by brain death and whether can it ever be a true diagnosis of death, and with this in mind feels that when medics are treating patients who are in that fragile state of life, they are exactly that, alive and should be treated as such. They should not be seen as a commodity to fulfil the need for suitable organs for transplantation.

The philosopher Peter Singer has described the brain death criteria as "a concept so desirable in its consequences that it is unthinkable to give up, and so shaky on its foundations that it can scarcely be supported." The new death was "an ethical choice masquerading as a medical fact,"[107] he has written:

"Legal ambiguities remained—people considered alive in one region of the country could be declared dead in another—and, in 1981, the President's Commission for the Study of Ethical Problems proposed a uniform definition and theory of death. Its report, which was endorsed by the American Medical Association, stated that death is the moment when the body stops operating as an 'integrated whole'. Even if life continues in individual organs and cells, the person is no longer alive, because the functioning organs are merely a collection of artificially maintained subsystems that will inevitably disintegrate."[108]

It is not just individuals who have concerns about the brain death criterion, some countries find it hard to accept any form of brain death criterion. For example, in 1968 in Japan, a

[106] ibid 132-140
[107] Peter Singer, (1995). Rethinking Life & Death the Collapse of Our Traditional Ethics, Oxford University Press.
[108] ibid

surgeon who performed the first heart transplant using a donor heart from a brain-dead donor was charged with murder.[109] It was not until 1997 that brain death was recognised in Japan and only then it is when the patient has specified that they wished to be an organ donor and that the family do not want to overrule their decision. Only when these two conditions are met will a brain-dead patient be considered legally dead for the purposes of an organ transplant.[110]

Another problem that has been suggested is that as with many medical diagnostic tests, there are fears that there may be a misdiagnosis of death. This may have been the case in the past, but as medical advancements allowing for better diagnosis of death have been made, surely misdiagnosis has become less frequent too. But that is not to say that it does not happen, for instance, a patient suffering from locked-in syndrome could possibly be misdiagnosed as brain death.[111] Locked-in syndrome is usually a consequence of the destruction of the base of the pons which is situated in the brainstem. The patient cannot move the limbs, grimace, or swallow, but the upper rostral mesencephalic structures involved in voluntary blinking and vertical eye movements remain intact. Consciousness persists because the tegmentum, with the reticular formation, is not affected. The condition is most often caused by an acute embolus to the basilar artery which supplies the brain with oxygen-rich blood.[112] But more dramatic is the reversible Guillain–Barré Syndrome (GBS) is a disorder in which the body's immune system attacks parts of the peripheral and cranial nervous system. The progression occurs over a period of days, the first symptoms of this disorder include varying degrees of weakness or tingling sensations in the legs. In many instances, the symmetrical weakness and abnormal sensations spread to the arms and upper body. These symptoms can increase in intensity until certain muscles cannot be used at all and, when severe, the person is almost totally paralysed. In these cases, the disorder is life-threatening potentially interfering with breathing and, at times, with blood pressure or

[109] Emily Jackson, *Medical Law: Text, Cases and Materials*, Oxford University Press, 2nd Edition 2010
[110] ibid
[111] James R Patterson, Martin Grabois, *Locked-in syndrome: a review of 139 cases*. Stroke 1986; 17:758-764
[112] ibid

heart rate but a knowledge of the history of the patient should prevent the dangerous error of diagnosing brain death.[113]

But the question remains, can a person who has been diagnosed as brain-dead be truly dead when it can be clearly seen that there are still some lifelike events occurring, even after a person's brain appears to have lost the ability to totally function? There is growing empirical evidence that suggests total brain failure is not enough for human death, the challenge to the brain death criterion is that many of the body's integrative functions are not mediated by the brain and can therefore persist in individuals who meet the criteria for death by standard clinical tests. The human body is a biological organism, with billions of cells, most of which can continue to live in some way after total brain death.[114] The heart may well continue to beat for as long as twenty minutes after a ventilator is removed from a person whose brain has totally ceased to function. Sperm live on and can be harvested for up to forty-eight hours after the declaration of death. Continued muscle reflexes may cause a corpse's hand to twitch or an eye to wink. The stomach can continue to digest. Hormone secretion and regulation of body temperature may continue, and wound healing, fighting of infections, and cardiovascular and hormonal stress responses to unanaesthetised incisions (for organ procurement) can occur. It is also possible for a brain-dead pregnant woman to continue the gestation of their foetus and give birth and in a few brain-dead patients, there has been evidence of reaching sexual maturity or growth in size with the help of continuing ventilator maintenance. [115,116]

It has been argued that most brain functions commonly cited as integrative merely sustain an existing functional integration, suggesting that the brain is more an enhancer than an indispensable integrator of bodily functions.[117] Moreover, several studies have

[113] Harriet Kotsoris, L Schleifer, M Menken, Fred Plum, *Total locked-in state resembling brain death in Polyneuropathy,* Annals of Neurology, 1984;16:150-150
[114] Norman L Cantor, *After We Die: The Life and Times of the Human Cadaver*, Washington, DC, USA: Georgetown University Press, 2010.
[115]Alan Shewmon, 2001, "The Brain and Somatic Integration: Insights into the Standard Biological Rationale for Equating 'Brain Death' with Death," *Journal of Medicine and Philosophy*, 26: 457–78.
[116] Michael Potts, 2001, "A Requiem for Whole Brain Death," *Journal of Medicine and Philosophy*, 26: 479–92.
[117] Shewmon (n 115)

demonstrated that most patients diagnosed as brain dead continue to exhibit some brain functions including the regulated secretion of vasopressin, a hormone critical to maintaining a body's balance of salt and fluid.[118] This hormonal regulation is a brain function that represents an integrated function of the organism as a whole.[119] Perhaps it is more accurate to say the current methods of testing suggest that functionality has been lost and potentially there may be some activity that cannot yet be registered with the current equipment being used. It is this continuing cellular, hormonal, and electrical functions after total cessation of brain function that has prompted some bioethicists and philosophers to question whether total brain death is an accurate alternative definition of death.[120]

The continuing uncertainty of brain death has been highlighted again in recent years with the case in the United States of Jahi McMath.[121] In 2013 a thirteen-year-old girl went to the hospital for an operation to have her tonsils removed, there were post-operative problems that led to her being declared brain dead two days later after failing a series of tests. Her pupils did not react to light, she did not have a gag reflex, and her eyes remained still when ice water was dripped in each ear. She was briefly disconnected from the ventilator, as a test, but her lungs filled with carbon dioxide. On an EEG test, no brain-wave activity could be seen. The hospital wanted to start withdrawing life-sustaining treatment, but the family refused to accept that their daughter had died so sought legal representation to force the hospital to continue treatment, on the grounds that the hospital was infringing on the mother's right to express her religion. Her lawyer argued that, as a Christian, she believed that her daughter's soul inhabited her body as long as her was heart beating.

After several weeks of discussions and court appearances, the family lawyer and hospital representative reached an agreement, that the hospital would release the girl's body to the

[118] Amir Halevy, Baruch Brody, 1993, "Brain Death: Reconciling Definitions, Criteria, and Tests," *Annals of Internal Medicine*, 119: 519–25.
[119] Franklin G Miller, Robert D. Truog, 2010, "Decapitation and the Definition of Death," *Journal of Medical Ethics*, 36: 1–6.
[120] Norman L Cantor, *After We Die: The Life and Times of the Human Cadaver*, Washington, DC, USA: Georgetown University Press, 2010. p 20
[121] *Winkfield v. Children's Hospital Oakland et al.* Case No: C 13-5993 In: California Northern District Court Oakland Division

Alameda County coroner, who would declare her dead. Then the family would become "wholly and exclusively responsible" for her. This occurred on the 3rd of January 2014, the coroner issued a death certificate citing that the cause of death was pending an investigation. Two days later she was moved from California to a hospital in the State of New Jersey, where they performed a tracheotomy and inserted a feeding tube, which provided nutrition and vitamins. This of course has caused some bioethicists to speak out, Arthur Caplan has written that: "Keeping her on a ventilator amounts to desecration of a body"[122] He has also stated, "There isn't any likelihood that she's gonna survive very long and that, you can't really feed a corpse, she is going to start to decompose."[123]

In 2017 more than four years after she was declared dead in California, Jahi was on a ventilator, being fed through a tube and is provided with supplementary hormones. She continued to grow and even progressed through puberty, so can this 'patient' really be seen as dead? Following a test in 2014 it was shown on an MRI scan that her brainstem was damaged but large areas of her cerebrum, which mediates consciousness, language, and voluntary movements, were structurally intact. In 2015 a report was submitted by three medics and Shewmon,[124] that stated, "With the passage of time, her brain has recovered the ability to generate electrical activity, in parallel with its recovery of ability to respond to commands." they described her as "an extremely disabled but very much alive teenage girl." On 22nd of June 2018 it was announced that Jahi had died,[125] a preliminary second death certificate stated that she had died from extensive bleeding related to liver failure. Little is known about her later condition as no information has been published so it remains uncertain as to the state of her brain activity and her ability to function at the time of her death.

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[122] Arthur Caplan, *The case against care for those who are brain dead, https://www.newsday.com/opinion/oped/caplan-the-case-against-care-for-those-who-are-brain-dead-1.6767446,* January 2014 (Accessed 10th May 2018)

[123] https://www.usatoday.com/story/news/nation/2014/01/09/ethicists-criticize-treatment-brain-dead-patients/4394173/

[124] Alan Shewmon was the chief of the neurology department at Olive View-U.C.L.A. Medical Centre and a leading writer on the issue of Brain death diagnosis.

[125] [The Washington Post] Jahi McMath, the Calif. girl in life-support controversy, is now dead. https://www.washingtonpost.com/news/morning-mix/wp/2018/06/29/jahi-mcmath-the-calif-girl-declared-brain-dead-4-years-ago-is-taken-off-life-support/ (accessed website 12th August 2020)

This case does not appear to be unique, there has been a report of a child[126] who regained consciousness moments before their life support was due to be switched off after being declared brain dead following a severe head injury. Does the above just show that if you declare someone brain dead and then remove their ventilation, then of course they are going to die, or is it something much worse? The brain death criterion is described as the irreversible loss of function of the brain. Therefore, if the brain function was not irreversibly lost then what allows them to be defined as such (the interpretation of the tests or the tests themselves) is manifestly wrong? Or perhaps these patients have been misdiagnosed as brain dead when in fact they may well have been suffering from another condition, such as Locked-in syndrome, Guillain–Barré Syndrome (GBS), or ischemic penumbra, which is what Shewmon suggested Jahi could have been suffering from. Ischemic penumbra is a brain state that may lead to a misdiagnosis of brain death in patients whose cerebral blood flow was diminished enough that it could not be detected by the standard tests. Ischemic penumbra has been defined in a variety of ways, but the most clinically relevant definition is that portion of the ischemic territory that is still potentially salvageable if appropriate treatment is given. In other words, if blood was still flowing to parts of the brain, however slowly, then, in theory, some degree of recovery could be possible if appropriate treatment is given.

A recent case in the English family courts saw the family of Archie Battersbee finally lose their battle to prevent his mechanical ventilation from being switched off[127] after initially winning the right to appeal the ruling on their case on the grounds that evidence had not shown beyond reasonable doubt that Archie was dead and that religious views were not considered. The initial ruling from the family court was it was not in the third respondent's (Archie) best interests for him to continue medical treatment in the form of mechanical ventilation.[128] It was argued in the appeal hearing that the original ruling that Archie on the balance of probabilities he had died was wrong. The judgement was made on an MRI scan and not using standard brainstem tests, and the family believed that this was the first case

[126] http://www.bbc.co.uk/news/av/world-us-canada-44048189/boy-wakes-up-just-before-his-life-support-was-to-end (8th May 2018 BBC News website)
[127] Archie Battersbee had his life support switched off in accordance with the ruling of the Court of Appeal.
[128] *Bart's Health NHS Trust v Dance and Others* [2022] EWHC 1435 (FAM)

that someone was declared "likely" to be dead based on an MRI scan. This occurred as the hospital was unable to administer the approved brainstem test for neurological death, therefore it was argued that the brainstem definition of death should not have been applied. The family and their legal team argued that the medical expert opinion presented in court was clear in that the whole concept of brain death had been now discredited, and in any event, Archie could not be reliably diagnosed as braindead. They suggested that by declaring Archie dead meant the court had extended the common law definition to brainstem dead and because no brainstem testing was carried out the court should have started from a presumption that a person was alive. The family also argued that the Hospital and the Judge in the original hearing had failed to consider the wishes of the family, that they want Archie to die naturally in accordance with their Christian faith.

The most concerning point, in this case, is the fact that the courts decided that it was not in Archie's best interests to continue medical treatment in the form of mechanical ventilation and the ancillary care that accompanies the ventilation, even though no formal brainstem tests were carried out. Archie may have been gravely ill and possibly in the process of dying but from the evidence given brainstem death should not have been presumed. With someone's life at stake why is it the starting point of death, should we not err on the side of caution and protect life no matter how fragile it is? This point was discussed during the appeal hearing where the appeal the Court of Appeal concluded that such an approach was wrong in law. Hayden J was also critical of Arbuthnot J's judgment: It strikes me that it is also wrong, clinically. The law and good medical practice will rarely, if ever, diverge. Ascertaining death requires the application of clear clinical guidelines. Where they are not met, brain stem death cannot be identified with the certainty that such a conclusion requires.[129]

The family and their legal team also argued that the decision to end Archie's LST would breach his human rights. After all, Art. 10 of the UN Convention on the Rights of Persons with Disabilities reaffirms that every human being has the inherent right to life and shall

[129] *Dance & Others v Barts Health NHS Trust (Re Archie Battersbee)* [2022] EWFC 80, [2].

take all necessary measures to ensure its effective enjoyment by persons with disabilities on an equal basis with others. At this stage because there was no conclusive evidence that Archie was brain dead surely, he should have been seen as severely disabled and therefore be protected under Art. 10. There is also Art. 6 of the UN Convention of Rights of the Child that states, parties recognise that every child has the inherent right to life and that parties shall ensure to the maximum extent possible the survival and development of the child. Yet despite the arguments and evidence put forward by the family and their legal team, the courts did not agree with them and made the decision to remove Archie's life support.

Reports and cases like these no matter how rare they are should have repercussions on the whole scenario of diagnosing death via the brain death/brainstem criterion. Death is supposed to mean irreversible loss of brain function, if it can be shown that there is a brain function, then can we truly say that the patient is actually brain/brainstem dead? Reasons suggested for the misdiagnosis of the brain death criterion could be the fact that there is no continuity amongst the medical community within the same country let alone different countries. Of greater worry is that misdiagnosis could be down to the competence of the physician, and it is for this reason that Bernat has great cause for concern. On the matter of misdiagnosis, he has said that:

"Of greater concern, empirical studies of the adequacy of physicians' bedside testing for brain death, including apnoea testing, have shown unfortunate and widespread variability in performing the tests properly and recording the results completely… These discouraging findings suggest the disquieting implication that some physicians probably are declaring patients dead using brain tests when the patients may not be dead. This inaccuracy suggests the need for better standardisation of brain death testing and adequate training to assure that testing is performed and recorded properly."[130]

[130] James L Bernat, (2008) Brain Death Chapter 12 at 158 in The Neurology of Consciousness, p.151-162, edited by Steven Laureys, Giulio Tononi, Elsevier Science & Technology

Even though it has been shown that there are weaknesses in the whole-brain formulation, these arguments have not swayed the majority of scholars, medical professionals, or the public who experience a conceptual and intuitive attraction to the whole-brain formulation and find it sufficiently coherent and useful to wish to preserve it as public policy.[131] Arguments against whole-brain death challenge the assumption that all functions of the entire brain must be lost for someone to be declared dead. Some are against the idea of the brain death criteria as they feel this criterion was created in response to the growing development of transplant medicine. Another approach attacks the premise by defending the traditional biological definition of death associated with circulatory and respiratory function. Even now there are arguments against the brain death criteria; many critics state that brain death never has been the equivalent of human death, that we should stop pretending that it is, and return to a traditional criterion of death requiring permanent cessation of circulation. The critics argue that patients currently declared brain dead may be dying and hopelessly ill, but they are not dead. Not until their circulation ceases irreversibly are such patients dead,[132] this traditional view of defining death with the acceptance of the DDR has led to some liberal thinkers concluding that organs may not be procured from living people with dead brains, thus potentially eliminating a major source of organs for transplantation.[133]

2.5 A critical analysis of the circulatory approach to death

This leads us back to the traditional cardiopulmonary or circulatory criterion of death, which according to supporters of neurologically centred standards for determining death is no different as circulatory and respiratory functions are merely an indirect method of testing

[131] James L Bernat, (2006) The whole brain concept of death remains optimum public policy, Journal of Law and Medical Ethics 34: 35-43

[132] James L Bernat, *A Defence of the Whole-Brain Concept of Death*, Hastings Centre Report, 28, no. 2 (1998): 14-23

[133] Alan Shewmon, 2001. The brain and somatic integration: Insights into the standard biological rationale for equating 'brain death' with death, Journal of Medicine, and philosophy 26: 457-78
The minority position from the US President's Council, 2008- President's Council on Bioethics, 2008 Controversies in the Determination of Death: A White Paper by the President's Council on Bioethics. Washington, DC 52-58

for the absence of brain function.[134] Alan Shewmon has rigorously championed a position that has completely rejected a brain-based concept of death in favour of one based on the cessation of systemic circulation. This is interesting as Shewmon was once one of the staunchest defenders of brain death, he changed his viewpoint because of the influence of the writings of Josef Seifert.[135]

The circulatory criterion of death, states that a person is dead if the function of the circulatory system has irreversibly ceased. The circulatory system along with the respiratory system provides oxygenated blood to muscles and organs while also removing carbon dioxide from the body. Oxygenated blood from the lungs arrives through the pulmonary vein to the left atrium. It passes into the left ventricle through the mitral valve during atrial systole. During ventricular systole, this blood is pumped into the aorta to be circulated in the body through arteries, arterioles, and capillaries. The exchange of materials occurs through the single-celled endothelial walls of capillaries. Deoxygenated blood from various tissues then returns to the right atrium of the heart through two major veins the superior and inferior vena cava. Once deoxygenated blood reaches the right ventricle through the tricuspid valve, it is pumped to the lungs during ventricular systole through the pulmonary artery. When the blood reaches the lungs, it passes through the alveoli where gas exchange happens. The contributions of these systems are crucial for life. If air is not taken in by the lungs, and if blood is not pumped by the heart, organs begin to die. It does not matter which function ceases first because the cessation of either will soon cause the cessation of the other. It is important to stress that irreversible cessation of circulatory functions is the criterion for death. Temporary cessation of circulatory functions does not mean the person is dead. Some cessations of pulse and breathing are reversible, although seldom after twenty minutes or so.[136]

[134] Franklin G Miller, Robert D, *Death, Dying, and Organ Transplantation; Reconstructing Medical Ethics at the End of Life*, 2012, Oxford University Press
[135] Josef Seifert, (1993) Is brain death actually death? A critique of redefinition of man's death in terms of 'brain death', Monist 76: 175-202
[136] Raymond J Devettere, *Practical Decision Making in Health Care Ethics: Cases and Concepts*, 3rd Edition 2009, Georgetown University Press

2.5.1 The development of Donation after Circulatory Death (DCD)

As with brain death diagnosis, there are different types, principally there are two types of DCD, controlled and uncontrolled. Uncontrolled DCD refers to the practice where organs are procured after a cardiac arrest that is unexpected and from which the patient cannot or should not be resuscitated. In contrast, controlled DCD takes place after death which follows the planned withdrawal of life-sustaining treatments. This usually happens when it has been decided that the continuation of treatment has no overall benefit to a critically ill patient. The clinical circumstances in which DCD can occur are described by the Maastricht classification, which has been modified over the years.

Type	Description
Uncontrolled Type I	Dead on arrival-this includes patients of sudden death, traumatic or not, occurring outside a hospital setting, who have not been able to be resuscitated.
Uncontrolled Type II	Unsuccessful resuscitation includes patients who have had a cardiac arrest, and who have received CPR which has failed.
Controlled Type III	Awaiting cardiac including withdrawal of life-sustaining therapies is applied, as agreed on within the healthcare team and with the relatives or representatives of the patient.
Controlled Type IV	Cardiac arrest while brain-dead-includes patients who have a Cardiac arrest in the process of the determination of death by neurologic criteria.

Table 1. Maastricht Categories for Donors after Circulatory Death[138]

Table 1 shows the first descriptions that were decided upon during a workshop held in Maastricht in 1995, which then went on to be used worldwide over the past 15 years. In 2011 during a meeting in Madrid a Spanish national consensus proposed a "Modified

[138] Gauke Kootstra, Jan Wiillem H.C. Daemen, Arno P A Oomen, Categories of non-heart-beating donors Transplantation Proceedings, 27 (1995), pp. 2893-2894

Maastricht classification for DCD" in order to reflect the reality and experience of its country with type I and II donations.[139]

Type	Description
Uncontrolled Type I	Patient dead in an outside hospital setting-includes patient of sudden death, occurring outside a hospital setting, who have not been able to be resuscitated.
Uncontrolled Type II	Unsuccessful resuscitation-includes patients who have had a cardiac arrest, and CPR which has failed. II.a. Out-of-hospital Cardiac arrest occurs in the out-of-hospital setting and is attended by an extra-hospital emergency service that transfers the patient to the hospital with cardiac compression and ventilatory support. II.b. In-hospital Cardiac arrest occurs within the hospital, being attended by healthcare personnel with immediate initiation of CPR
Controlled Type III	Awaiting cardiac including withdrawal of life-sustaining therapies is applied, as agreed on within the healthcare team and with the relatives or representatives of the patient.
Controlled Type IV	Cardiac arrest while brain-dead-includes patients who have a Cardiac arrest in the process of the determination of death by neurologic criteria.

Table 2. Modified Maastricht Classification for Donors after Circulatory Death[140]

Table 2 shows the modifications that the Spanish proposed to take into account that they allow for cardiac support en route to a transplant centre, as Spain has a presumed consent system. The final modification to the Maastricht classification occurred in 2012 when the

[139] Donation after circulatory death in Spain: Current situation and recommendations. National Consensus Document (2012)
[140] Donation after circulatory death in Spain: Current situation and recommendations. National Consensus Document (2012)

Eurotransplant organisation officially recognised the process of organ donation after euthanasia in The Netherlands, Belgium, and Luxemburg. This modification became known as 'Controlled Type V', and this too can be split into two components; 5A. Medically assisted cardiocirculatory death in the ICU or ward, 5B. Medically assisted cardiocirculatory death in the operating room.

2.5.2 The different criteria for DCD

It has been recommended in the UK by both the Academy of Royal Medical Colleges and the Intensive Care Society[141] that death can be certified after a period of 5 minutes of continuous cardiorespiratory arrest. Up until the publication of this review there was no guidance for doctors in the UK on how to confirm death after a cardiorespiratory arrest.[142,143] One reason suggested for this is due to the fact that before the widespread introduction of the donor after circulatory determination of death (DCDD or DCD), there was less of a need for prescriptive criteria, as in practice there was no necessity to confirm death in such a time critical manner.[144] The UK review reflects what is recommended by the United States Institute of Medicine in a paper that was published in 2000,[145] although the authors of this paper acknowledge the fact that there is uncertainty and a lack of scientific evidence for this guidance.

Essential components for diagnosing death using circulatory criteria include an agreement that further resuscitation will not be attempted, a minimum observation period, and a prohibition against activities that might restore cerebral circulation. The observation time begins at the point in time when there is a loss of the circulation. The minimum acceptable duration for observation can vary, but it is usually between two and five minutes. In the UK,

[141] Department of Health and Academy for Royal Medical Colleges, *A Code of Practice for the Diagnosis of Death*, London: Department of Health and Academy for Royal Medical Colleges, 2007 www.aomrc.org.uk
[142] Gilbert R Park, Editorial: *Death and its diagnosis by doctors*, British Journal of Anaesthesia 2004; 92: 625–8
[143] Dale Gardiner, Sam Shemie, Alex Manara, Helen Opdam, *International Perspective on the Diagnosis of Death,* British Journal of Anaesthesia, 2012 108 (S1): i14–i28
[144] ibid
[145] US Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, Washington DC National Academy Press 2000:22-24

Belgium, France, The Netherlands, Spain, and Canada the observation time or so-called no-touch time is five minutes. In the United States it can range from five minutes down to two minutes and more controversially it has been reported that death was certified, and organs were removed after waiting only seventy-five seconds.[146] Australia has a similar rule to the US where the no-touch time is no less than two minutes and no more than five minutes. Austria, Czech Republic, and Switzerland have a time of ten minutes, and since 2016 so has Portugal.[147] In Latvia, the no-touch time is fifteen minutes, while Italy has a no-touch time of twenty minutes, and organs can only be taken from uncontrolled DCD.[148] The practice of DCD is forbidden by law in Finland, Finnish law states that a person is dead when his brain activity has ceased. For this reason, "only a braindead person can be an organ donor."[149] In Poland, Polish law does not provide for donation from DCD category III. There are several legal barriers to that type of donation, including lack of precise regulation on withdrawal of life support, lack of a definition of the persistent therapy and regulation on its cessation, lack of clear distinction between end-of-life care and the persistent therapy, lack of clear distinction between cessation of the persistent therapy and euthanasia, and lack of positive standards on palliative care. Germany and Greece have no DCD activity since they have no legislation to permit it, therefore a no-touch time is irrelevant.[150]

The main issue related to this timing is the concern that there may be a spontaneous resumption of cardiac function sometime after the onset of apparently irreversible asystole; this is called the Lazarus phenomenon, which may result in a (partial) return of neurological

[146] Rob Stein, *Infant Transplant Procedure Ignites Debate*, Washington Post, 14th August 2008 http://articles.washingtonpost.com/2008-08-14/news/36802270_1_transplant-advocates-patient-brain-dead-donation-after-cardiac-death; Robert M Veatch, *Transplanting Hearts after Death Measured by Cardiac Criteria: The Challenge to the Dead Donor Rule*, Journal of Medicine and Philosophy 2010 35(3): 313-329

[147] Mar Lomero , Dale Gardiner , Elisabeth Coll, Bernadette Haase-Kromwijk, Francesco Procaccio, Franz Immer, Lyalya Gabbasova, Corine Antoine, Janis Jushinskis, Nessa Lynch, Stein Foss, Catarina Bolotinha, Tamar Ashkenazi, Luc Colenbie, Andreas Zuckermann, Miloš Adamec, Jarosław Czerwiński, Sonata Karčiauskaitė, Helena Ström, Marta López-Fraga, Beatriz Dominguez-Gil Donation after circulatory death today: an updated overview of the European landscape. Transplant International 2020, 33: 76-88.

[148] Paolo Bruzzone, *Ethical and Legal issues in donation after cardiac death in Italy*, Transplantation Proceedings, 42:4 2010 pp 1046-1047

[149] A person is considered to be dead when brain function has totally ceased. Chapter 7 S21 Definition of death No. 101/2001 Act on the Medical Use of Human Organs, Tissues and Cells

[150]Lomero (n 147)Corine AntoineNessa LynchCatarina Bolotinha

function.[151] In one review on this subject one case considered showed that there was a return of circulation which was not detected until 20 minutes after resuscitation was abandoned.[152] In another paper by Rodriguez et al.,[153] they studied patients who were resuscitated following an out-of-hospital cardiac arrest. In those who failed to respond to advanced life support, CPR was abandoned, and the patient was confirmed dead after 5 min of circulatory arrest. However, if a patient was considered suitable as a potential non-heart-beating organ donor, ventilation and chest compressions were continued, the latter either manually or using a mechanical device such as a LUCAS chest compression system, to maintain organ perfusion during transfer to the transplant centre. Three of the 48 patients who were entered into this uncontrolled non-heart-beating donation protocol had a return of spontaneous circulation during the transfer, one of whom went on to make a good neurological recovery. These three patients would have been declared dead at the scene had they not been considered suitable as potential organ donors.[154] Ironically, the fact that these three patients were considered good candidates for organ donors probably saved their lives.

A very rare and remarkable case of recovery after an extensive time of cardiac arrest was reported in 2019 by doctors at a hospital in Barcelona. The female British patient was revived after having had a six-hour cardiac arrest after developing hypothermia while hiking in the Catalan Pyrenees.[155] Once rescued during the doctor's first assessment, they could not find any vital signs using pre-hospital techniques. The patient had severe hypothermia and her body temperature had fallen to just 18^{o}C; normal body temperature is 37^{o}C. She was then taken by helicopter to a hospital in Barcelona, which has an Extracorporeal

[151] Paul Murphy, Alex Manara, D. Bell, Marz Smith, *Controlled non-heart beating organ donation: neither the whole solution nor a step too far*, Anaesthesia, 2008, 63:526-530; Wolfgang H Maleck, Swen N Piper, Johannes Triem, Joachim Boldt, Franz U Zittel, *Unexpected return of spontaneous circulation after cessation of resuscitation (Lazarus phenomenon)*, Resuscitation, 1998; 39: 125-8

[152] ibid

[153] Alonso Mateos-Rodríguez, Luis Pardillos-Ferrer, José María Navalpotro-Pascual, Carlos Barba-Alonso, María Eugenia Martin-Maldonado, Amado Andrés-Belmonte Kidney transplant function using organs from non-heart-beating donors maintained by mechanical chest compressions, Resuscitation (2010)

[154] ibid

[155] Doctors in Spain revive British woman after six-hour cardiac arrest, 5th Dec 2019 https://www.theguardian.com/world/2019/dec/05/doctors-in-spain-revive-british-woman-after-six-hour-cardiac-arrest (accessed 18th August 2020)

Membrane Oxygenation machine (ECMO). Once connected to ECMO the machine took over the function of the heart and lungs, oxygenating the blood outside the body then reintroducing it, allowing both organs to rest. When the patient's body temperature had risen to 30°C the doctors tried again to revive her, using a defibrillator, and it was successful. The medics who were treating her said that "while hers was the longest instance of cardiac arrest survival documented in Spain, similar cases had occurred in the Alps and Scandinavia".[156]

With regards to controlled DCD patients is there an argument to suggest that a no-touch time period is not needed as there is no intention to try and restart the circulatory system? That's not to say that the circulatory system has irreversibly ceased, it is more than likely down to the fact that the decision has been made not to attempt to restore it. So, the question has to be asked what is meant by irreversible, and are the legal/medical profession interpreting it in such a way that is beneficial to transplant programs?

2.6 The 'irreversible' argument

The Oxford English Dictionary's definition of irreversible is that something is not able to be undone or altered.[157] This has only become an issue with advancements in medicine. When the first transplants were conceived, cardiac resuscitation was still in its infancy and had not yet become widely established, and therefore a patient was considered dead when pronounced dead by simple cardiac criteria, reversibility was hardly ever considered. But as with the brain death criteria, advancements in medicine have changed this, can the loss of circulatory function be classified as irreversible if it is possible to restart the heart after some time by means of external stimulation? In this situation can it be true to say that cardiac arrest is irreversible if circulation can be restored but no resuscitation efforts are

[156] ibid
[157] The English Oxford Dictionary, http://oxforddictionaries.com/definition/irreversible

made, or is it only irreversible when circulatory function cannot be restored even if resuscitation efforts are undertaken? [158]

For example, in a controlled DCD situation, life-sustaining treatment would have been removed on grounds of futility so no attempts would be made to resuscitate the patient. In this case, is loss of circulatory function irreversible because it cannot be resorted, or is it because it will not be restored? Maybe a better definition would be to say that circulatory arrest is permanent because no efforts will be made to restore it, but some would say that this violates the DDR as you cannot simply say something is permanently lost just because no attempt has been made to restore it. The explanation and use of permanent in this context are not what the permanent is intended to mean, with the proper use of semantics irreversible loss means the same as permanent and both mean that the circulatory output cannot be restored rather than the choice has been made not to, which is the traditional requirement for declaring death.[159]

There is gathering support to change the term irreversible to something more suitable.[160] In the US there is still an ongoing debate about what 'irreversible' means, is it biologically cannot be reversed or legally cannot be reversed. From early on, the understanding was that the definition of death accepted the interpretation that circulation must be legally irreversible.[161] This distinction has recently been redefined to use irreversible to mean biologically irreversible, and permanent to mean that it will not be reversed because it will be illegal. [162]The application of criteria for organ donation after cardiac death becomes even more questionable since artificial circulatory and ventilatory support is sometimes resumed

[158]Gail A Van Norma, *Another Matter of Life and Death-What Every Anaesthesiologist Should Know about the Ethical, Legal and Policy Implications of NHB Cadaver Organ Donors*, Anaesthesiology, 2003:99, 736-73
[159] Jerry Menikoff, *The importance of being dead: non-heart-beating organ donation*, Issues in Law and Medicine, 2002 18:3-20; John G. Younger, Robert J. Schreiner, Fresca Swaniker, Ronald B. Hirschl, Robin A. Chapman, Extracorporeal *resuscitation of cardiac arrest*, Academy of Emergency Medicine, 1999 6:700-707
[160] James L Bernat, *The debate over death determination in DCD*, Hastings Centre Report, May-June 2010: 3; James L Bernat, *How auto-resuscitation impacts death determinations in organ donors*, *Critical Care Medicine* 2010;38:1377-1378
[161] John A Robertson, Policy issues in a non-heart-beating donor protocol. Kennedy Institute of Ethics Journal 1993 3:241-50
[162] Don Marquis, DCD donor's dead? The Hastings Centre Report, May-June, 2010 40: 24-31

after death in order to maintain the viability of abdominal and thoracic organs in potential donors.[163] Extracorporeal circulatory support is widely used in Spain and the Netherlands, where there is a well-organised system for ECMO-assisted DCD being utilised for Maastricht type II donors. Intravenous heparin is given as in the case of routine ECMO, and cannulas are placed in the femoral artery and vein on the same side. An aortic occlusion balloon is advanced up to the thoracic aorta through the other femoral artery and inflated. This ensures selective perfusion of abdominal viscera and excludes the heart and brain from circulation thereby preventing their reanimation. There are concerns from some who say that this procedure to preserve organs for transplantation can lead to the return of neurological function in people who were neurologically intact before cardiac death,[164,165] and that this could lead to the patient falling into a PV state.

Finally, it is now widely known that a patient whose heart has stopped beating for 15 minutes after cardiac arrest can recover if they are treated by cooling the body to 33ºC (this cooling albeit drastically cooling was one reason given as to why the British woman survived six hours after a cardiac arrest), cardio-pulmonary bypass, cardioplegia (stopping the heartbeat chemically) and a slow increase in oxygenation for 24 hours. Up to 80 percent of these patients can be discharged from the hospital, with 55 percent having a good neurological outcome. Clearly, the assumption made by physicians that a patient is dead five minutes after the heart has stopped beating is incorrect.[166] The counterargument for declaring a patient is dead after five minutes rests on the idea that patients who are potential organ donors tend to have catastrophic injuries which can drastically reduce their chances of survival. Therefore, this group of patients once they have their ventilation removed before transplantation are less likely to survive and would meet the criteria of declaring death after the five-minute no-touch period.

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[163] Institute of Medicine Committee on Non-Heart-Beating Transplantation. *The scientific and ethical basis for practice and protocols, executive summary.* Washington, (D.C.): National Academy Press, 2000.

[164] Joseph F Magliocca, John C Magee, Stephen A Rowe, Mark T Gravel, Richard H Chenault, Robert M Merion, Jeffrey D Punch, Robert H Bartlett, Mark R Hemmila Extracorporeal support for organ donation after cardiac death effectively expands the donor pool, The Journal of Trauma. 2005; 58:1095-1201

[165] John G. Younger, Robert J. Schreiner, Fresca Swaniker, Ronald B. Hirschl, Robin A. Chapman, Extracorporeal *resuscitation of cardiac arrest*, Academy of Emergency Medicine, 1999 6:700-707

[166]Myron L Weisfeldt, Lance B Becker "Resuscitation After Cardiac Arrest" A 3 – phase Time-Sensitive Model. *JAMA.* Dec. 18, 2002, vol. 288, no. 23, pp. 3035-8

DCD has been described as conflicting with utilitarian and altruistic values, confusing regarding the concepts of end-of-life organ donation and active euthanasia, there is suspicion regarding professional motivations and patient outcomes, there is also emotional ambiguity for the families of the loved ones facing withdrawal of life-sustaining care and finally uncertainty about the timing of declaration of death.[167] Some neurologists have raised concerns that DCD may represent an attempt to circumvent brain death criteria for the purposes of organ donation and may allow or even promote subjectivity in evaluations of prognosis and medical futility in neurologically impaired patients.[168]

While the philosophical debate on the definitions of life and death is extremely interesting and needed, there needs to be awareness of the practical problems the intensive care physician is confronted with. There is a need for an operational criterion to guide medics in their daily practice, and while the debate on life and death continues, they must make decisions based on the best available guidelines. But could this be part of the problem, could the issues with the definition/test for death, be because most decisions about guidelines, regulations, etc, are decided in-house? But why has this been allowed, why does the medical profession seem to get to set its own boundaries when it comes to practices, could it be down to how the profession was given its powers in the place?

2.7 Deference to the medical profession and its significance in the death context

The 1858 Medical Act, which established the General Medical Council (GMC) was the first social contract between the state, public, and profession in the UK. The Act empowered the Council to create/maintain a register of recognised doctors, with the aim of controlling entry into the profession. Significantly, the Act also granted the medical profession self-regulatory powers, in the sense of "deliberate delegation of the state's law-making powers to an

[167] Michael Souter, Gail Van Norman, *Ethical controversies at end of life after traumatic brain injury: Defining death and organ donation,* Critical Care Medicine, 2010 38:9

[168] M. Susan Mandell, Stacy Zamudio, Debbie Seem, Lin J. McGaw, Geri Wood, Patricia Liehr, Angela Ethier, Anthony M. D'Alessandro *National evaluation of healthcare providers attitudes towards organ donation after cardiac death*, Critical Care Medicine, 2006 34:2952-2958

agency, the membership of which wholly or mainly comprises representatives of the firms or individuals whose activities are being regulated."[169] The reasons given for granting self-regulatory powers were based on four key assumptions. First, the interests of the public and the profession were assumed to be sufficiently well aligned to avert the risk of shirking either by individual doctors or a collective of doctors.[170] Second, non-professionals were assumed to be incapable of understanding or judging the specialised expertise of doctors.[171] Third, physicians were assumed to be especially virtuous and trustworthy because of the values expressed in their codes of conduct.[172] Finally, professionals were assumed to be willing to take action when individual members fell short. [173]

This mindset continued for over a century and a half, surviving several major crises with its self-regulatory structures largely intact. Even the highly publicised scandals involving medical research in the 1960s resulted in official exhortations to live up to professional virtues rather than any more fundamental change.[174] This tradition within the medical community can trace its foundations to the assumption that non-professionals were assumed to be incapable of understanding or judging the specialised expertise of doctors.[175]

Some examples of how self-regulation has benefitted the medical profession within the court system in England can be seen in cases such Bolam[176] where it was decided that if a doctor reaches the standard of a responsible body of medical opinion (self-regulated), they are not negligent. In Sidaway[177] where the case was centred on consent and how much information a doctor was required to give their patient. The court rejected a patient's claim for damages and held that consent did not require an elaborate explanation of remote side

[169] Anthony Ogus 'Self-regulation' Boudewijn Bouckaert, Gerrit De Geest (Eds.), Encyclopaedia of law and economics, Vol. I, Edward Elgar, Cheltenham (2000)
[170] Michael J Roberts, The politics of professionalization: MPs, medical men, and the 1858 medical act, Medical History, 53 (2009), pp. 37-56
[171] Alec W Merrison, Committee of Inquiry into the regulation of the medical profession, HMSO, London (1975)
[172] ibid
[173] Eliot Freidson, Profession of Medicine, Dodd, Mead & Company, New York (1973)
[174] Mary Dixon-Woods, Richard E Ashcroft, Regulation, and the social licence for medical research Medicine, Health Care, and Philosophy, 11 (2008), pp. 381-39
[175] Merrison (n 171)
[176] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582
[177] *Sidaway v Bethlem Royal Hospital Governors* [1985] AC 871

effects. Which in effect states that the doctor knows best and that a patient is on a 'needs to know basis. It was not until a negligent case in 1997[178] that it was considered that the courts could intervene and potentially set the laws regarding medicine. In Bolitho, the House of Lords held that a judge will be entitled to choose between two bodies of expert opinion and to reject an opinion that is 'logically indefensible'. This has been interpreted by some as being a situation where the court could set the law, not the profession.

In terms of diagnosing death, all the guidelines and codes of practice have been written and reviewed by the medical profession itself in the forms of the Academy of Royal Medical Colleges, the Intensive Care Society, and the Working Group of the Royal College of Physicians. From an outsider's viewpoint, it seems that this type of self-regulation could have a biased result in favour of the profession, as they are hardly going to create guidelines that are going to disadvantage themselves. But why is this allowed to carry on, I can understand that maybe forty-fifty years ago when brainstem death was first considered that yes, potentially it would have only been medics involved, but the latest revised documents were written in 2008. A lot has changed in the intervening years and supposedly the profession has moved to a more patient-centred approach where they are encouraged to involve the patient. Yet when it comes to a decision that truly affects them, such as how to define death the profession still takes the self-regulated stance.

Currently, in England and Wales, there is no statutory definition of death, so the law turns to the medical profession for guidance, which then vindicates the process of self-regulation within the medical profession. For example, Lord Lane C. J. in *R v Malcherek*[179] on the subject stated that: *"*Modern techniques have undoubtedly resulted in the blurring of many of the conventional and traditional concepts of death... There is, it seems a body of opinion in the medical profession that there is only one true test of death and that is the irreversible death of the brainstem, which controls the basic functions of the body such as breathing.

[178] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771
[179] [1981] 2 All ER 422

When this occurs, it is said that the body has died, even though by mechanical means the lungs are being caused to operate and some circulation of blood is taking place"

The clear take-home message from Lord Lane C. J. is that it is the medical professionals who appear to get to decide on the criteria, tests, and results for diagnosing death. In England and Wales, two key cases discuss using brainstem death as the definition of death the first being *Re A*[180] where a child satisfied the clinical criteria for brainstem death, so was declared to be dead for all legal, as well as medical, purposes.[181] The judge who heard the case held that the child had been dead since the first attempt to remove the ventilator and that the criteria for brainstem death were satisfied, and therefore the patient was dead for all legal as well as medical purposes allowing ventilation to be lawfully discontinued. While this was a first-instance case, the same approach was confirmed in the *Bland* case[182] although in this particular case, no brainstem tests were applicable as the patient continued to breathe for himself, the courts discussed and emphasised that it is the death of the brainstem and not the loss of higher brain functions that is the minimum criterion for death.

From these examples alone, it appears that the courts are willing to allow the medical profession to have free reign on the issue of diagnosing death. This has left the general public, reliant on practices that were decided upon over fifty years ago by a group of select individuals who had a vested interest in the outcome. This situation is also reflected in the US, where during the 1960's they began to develop their version of brain death criteria.

When the Harvard Medical School Committee was set up in 1968 it was made up of thirteen members consisting of ten medics, one theologian, one law professor; and a historian of science.[183] With a committee so heavily weighted in favour of the medical profession,

[180] [1992] 3 Med. L.R. 303
[181] ibid at 305
[182] *Airedale NHS Trust v Bland* [1993] AC 789
[183] Robert M Veatch, Would a Reasonable Person Now Accept the 1968 Harvard Brain Death Report? A Short History of Brain Death," Defining Death: Organ Transplantation and the Fifty-Year Legacy of the Harvard Report on Brain Death, special report, Hastings Centre Report 48, no. 6 (2018): S6-S9.

surely it should have come as no surprise that they would come to the conclusion which benefitted the current new trend in medicine. In this case the development of so-called cadaveric organ transplantation. The medics who were on the committee could potentially claim to have expertise on the subject when they attempted to answer the question 'When has a brain irreversibly ceased to function?' But then they went a step further and assumed without argument that the brain's death can be equated with human death. They appeared to ignore the social aspects of the question and failed to consider whether should we treat individuals with dead brains and beating hearts as dead humans. Of course, it could be argued that the other members of the committee were more informed to discuss and argue for this social aspect. But when you are in a minority (3-10 in favour of the medical profession) the chances are your voice is never going to be heard, and when you start to consider what Byrne and Weaver[184] said "you can start to see why the idea of brain death equating to death evolved. But there has never been a clear explanation as to why the brain was chosen as the organ that would define death."

Historically, it was always the cessation of the heart and lungs and the persistent absence of these vital signs that confirmed that the person was to be declared dead. This was until the longstanding definition of death was critically undermined by the developments in medical technology. Firstly, there was the introduction of assisted ventilation and heart-bypass machines, these showed that it was possible to maintain artificially the biological functions of the lungs and heart. Once the delivery system for life could be replaced, a consensus started to form amongst the medical profession and some ethicists that perhaps the heart and lungs need no longer be considered constitutive of human life. This thinking was further compounded in 1967 after the first human heart transplant operation was successfully performed. Therefore, if the heart can be bypassed or even entirely replaced, is it not then logical to think, that it cannot contain the crux of the human person? As time went on and with every new medical advancement it now seems that every organ is replaceable by transplantation, all apart from one, the human brain. So, could the reason for choosing

[184] The agenda from the outset, was to find that brain death equated to death, therefore the data could be made to fit the already arrived at conclusion, and therefore there was a serious lack of scientific method in the process.

brain death equate to the death of a human being down to the simple fact that this is the one organ that cannot be transplanted (yet)? As one commentator puts it "Your heart can die without you dying, but, if your brain dies, you die."[185]

2.8 Conclusion

It seems that the success of organ transplantation over other methods, such as prevention has led to an overreliance on organ donors to the point that those who feel that the supply of organs should be maintained/or increased have widely different views on what constitutes an acceptable measure to be employed to achieve this end. The main example is the declaration of death to enable organ procurement to take place. The declaration of death has been and still is proving very controversial because there are concerns that some or all the various approaches to death that are currently being employed are potentially not credible, with there being persistent concerns within legal and ethical circles that so-called cadaveric donors may actually be alive.[186] There are some commentators, like DuBois[187] and Caplan,[188] who suggest that the issues around diagnosing death have been resolved and that there should be no further debate on the matter whereas others, such as Shewmon,[189] disagree with a view that has also been expressed by the President's Commission.[190] The Commission stated that to count an organism as alive it should function as an integrated whole. Once you start to consider this statement you realise that this does not support a whole-brain definition of death, but it does succeed in explaining why an organism can be dead when some of its parts are still alive. Another obvious problem with this account is

[185] David A Jones, The UK definition of death, *The Linacre Centre*. http://www.lifeissues.net/writers/jon/jon_01death.html

[186] Alan Shewmon is a neurologist who withdrew his prior support for the concept of brain death after research showed that many patients' who were considered brain dead still retained considerable measurable brain function. Alan Shewmon, (1998) "Brainstem death", "brain death" and death: A critical re-evaluation of the purported equivalence, Issues in Law and Medicine 14(2): 125-45

[187] James M DuBois, *The Ethics of Creating and Responding to Doubts about Death Criteria,* The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine, Volume 35, Issue 3, 1 June 2010, Pages 365–380

[188] Arthur Caplan, *The case against care for those who are brain dead, https://www.newsday.com/opinion/oped/caplan-the-case-against-care-for-those-who-are-brain-dead-1.6767446,* January 2014 (Accessed 10th May 2018)

[189] D Alan Shewmon, Brain Death or Brain Dying? Journal of Child Neurology, January 2012, Vol.27(1), pp.4-6

[190] The President's Council on Bioethics. *Controversies in the determination of death: a white paper by the President's Council on Bioethics*. Washington, D.C.: U.S. Department of Health and Human Services, 2008

that it does not quantify how much integration is required, and therefore does not help to sufficiently narrow down the zone of indeterminacy.

Having conducted a literature search in this field, it is evident that conflicts of opinion persist with respect to all relevant medico-legal aspects of death, and I must conclude that based on the balance of probabilities a potential organ donor is in fact not dead but is in the dying process at the time their organs are removed. This conclusion should create a huge dilemma in the transplant community, but the chances are that it will not as there are many[191] before me who have come to the same conclusion, and nothing has changed. But with new dimensions to the debate emerging with developments in scientific understanding, for example, an emergent body of evidence suggesting that Electroencephalography (EEG)[192] silence does not mean that the individual under observation is dead.[193] It could be simply that after a severe trauma, the brain may shut itself down to aid recovery, in a similar way that medics place patients into an induced coma.

Is now the time for the medical profession to recognise that they are just paying lip service to the DDR, or even potentially that the wrong question is being asked? As with most debates, there is another angle that could be taken, there is a school of thought that thinks the debate should not centre on whether we can define 'life' and 'death' or not; it should be centred on the question whether current practices of establishing death and organ donation are ethically justifiable. By taking this approach it shifts the argument from the current defining/diagnosis of death to discussions about the abandonment of the DDR, which is a highly controversial viewpoint. But it could also potentially allow for greater scrutiny of current practices of establishing death and organ donation allowing the power of decision-

[191] Alan Shewmon, Franklin., G, Miller, Robert D, Truog

[192] Electroencephalogram is a test used to investigate problems related to electrical activity of the brain. An EEG tracks and records brain wave patterns.

[193] Jens P Dreier, Sebastian Major, Brandon Foreman, Maren K L Winkler, Eun-Jeung Kang, Denny Milakara, Coline L Lemale, Vince DiNapoli, Jason M Hinzman, Johannes Woitzik, Norberto Andaluz, Andrew Carlson, Jed A Hartings. Terminal spreading depolarization and electrical silence in death of human cerebral cortex. Annals of Neurology 2018 83(2), 295-310

making to move away from the select few within the medical profession and allow for an open and clear debate that involves society.

One final thought to consider is that possibly our ability to define death is limited by our technological abilities. Should we redefine death from a failure of critical bodily organs to death occurring when technological interventions no longer work? In other words, death is defined as a technological failure, it occurs because we are currently at our technological limits for preventing the failure of critical bodily organs. When you first consider this concept it does seem strange, but has this not always been the case, for example, before the advent of cardiopulmonary resuscitation (CPR) techniques and defibrillators, patients routinely died from cardiac arrest. Technology and knowledge have created a double-edged sword in medicine, in trying to solve one problem they have created a whole set of new problems, namely the highly probable fact that potential organ donors are not dead at the time of procurement.

It has been over fifty years since the brain death concept was first considered, yet there still appears to be a mismatch between social values held by the public and the definition of death. As discussed in this chapter there are currently several significant arguments that are ongoing about brain-based death pronouncement: whether patients or families should consent to tests such as apnoea testing, which criteria should be used in measuring brain function loss, is clinician error in applying tests too great, is the brain function/circulatory loss really irreversible, whether loss of all functions of the entire brain can be measured with existing criteria sets, and, most critically, whether the current brain death concepts of death should be favoured/abandoned over some erosion of a circulatory or even moving to a higher-brain concept.

Based on probability, I would have to agree with the argument that at the time of organ procurement, donor patients do not fulfil the requirements for brain death or circulatory death, therefore the removal of the organ violates the DDR. I take this stance even before I

factor in other controversies such as cultural, religious, and ethical issues. It appears that over time as evidence starts to show that the brain can remain active even after a catastrophic injury, rather than considering that the original total brain death equates to the death of a human to be wrong, the medical profession has watered down the requirements of the definition.

As for circulatory death, why should the declaration of a patient's death depend on what country they reside in, and sometimes even which state or hospital they happen to be in? To make circulatory death more credible at the very least there needs to be a standardisation of the time for the no-touch period. But even if this occurs there will be critics who argue that irreversible asystole can be equated only with a clinically determinable point of no return in the process of dying and cannot define human death.[194]

With the ongoing debate about the current standards that we use for defining death being questioned and potentially are inconsistent with what we value in a person, is now the time to finally address these incompatibilities. As it has been shown in this chapter the requirements for diagnosis of death may have been restricted to those with the requisite clinical expertise, but the parameters for deciding the social and legal significance of such crucial concepts as death is not and should not be limited to clinicians alone. By engaging in a widespread consultation and examination of the question of a definition of death, at the political and legal level, it would place this decision where it belongs, at the level of society and not just with the medical profession, which is still the case. Medical dominance on how we define death is still seen today with death being defined by medical colleges,[195] not legislation. Of course, that's not to say a legislative approach would be any more inclusive as potentially it too would almost certainly exclude the public from the debate on a new way to determine death. Overall, there has been and continues to be a failure to recognise that the public as a whole is greatly affected by the current death standards, we apply without them being involved in the process. This situation has to change and it should apply

[194]Nereo Zamperetti, Rinaldo Bellomo, Claudio Ronco, Defining death in non-heart beating organ donors. *Journal of Medical Ethics. 2003 Jun; 29(3):182-5.*

[195] *A Code of Practice for the Diagnosis and Confirmation of Death*, Academy of Medical Royal Colleges 2008

to all settings where death occurs not just in the organ procurement sector. In the meantime, do the current underlying issues regarding the diagnosis of death mean that the medical community should suspend all organ procurement programs from so-called cadaveric donors until this debate is completed or is there an ethical argument that can be utilised regardless of the outcome to justify the removal of organs from severely compromised patients? The next chapter will discuss this issue in depth.

3.1 Introduction

The current ethical framework for the transplantation of vital organs requires that donors are determined to be dead before organ procurement, this is known as the DDR. In the previous chapter on death, I argued that there are fundamental problems with the credibility of current approaches to death is the fact that they seem to be at odds with the DDR, in fact, they appear to violate it. During the chapter, I reviewed the latest research, and it suggests that brain-dead donors, although drastically compromised neurologically remain fully alive while being maintained on life support. As for donors who come under the donation after circulatory determination of death (DCDD) protocols, they are not known to be dead, based on the irreversible cessation of circulatory functioning, when organs are procured a very short time after asystole.

If this is true or even based on the balance of probabilities deemed to be true, then under the DDR current practices of procuring vital organs for transplantation should cease. Furthermore, it is important to stress in this context that whilst the DDR is, on one level, a reflection of broader norms of medical ethics and law – specifically, norms that entail construing human worth in such a way that it is impermissible to subject an individual to what is considered undue harm, with some harm being considered undue even if the individual concerned is the willing subject of it. Nonetheless, there are competing, more libertarian, notions of worth that might, if prioritised, enable the continuation of some procurement activities that appear to be inconsistent with the DDR. Furthermore, there is also a range of approaches to ethics that dilute emphasis on worth or deviate from it entirely in favour of an alternate emphasis, such as interpersonal justice, distributive justice, or liberty. These may also open the potential for procurement that appears inconsistent with the DDR.

This chapter serves as the end of explaining and evaluating the current approach and key alternatives. This is partly done to provide a platform for clear analysis in part two of the thesis of the range of approaches to reform the system of so-called cadaveric procurement

that might be taken. However, it is also carried out with a view to ultimately providing a reasoned analysis of which kind of approach to reform would be preferable.

In the death chapter I argued that there are fundamental problems with the credibility of current approaches to death is the fact that they seem to be at odds with the DDR. The question to be addressed in this chapter is what should be made ethically of this apparent inconsistency? Should approaches to death be revised to be actually compatible with the DDR or is it preferable to jettison the DDR in certain circumstances and, if so, when, and why? The DDR reflects what can be seen as a dignitarian or worth-based approach to ethics but there are also other approaches to ethics that may be capable of bringing about a different result - most notably certain utilitarian, libertarian, and justice-based approaches. The purpose of this chapter is to critically explore the nature and precise implications of these approaches and arrive at a conclusion as to which is preferable. It will also try to answer the question of whether can it ever be ethically justified to carry on with the current procurement system that is effectively taking vital organs from still-living patients, rather than dead bodies.

To set the scene, the chapter begins by providing a brief context into the nature and purpose of ethics or moral philosophy as a branch of knowledge before going into detail critically reflecting, and ultimately concluding upon the competing merits of the key approaches to ethics that are pertinent to this context.

3.2 The concept of bioethics/moral philosophy as a branch of knowledge

The concept of ethics or moral philosophy generally denotes reflection on morality and is a generic term for various ways of understanding and examining the branch of knowledge dealing with moral life/principles. It can also have a wider reference that includes law and politics as well as personal conduct and religion.[196]

[196] Oxford English Dictionary, www.oed.com

While ethics has always been viewed as a branch of philosophy, its comprehensive practical nature means that it has links with many other subject areas, for example, biology, politics, sociology, and theology to name but a few. Yet, ethics remains distinct from such disciplines because it has been suggested that it is not a matter of factual knowledge in the way that science is as it is not empirical or repeatable. Rather, it has to do with determining the nature of normative theories and applying these sets of principles to practical moral problems.

Medical ethics is a broad discipline in which ethical obligations in medicine and health care are analysed. In the early days of philosophical medical ethics (i.e., during the 1970s) there was an attempt to try to fit responses to moral dilemmas into the general framework offered by standard moral theories, especially utilitarianism and Kantian deontology. Although, it became apparent quite early on, that the simple appeal to theory and principle did not offer a satisfying analysis of the sorts of dilemmas that arise in medical ethics.[197] One proposal put forward for this apparent situation is that the fundamental problem with bioethics is, ethics are inherently stabilising and biotechnology/medicine are inherently destabilising; one resists change, one promotes it, therefore it could be said that there is always going to be a conflict.[198] But is this true, Garwood-Gowers has suggested: "Ethics resists unethical change rather than change per se. It is often co-opted by medicine to suit its ends need."[199]

There are several different bioethical methodologies that have been advanced for the incorporation of bioethics into clinical practice, but it is not the role of this thesis to be encyclopaedic about all the different approaches to ethics and how they could relate to the question that I will be examining. Rather the role is to locate what sorts of arguments are or

[197]Nancy S Jecker, Albert R Jonsen, Robert A Pearlman, *Bioethics: An Introduction to the History, Methods, and Practice,* Jones & Bartlett Publishers, 15 Feb 2011

[198] Eric S Rabkin, *Science Fiction and Bioethical Knowledge,* published in Daniela Capri, *Bioethics and Biolaw through Literature*, Walter de Gruyter, 2011

[199] This point was raised and discussed by Austen Garwood-Gowers during a meeting to discuss the progression of this chapter 16th January 2020

could be treated as central to determining the ethics of use of essential organs from the (at least arguably) not yet dead.

3.3 Dignity and Respect for the Person

Whilst the concept of respect per se is not often used in ethics discourse, one does find frequent references to the concept of respect for persons.[200] When considering respect for the person, the first question that needs to be answered is who or what are persons that are owed respect? There have been many different answers offered in literature, including all human beings; only those humans who are themselves capable of respecting persons; any living being capable of rational activity, whether human or not; any beings capable of functioning as moral agents, whether human or not. If these are accurate descriptions for respect then the second, third, and fourth seem to imply that deceased humans and humans who lack sufficient mental capacity, such as the severely mentally ill, those in persistent vegetative states, the pre-born, and perhaps very young children, do not meet the requirements to demand respect for the person. Yet the third and fourth answers can potentially include artificial beings (androids, sophisticated robots), spiritual beings, and certain animals. Surely, the only correct answer should be that all human beings are owed respect and that all human beings have equal claim to respect; including deceased humans and humans who lack sufficient mental capacity, such as the severely mentally ill, those in persistent vegetative states, very young children, and the foetus.

When researching respect and its protection, much of the discourse discusses respect in the context of dignity. For example, Dillon states that;" in modern philosophical discussions, humans are universally regarded as the paradigm objects of moral respect; if anything has moral standing or dignity and so warrants respect, it is the individual human being."[201] But

[200]Austen Garwood-Gowers, Medical Use of Human Beings Respect as a Basis for Critique of Discourse, Law and Practice, (2019) by Routledge

[201] Robin S Dillon, "Respect", *The Stanford Encyclopaedia of Philosophy* (Spring 2018 Edition), Edward N. Zalta (ed.)

what is dignity? According to the dictionary, dignity is the quality of being worthy or honourable; worthiness, worth.[202]

The concept of dignity is based largely on Western cultures, and it originates from the belief that all human beings have inherent worth. Important notions of human dignity can be found both in classical antiquity[203] and in Biblical scripture,[204] each of which has had a lasting influence on modern thought. In the modern era, both the moral philosophy of Kant and various constitutions and international declarations[205] of the twentieth century, all provide support for a belief in dignity and that all human beings are equally entitled to it.

Much of today's thinking/understanding of dignity can be said to have its foundations partly in Immanuel Kant's work, whose teaching states that we should not use others but should respect their integrity as individuals. Respect for human dignity, in its Kantian definition, is ''the absolute inner worth of the human being as a person,'' and lays the ground for all ethical duties.[206] The human capacity for rationality, autonomy, and human dignity are systematically interlinked, and human dignity has a central role in ethics because people as rational beings can give themselves moral laws. They have increasingly been put forward as an important basis for bioethics, with the idea that we are owed a certain kind of respect as persons being relatively common, but it is also often understood in terms of respecting people's autonomous choices, dignity, integrity, privacy, and vulnerability.

[202] https://www.oed.com/view/Entry/52653?redirectedFrom=dignity#eid
[203] The word "dignity" comes to us, via the Latin *dignus* and *dignitas*, from Greek and Roman antiquity, in whose literature it means something like "worthiness for honour and esteem."
[204] Human dignity is the Biblical account of man as "made in the image of God." This teaching, together with its further elaborations in Jewish and Christian scripture, has been interpreted in many ways, but the central implication seems to be that human beings, because they are in some respects godlike, possess an inherent and inalienable dignity.
[205] Discussed later in the chapter
[206] Immanuel Kant. (1996a). The metaphysics of morals. In Mary Gregor (Ed.), Practical philosophy (pp. 363–603). (Mary Gregor, Trans.). Cambridge: Cambridge University Press. (Original work published 1797).

Kantian principles of dignity and worth are becoming viable again in bioethics as his principles of ethics are typically invoked to put forward a strict restriction on what should be allowed. Kant says:

"So, act that you use humanity, in your own person as well as in the person of any other, always at the same time as an end, never merely as a means."[207]

Being of absolute value, human beings should not sacrifice themselves or one another for merely relatively valuable ends. Kant also goes on to state that we should be able to develop our own rational capacities and promote one another's rationally chosen ends. Human dignity more than ever is of paramount importance, especially in matters of bioethical. As the medical community takes an increasing interest in the world of biotechnology, there is an increasing sense that if we start to neglect human dignity, especially in light of gathering powers to intervene in human bodies and minds, the very nature of human dignity could be changed in ways that will affect our very humanity.[208]

The ethical perspective of the Catholic Church is that the notion of altruism and of giving organs and tissues is important to preserving human dignity. Pope John Paul II wrote that allowing the body to be used as an 'object' is to violate the dignity of the human person. He said that:

"This first point has an immediate consequence of great ethical import: *the need for informed consent.* The human 'authenticity' of such a decisive gesture requires that individuals be properly informed about the processes involved, in order to be in a position to consent or decline in a free and conscientious manner. The consent or relatives has its

[207] Immanuel Kant, Groundwork of the Metaphysics of Morals, Revised Edition, Edited by Mary Gregor and Jens Timmermann, 2012 Cambridge University Press, pg. xxv (4:429)
[208] Leon R Kass, Chapter 12 Defending Human Dignity, Part 4: The Source and Meaning of Dignity, The President's Council on Bioethics, Washington, D.C. March 2008

own ethical validity in the absence of a decision on the part of the donor. Naturally, an analogous consent should be given by the recipients of donated organs."[209]

These principles of human dignity and worth are reflected in a raft of human rights legislation and frameworks that were developed during the twentieth century. For example, the Universal Declaration on Bioethics and Human Rights (UNESCO, 2006)[210] justified respect for ''[h]uman dignity, human rights, and fundamental freedoms'' (Art. 3.1) and ''[t]he autonomy of persons to make decisions'' (Art. 5) as the foremost principles. More importantly, it declares that ''[t]he interests, and welfare of the individual should have priority over the sole interest of science or society'' (Art. 3.2.).

The importance of dignity can be found in health-specific international human rights instruments such as the Universal Declaration on the Human Genome and Human Rights (UDHGHR) 1998, which deals with the rights of the persons concerned by human genome research and provides a reference legal framework for both stimulating the ethical debate and the harmonization of the law worldwide, favouring useful developments that respect human dignity. It recognises "inherent dignity" and that "everyone has a right to respect for their dignity" (Art. 1 and Art. 2). The Universal Declaration on Bioethics and Human Rights (UDBHR) 2005, aims to promote respect for human dignity and protect human rights (Art. 2(c), Art. 3(1), Art. 11, and Art. 12).

Dignity and the respect for it are also mentioned in the UN Convention on the Rights of Persons with Disabilities. Article 1 describes a person with a disability as "a person who has long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society." It goes on to state the need to "promote respect for their inherent dignity" as well as stating that anyone

[209] Pope John Paul II Address to the 18th International Congress of Transplantation Society (29th August 2000)
[210] UNESCO. (2006). Universal declaration on bioethics and human rights. Paris: UNESCO

with a disability should be "treated on an equal basis with others".[211] It also describes how an individual autonomy, including the freedom to make one's own choices, and independence of persons is protected (Article 3), integrity of the person (Article 17), and respect for privacy (Article 22).[212] Just in these few pieces of legislation alone, it is clear that dignity is an important phrase, as Garwood-Gowers[213] puts it, dignity appears to be the 'golden thread' that runs through these instruments, yet there is no defined meaning of what dignity is.

Rosen[214] has stated that dignity "has no coherent meaning of its own" but it may be a receptacle of different ideas. Treating a person as an end requires treating that person as having a dignity or worth that is beyond the worth of what a person does or is. All humans have dignity simply because they are human and in order to protect this intrinsic[215] or inherent dignity[216] would mean to protect humans and humanity itself. When dignity is seen as inherent worth, some scholars state that dignity is something that cannot be made but can be violated.[217]

Sulmasy describes intrinsic dignity as "... the intrinsic value of entities that are members of a natural kind ... capable of language, rationality, love, free will, moral agency, creativity, aesthetic sensibility, and an ability to grasp the finite and infinite."[218] He defines intrinsic value as a "value something has by virtue of its being the kind of thing that it is." In his view, all members of a natural kind with intrinsic dignity, capable of exercising moral agency, have

[211] UNESCO. (2006). The Convention on the Rights of Persons with Disabilities and its Optional Protocol (A/RES/61/106)
[212] ibid
[213] Austen Garwood-Gowers, André Pereira, Organ and Tissue Human-Human Transplantation, In: A. Den Exter, ed., *European health law.* Antwerp: Maklu, pp. 391-418
[214] Michael Rosen, (2012) Dignity; It's history and meaning, Cambridge: Harvard University Press
[215] Carlo Leget, Analysing dignity: A perspective from the ethics of care, Medicine, Health Care and Philosophy, 2013 16(4): 945-952
[216] Lennart Nordenfelt, The varieties of dignity, Health Care Analysis 2004 12(2):69-81
[217] Rosen (n 214)
[218]Daniel P Sulmasy, Dignity and Bioethics: History, Theory, and Selected Applications, in HUMAN DIGNITY AND BIOETHICS: ESSAYS COMMISSIONED BY THE PRESIDENT'S COUNCIL ON BIOETHICS 469, 477 (Adam Schulman & Thomas W. Merrill eds., 2008).

a moral obligation to themselves and to all other entities with intrinsic dignity.[219] He suggests some rights that are based on this norm are the right not to be killed, not to be treated disrespectfully, and not to be experimented on without consent. When you consider these norms, it can be argued that it would be inappropriate to infringe on a dying individual's dignity for the sake of society and the organ transplant recipient.[220]

Similarly, Cohen puts forward the following interpretation of a Kantian position: “Human beings ... are of incomparable ethical worth and admit of no equivalent. Each has a value that is beyond the contingencies of supply and demand or of any other relative estimation. They are priceless. Consequently, to sell an integral human body part is to corrupt the very meaning of human dignity.”[221] Cohen's description backs up an argument put forward in favour of human dignity/worth within the subject area of bioethics that the sanctity of the human body, and its elevated moral status, should not be seen as property, and therefore no market value should be placed on the human body. In summing up on dignity it appears that it does have a purpose and a place in bioethics. As Garwood-Gowers puts it “Dignity is not the impractically vague concept that it is sometimes made out to be but rather a potentially sound foundation for the organization of bioethics and law generally and constraint of medical use of the human body specifically.”[222]

Yet the very idea of dignity has recently come under attack from one of its sharpest critics philosopher and bioethicist Ruth Macklin, who in 2003 claimed that "appeals to dignity are either vague restatements of other, more precise, notions or mere slogans that add nothing to an understanding of the topic."[223] She argues dignity acts as a slogan to substitute for substantive argument favouring a particular position. In the end-of-life context, she contends that appeals to dignity are in reality appeals to promote patient autonomy in

[219] ibid
[220] ibid
[221] Cynthia B Cohen, Selling bits and pieces of humans to make babies: the gift of the magi revisited. Journal of Medicine and Philosophy 1999; 24:288–306 at 292.
[222]Austen Garwood-Gowers, Medical Use of Human Beings Respect as a Basis for Critique of Discourse, Law and Practice, (2019) by Routledge
[223]Ruth Macklin, "Dignity is a Useless Concept," British Medical Journal 327 (2003): 1419-1420

decisions about life-sustaining treatment. Appeals to dignity may also stand in for other principles, such as respect for persons, confidentiality in the doctor-patient relationship, or bans on "discriminatory and abusive practices." Macklin concludes that dignity "is a useless concept in medical ethics and can be eliminated without any loss of content." She argues that respect for persons is a sufficient principle for bioethics, one that entails "the need to obtain voluntary, informed consent; the requirement to protect confidentiality; and the need to avoid discrimination and abusive practices.[224]

Others have argued that the idea of human dignity/worth is better protected by utilitarianism, a moral theory commonly thought to be a rival to Kant's theory, which has been suggested to be superior with regard to offering protection to the concept of respect.[225] Dillon suggests that a utilitarian might argue that it is sentience rather than the capacity for rational autonomy that is the ground of moral recognition respect, and so would regard mentally incapacitated humans and nonhuman animals as having moral standing and so as worthy of at least some moral respect in themselves.[226]

3.4 Utilitarian Ethics

There are many forms of Utilitarianism, but what they all hold in common is the rejection of the view that certain things are right and wrong in themselves, irrespective of their consequences.[227] The main aim of utilitarian thinking is that the consequences of a particular action are the overall happiness created for everyone affected by the action. Therefore, Utilitarian's are obliged to act on behalf of the greatest happiness for the greatest number. Although it is misleading to say simply that utilitarianism is a philosophy whereby the end, the greatest happiness for the greatest number, justifies the means, it does create an understanding to help grasp the basic dynamics of moral theory.

[224] ibid
[225] Robin S Dillon, "Respect", *The Stanford Encyclopaedia of Philosophy* (Spring 2018 Edition), Edward N. Zalta (ed.)
[226] ibid
[227]Ralph Levinson, Michael J Reiss, *Key Issues in Bioethics*, Edge of Life, 2003 vol. 85

In its earliest forms, utility was associated with pleasure and the absence of suffering, and evil, it began as an ethical theory in Britain at the end of the eighteen century with the influential work of Jeremy Bentham (1748-1832) and John Stuart Mill (1806-1873), it works on the assumption that most actions lead to pleasure and/or displeasure, and the actions that create more happiness are ethically justifiable. Bentham's philosophical doctrine was astonishing and completely against the current constitutional thinking at the time, as it removed all reference to God's will, the interests of society, customs and traditions, and the natural law. Instead, Bentham put forward the notion of what was thought to be the straightforwardly rational and scientific procedure of simply measuring the happiness of each individual person, and then adding up this happiness across the whole of a population.[228] Another remarkable, and indeed potentially revolutionary, feature of utilitarianism was its insistence on counting the happiness of all persons exactly the same: the happiness of kings and nobles counts no more or less than the happiness of tradesmen and peasants, the happiness of Englishmen no more than the happiness of Frenchmen, and so on.[229] There are some utilitarian thinkers, such as Singer, who have gone beyond Bentham's and Mill's initial concept to go on to highlight the need to also include other living beings.

What makes utilitarianism an attractive and popular theory is perhaps not so much strictly philosophical reasons, but it presents a form of ethics that is ideologically and religiously neutral and that claims to arrive at universal moral judgments without big metaphysical presuppositions. Since a range of themes with religious connotations plays a central role in bioethics, the non-religious perspective of utilitarianism has appealed to many secular thinkers. This is amplified by the fact that, in its basic form, utilitarianism has no fundamental prohibitions and demands. Instead, it is characterised by the weighing procedure, similar to the ones central to bioethics.[230] For instance, there is evidence in the

[228] Frank Lovett, Reader's Guides: Rawls's 'A Theory of Justice': A Reader's Guide (1). London, GB: Continuum, 2010. ProQuest ebrary. Web. 24 October 2016.
[229] ibid
[230] Marcus Düwell, *Bioethics: Methods, Theories, Domains*, Routledge, 2013

literature that supports the thinking that public health interventions and programs are rooted in utilitarian ethics,[231] and there are others who feel that they are a combination of ethical stances, for example, "…, public health is, in essence, paternalistic because it tends to use the power of the State to intervene on behalf of the health of individuals (even where this has not been requested), and utilitarian because it seeks to preserve the health status (something that contributes to the well-being of persons) of the maximum number of individuals possible, ideally the entire population."[232]

Modern utilitarian ethical theories stem from the works of Mill in *On Liberty*[233], which he describes in several ways,[234] including the freedom to act on one's own opinions.[235] This has been adapted further by viewing utility in terms of satisfaction of individual preferences (Hare 1981, Harsanyi 1977, Singer 1993)[236]. The main recurring theme with utilitarianism is that there is a moral obligation to always act from an impartial standpoint to generate the most utility and to always follow the rules that allow this to be achieved. The idea that a utilitarian stance is impartial appears on the face of it to be a suitable theory to be used in bioethics, but in practice, this can be a very demanding proposition, and for many, this could be too demanding. On the subject, Beauchamp and Childress have written that utilitarianism asks that we act like saints who are without personal interests and goals,[237] which for many just is not true.

[231] J Stuart Horner, For debate. The virtuous public health physician, *Journal of Public Health*, Volume 22, Issue 1, March 2000, Pages 48–53; Stephanie Nixon, Lisa Forman, Exploring synergies between human rights and public health ethics: A whole greater than the sum of its parts. BMC International Health and Human Rights 8**,** 2 (2008)

[232]Miguel Ángel Royo-Bordonada, Begoña Román-Maestre, Towards Public Health Ethics, Public Health Reviews (2015) 36:3

[233] J.S. Mill, On Liberty and Other Writings, ed. Stefan Collini, Cambridge, Cambridge University Press, 1989,

[234] ibid 15-16

[235] Candace Cummins Gauthier, 'Philosophical Foundations of Respect for Autonomy' (1993) 3(1) Kennedy Inst Ethics J 21-37, 25.

[236] Richard Marvyn Hare, Moral Thinking: Its Levels, Methods, and Point, 1981 Oxford: Clarendon Press/New York: Oxford University Press; John C Harsanyi, Morality and the theory of rational behaviour. Social Research, 1977 44(4), 623-656; Peter A Singer, Practical ethics. 2nd Edition. 1993 Cambridge: Cambridge University Press.

[237]Tom L Beauchamp, James F Childress, Principles of biomedical ethics. Fourth edition. 1994 Oxford: Oxford University Press p. 54

With regards to the main question posed throughout this thesis, what would be the ethical implication of procuring organs from donors who are not yet dead, Mills advocated a utilitarian principle, and his harm principle is intended to be applied in the way that best advances overall welfare.[238] In Mill's famous harm principle, he states, "The only purpose for which power can rightfully be exercised over any member of a civilised community, against his will, is to prevent harm to others"[239], which does appear to allow autonomy to be constrained by external circumstances.

If a utilitarian approach, such as Mill's principle is to be applied in the procurement of organs from donors who are on the balance of probability in the process of dying and not yet dead, but are said to be beyond harm then the removal of non-essential organs would be permissible and if followed strictly to advance overall welfare of potential recipients the removal of essential organs would be allowed too if it was deemed that the dying patients need were less than the potential recipients, and consequently satisfy Mill's principle.

Harris in 1975 suggested that a 'survival lottery' system should be considered, where everyone would be entered into a lottery draw and whoever had their number randomly selected would be forced to give up certain bodily materials to save the lives of others.[240] In a later publication, he states that cadavers should be considered to belong to the state and to be used as appropriate and has stated that 'it seems clear that the benefits from cadaver transplants are so great and the reasons for objecting so transparently selfish or superstitious, that we should remove altogether the habit of seeking the consent of either the deceased or relatives'.[241] On the issue of carrying a donor card, John Harris writes: "The donor card scheme is clearly failing us all. We must get away from the idea that people can allow their bodies and those of their relatives to be simply buried or burned when they die. This is a terrible and cruel waste of organs and tissue that may save life or restore

[238] David Molyneux, 'Should Healthcare Professionals Respect Autonomy Just Because It Promotes Welfare?' (2009) 35(4) Journal of Medical Ethics 245-250, 246
[239] ibid
[240] John Harris, (1975) The Survival Lottery, *Philosophy* 81-87
[241] John Harris, (1992) Wonderwoman and Superman: the ethics of human biotechnology, Oxford University Press, p 102

health."[242] Although he has conceded that deceased persons do retain interests after death, he has described them as artificial and of little consequence, easily outweighed by the needs of the sick.[243] Harris writes that all moral concern of our society have so far been focused on the dead and their friend and relatives. But there are two separate sets of individuals who have moral claims upon us, not just one. There is the deceased individual and their friends and relatives on the one hand, and the potential organ or tissue recipient and their friends and relatives on the other. Whose interests should take priority. [244] Harris argues that while the organ donor may have a posthumous preference frustrated, or a posthumous interest ignored, and their friends and relatives may be distressed and upset, the potential organ recipient stands to lose their very life and their friends and relatives will have grief to add to their distress.[245] It appears that Harris is arguing the case that the right of the organ recipient should take precedence over the rights of the organ donor and their friends and relatives, a stance that he has taken before.[246]

Harris is not the only commentator with strong views that everyone should donate bodily material to those in need, this issue was discussed in an article by Huffman back in 1979 where he wrote a scathing piece to the judgement in the US case of *McFall v Shimp* (1978) No. 78-17711.10 Pa D & C (3d) 90 (Ct Comm Pl, Pa). He suggested that the failure to give bodily material to those in need should lead to criminal charges – including manslaughter charges where an "unrescued" person dies.[247]

I cannot dispute that in theory taking a utilitarian approach to organ procurement could increase the pool of potential organs which in turn would be an enormous benefit to patients awaiting a transplant, by permitting such harm to donors cannot be justified morally, despite the great benefits that may be obtained. We should not forget the harm

[242]John Harris, Organ procurement: Dead interests, living needs (2003) 29 *Journal of Medical Ethics* 130
[243] ibid 131
[244] John Harris, What is it to do good medical ethics? *Journal of Medical Ethics*, 2015;41: 37-39
[245] ibid
[246] Harris (n 242) 130-4
[247] Fordham E Huffman, Coerced donation of body tissue: Can we live with McFall v Shimp? *Ohio State Law Journal* 1979 40, 409-440

caused by the organ retention scandal during the 1990s in the UK, during which it was found that human tissue, including children's organs, were systematically removed, retained, and disposed of, all of which was carried out without the authorisation from relatives.[248]

There should be a continuing challenge to the utilitarian principle of using one person to serve a greater good, not only because it is morally justifiable to defend dignity, autonomy, and freedom of choice, but, also because as shown in this thesis there is still uncertainty over the diagnosing of death. Jonas[249] on this subject has acknowledged that there is still a lack of knowledge regarding life and death and the boundary between them, so much so that he prefers to err on the side of life. By taking this stance it will keep the respect for individual life as an unwavering principle in the face of the perhaps compelling desire to use brain-dead patients' bodies as living corpses that can provide organs to others in need.

3.5 Justice Theory Ethics

When considering justice ethics with regard to organ donation, there seems to be a conflict between the protection of individuals and the potential overall social great from the perspective of public policy. This conflict seems to be between the utilitarian good-maximising approaches to justice and approaches that emphasise the equality of rights of individuals.[250] There are some commentators in the field of transplantation who feel that current systems in operation are too heavily weighted on respecting the deceased donor or family autonomy rather than concentrating on maximising the retrieval rate of organs to meet the demand.

For example, if a Rawls approach were to be taken when considering policies for organ donation, behind the Veil of Ignorance the question that could be asked would be about the

[248] The Royal Liverpool Children's Inquire Summary and Recommendations, *Royal Liverpool Children's Inquiry*. The Stationery Office. 30 January 2001
[249] Theresa Morris, *Hans Jonas's Ethic of Responsibility: From Ontology to Ecology*, SUNY Press, 2013 pg172
[250] Rosamond Rhodes, Leslie P. Francis, Anita Silvers The Blackwell Guide to Medical Ethics, 2007 Blackwell Publishing

worthiness of donors' vs donees'. Issues about who is the least favoured group, who has the most to gain, etc. could be asked at the time of considering organ donation. In this case, a Rawlian would first use the theory behind the Veil of Ignorance to derive a principle and then apply it, here it would be who would benefit more from the potential organs, the donee who is dying or the recipient who could potentially return to being a productive citizen after the operation. Rawls's theory of justice could also be used in the argument that the general public understands the need to increase the number of organ donations, behind the Veil of Ignorance the general public will recognise the need to increase the pool for organ donors and will agree to put policies in place to this effect, knowing full well that they may be the person in need or the person donating.

Various other authors on this subject have stated that organ donation should be seen as a social obligation, for example, Glannon[251] stated that "having one's medical needs met over the course of one's life entails a prima facie obligation to donate cadaveric organs in order to meet the medical needs of others, provided it does not violate one's belief in the value of the body." Yet in the same article he says that "the idea that the sick have a right to cadaveric organs is grounded partly in the belief that these organs are no longer of any use to the dead. Viable and therefore useful body parts can be treated as state property."[252]

A leading writer on justice-based ethics is Cecile Fabre who uses the rights-based theory of justice to describe the process of giving up one's organs to those in need in a similar way that the general public is obliged to pay taxes for such monies to be distributed to those in financial need.[253] In her book, she suggests that an approach to the use of an individual's body should follow a justice-based theory in which others can have limited claims on its use as a matter of interpersonal justice. She states that: "…if one thinks that the poor's interest in leading a minimally flourishing life, and a fortiori in remaining alive, is important enough to confer on them a right to some of the material resources of the well-off, by way of taxation and, in particular, by way of restrictions on bequests and inheritance, one must

[251]Walter Glannon, *Do the sick have a right to cadaveric organs?* Journal of Medical Ethics, 2003; 29(3) 153-6
[252] ibid
[253] Cecile Fabre, Whose Body is it anyway? (Oxford: Clarendon Press, 2006), p. 2

think that very same interest is important enough to confer on the sick a right to the organs of the now-dead healthy."[254]

Calabresi[255] asks the question should we be made to donate tissue that we have excess of such as bone marrow, hair, or potentially a kidney (as we can function perfectly well with one healthy kidney) whilst we are alive as we have no real need for them? He then further suggests that all body parts are of virtually no use to a person once they are dead and could be more efficient if they belonged to those who needed them; therefore, they should be considered for donation. But should someone be made to donate their tissue/organs, and can it still be called 'donate' when this word implies that you do something willingly, not because you must? Menzel advances this view further by saying that there is a moral duty to donate organs at death, based on the notion of easy rescue. He emphasises the fact that there is a great value in organ donation to living people who are suffering, and with the ease with which donation may be accomplished without any harm being suffered by the donor. He also goes on to talk about the special relationship we hold with the person to whom we owe a duty, hence, there is a moral duty to donate organs at death.[256]

One major problem with justice-based ethics appears to go against the principle of autonomy, and the basis that people should be protected from unwanted intrusions of which the removal of organs most definitely is. There is also the potential to cause real harm to the dead because they can be harmed by having their organs excised contrary to their pre-mortem wishes, despite what most justice-based theorists will have you believe. It appears that advocates of a justice-based theory have forgotten that the fundamental principle of organ donation, is that the act of giving up one's organs should be an altruistic act, whereby the donating of an organ(s) is voluntary, and the said organs are seen as a gift. No one should be made to donate their organs just because they no longer need them, and

[254] Cecile Fabre, Justice and the Coercive Taking of Cadaveric Organs, British Journal of Political Science 34, 69–86, 2004 Cambridge University Press
[255]Guido Calabresi, *Do We Own Our Bodies*, Health Matrix, vol.1:5, 1991
[256] Paul T Menzel, *The Moral Duty to Contribute and its Implications for Organ Procurement Policy*, (1992) 25 Transplantation Proceedings 2175

that person should definitely not face potential manslaughter charges if they refuse as suggested by Huffman.[257]

In considering a utilitarian or justice-based theory a similar notion runs through them and that is they appear to dilute emphasis on worth or deviate from it entirely in favour of an alternate emphasis. As Garwood-Gowers puts it "The emphasis utilitarianism places on happiness is a poor substitute for an emphasis on a deeper vision of the development of human capacity and well-being."[258] He argues and I agree that utilitarianism is politically naïve and dangerous in the way that it encourages abuse, not least in the context of medical use of the human body.[259] We are already starting to see a utilitarian influence within the medical community in England, with the recent introduction of a so-called 'opt-out' donation system.[260]

With regards to a justice-based system, why should a complete stranger have a moral duty to save someone else by donating their organs? Furthermore, why should this refusal lead to you being told you have *caused* harm, and that effectively you are *morally responsible* for it? Individuals might be argued to have moral responsibility for leading a good life in general terms but attempts to prescribe how they fulfil this responsibility violate another moral principle that what constitutes a good life and even the choice of whether or not to try and live one should be down to the individual.[261]

[257] Fordham E Huffman, Coerced donation of body tissue: Can we live with McFall v Shimp? *Ohio State Law Journal* 1979 40, 409-440
[258] Austen Garwood-Gowers, Medical Use of Human Beings Respect as a Basis for Critique of Discourse, Law and Practice, (2019) by Routledge
[259] ibid
[260] Organ Donation (Deemed Consent) Act 2019 receiving Royal Assent on 15 March and came into force on 20th May 2020
[261] Garwood-Gowers (n 258)

3.6 Libertarian Theory Ethics

Libertarianism is an ethical theory that holds that the idea of what is best for an individual should be decided by the person in question. A Libertarian theory promotes minimising social and governmental power, action, control, and regulation, by maximising individual liberty and freedom. Libertarians believe that people are the best judges and masters of their self-interest and that they make the best choices when they choose freely for themselves. As with every theory, there are different forms, for example, there is the full-blown anarchist who favours no governmental constraints at all. Their thinking assumes that any rules and laws are unnecessary because, in the absence of government, individuals will naturally form self-governing social bonds and rules. Through to the minarchist libertarians which is a term that has been employed in the literature to describe the minimal state that libertarians allow.[262] Libertarians are still individualists, who emphasise the importance of individual liberty, but they also only consider government necessary for the sole purpose of protecting the rights of the people. This includes protecting people and their property from the criminal acts of others.

Kass notes "how in times past, our successful battles against slavery, sweatshops, and segregation, although fought in the name of civil rights, were at bottom campaigns for human dignity—for treating human beings as they deserve to be treated, *solely because of their humanity.* Likewise, our taboos against incest, bestiality, and cannibalism, as well as our condemnations of prostitution, drug addiction, and self-mutilation—having little to do with defending liberty and equality—all seek to defend human dignity against (voluntary) acts of *self*-degradation."[263]

Kass's viewpoint although dealing with different issues can effectively be applied to organ donation programs, this would then ensure that donors would be treated as humans and as such would have their dignity protected. But, because there is a drive to increase the

[262] Tibor R Machan, "Anarchism and Minarchism: A Rapprochement", From *Journal des Économistes et des Études Humaines* 2002 12(4): 569–588.
[263] Leon R Kass, Defending Human Dignity, Part 4: The Source and Meaning of Dignity, The President's Council on Bioethics, pg. 297 Washington, D.C. March 2008

number of potential organ donors, more jurisdictions are moving to opt-out/implied-based consent, and as such it feels like the idea of protecting dignity is being eroded. I find it hard to argue that having an opt-out/implied consent system is a suitable way to protect a person's dignity, how is expecting one to donate their organs just because they do not need them anymore respecting their dignity?

Libertarian thinkers such as Smith,[264] claims that libertarian ideas are inherent in our ordinary moral psychology. He grounds his view in a deeply social view of moral psychology and argues that although benevolence along with justice are pillars of society, we cannot expect people to have the obligation to assist others. Again, as with Kass, this demonstrates that we cannot expect or force people to care for distant strangers in the same way as they care for themselves. As humans we have the absolute right to control what happens to our bodies, this means that others do not have an automatic right to any of our body parts, no matter how great their need, even after death. Sperling remarks, "More generally, it will be argued that members of the human community have elementary interests which must not be sacrificed or overridden for the sake of collective welfare or other goals in society. One such interest is the interest in having one's body left alone unless proper authorisation is given."[265] Another argument to consider is that if human dignity can be violated by opt-out/implied consent programs, then the same can be said if a donor has given informed consent/authorisation and there is an attempt to overturn this by the relatives as this too goes against the interests of the potential donor.

This issue has been discussed by Kluge,[266] who in 1997 was very critical of the organ protocols in Canada, mainly because those who were implementing them were ignoring the current organ-donor laws in Canada. He stated that because relatives were allowed to refuse donation even though the donors had given consent was potentially causing an organ

[264] Adam Smith, 1759 [1976], *The Theory of Moral Sentiments*, D.D. Raphael and A.L. Macfie (eds.), Indianapolis: Liberty Fund

[265]Daniel Sperling, *Posthumous Interests: Legal and Ethical Perspectives* (Cambridge University Press, 2008), p. 117 [Sperling, Posthumous Interests].

[266]Eike-Henner Kluge, *Decisions about organ donation should rest with potential donors, not next of kin*, Canadian Medical Association Journal, 1997; 1517:160-161

shortage. He went on to say: "Every organ that is not retrieved represents not only a potential death or continued disability but also an increased drain on society's health care resources. The retrieval protocols also raise serious ethical issues. In effect, the societies are saying that they do not consider informed donor consent to be binding. The societies have argued in favour of the protocols by saying that if they retrieved organs against the wishes of next of kin, they would be perceived as ghouls."[267]

With regards to organ donation, my preferred stance is that of a minarchist libertarian as it allows for the individual, if they can, to make their own decision on the subject, yet will offer protection to those who lack the capacity to do so. Minarchist libertarianism as a theory could allow organ donation to continue from potential donors who are not yet dead. If carried out properly, informed consent, which would include the information that based on the balance of probabilities at the time of organ procurement the patient may not be dead, would be sought from the individual which should not be able to be overruled by relatives when the time comes. It will also mean that if no decision was made then relatives cannot be asked to second guess what the individual would have wanted. The flip side of this it can be argued that a relative is best placed to protect the dignity and worth of their relative, it may be the fact that at the time the potential donor decided to donate their organs they were not in fact fully informed of the process, especially in relation to the diagnosis of death.

There is an impulse in society to protect individuals from themselves, this paternalistic view has often been seen in medicine in the past, but there comes a point where individuals should be left free to do certain things that are against what others regard as their real interests, for example refusing treatment.[268] This is important, not just as a matter of

[267] ibid

[268]Lord Donaldson MR in Re T *(Adult: Refusal of Treatment)* [1993] Family Law 93, "This situation gives rise to a conflict between two interests, that of the patient and that of the society in which he lives. The patient's interest consists of his right to self-determination—his right to live his own life how he wishes, even if it will damage his health or lead to his premature death. Society's interest is in upholding the concept that all human life is sacred and should be preserved if possible. It is well established that in the ultimate the right of the individual is paramount".

respect for them and in order to avoid a slide to totalitarianism but because there is no reason to assume, all things being equal, that society knows best, after all surely it is the individual who really knows what is in their best interests better than any others do. While it can be argued that the dead may be harmed by having their organs excised contrary to their pre-mortem wishes, the same should apply in cases where potential donors have their wishes thwarted because a relative refuses to allow the donation to go ahead.

3.7 Conclusion

Ethical or moral theories can be described as either compatible with respect or they can be seen to be incompatible. This is either because they formally reject the notion that respecting human beings as ends is imperative or because they undermine what such treatment entails. As seen within this chapter, those theories which can potentially fall into the incompatible category are typically underpinned by specific notions such as justice and utility. These notions appear to disregard the fact that all human beings are owed respect and that all human beings have equal claim to respect; including deceased humans and humans who lack sufficient mental capacities, such as the severely mentally ill, those in persistent vegetative states, very young children, and the foetus. It is important that the notion of respect is maintained and at the center of any decisions that are made with regard to the use of the human body.

The subject of death and the subsequent decisions surrounding organ transplantation is a very complex area because the human body evokes various beliefs, symbols, sentiments, and emotions as well as various rituals and social practices. From a rationalistic standpoint, some policies to increase the supply of transplantable organs may appear to be quite defensible but they turn out to be ineffective and perhaps even counterproductive because of inadequate attention to these rich and complex features of human body parts.

Excessively rationalistic policies neglect deep beliefs, symbols, sentiments, and emotions, and the like, that deficiency marks many actual and proposed policies.[269]

Having considered several different ethical principles and the implications that they can have on organ donation it becomes clear that all is not satisfactory. I am not the first and probably will not be the last to come to this conclusion. After all, Engelhardt over the last thirty years has maintained that the relevant parties have radically different first premises and rules of evidence and that philosophical reflection not only does not, but simply cannot deliver common bioethics.[270] Other commentators feel that bioethics faces a crisis of purpose, a crisis of principle, a crisis of expectations, and a crisis of authority.[271] Hall, for example, states that "… bioethics is no longer entirely sure what it is supposed to be doing. What purpose does it serve? Bioethics should help us identify ethical principles to control or at least influence medical decision-making. In reality, the picture is much more complex."[272] But, should it be, Miller and Truog[273] make an argument that rather than the current practices of death and organ procurement being constantly having their ethical merits scrutinised, they think that bioethics should be made to "harmonised with the reality of the practices." To achieve this, they call for the abandonment of the DDR, and for it to be acknowledged that death in the eyes of the law is not the same as death in fact according to a biological definition.

Many of the continuing problems of cadaveric organ procurement are based on the issue of balance. Although there are some who call for the complete abandonment of cadaveric organ procurement programs, much of the community wants to see a balance between conflicting issues. There needs to be a balance between procurement programs, saving

[269]James F Childress, The failure to give? Reducing barriers to organ donation, *Kennedy Institute of Ethics Journal*, 2001 Mar; 11(1) 1-16
[270] H. Tristram Engelhardt Jr. Foundations of Bioethics, 1996 New York: Oxford University Press; H. Tristram Engelhardt Jr. Foundations of Christian Bioethics, 2000 Amsterdam, The Netherlands: Swets & Zeitlinger
[271]Lauren K Hall, A Classical-Liberal Response to the Crisis of Bioethics, The Independent Review, v.15, n.1, Summer 2010
[272] ibid
[273] Franklin G Miller, and Robert Truog, 2010 The dead donor rule: Can it withstand critical scrutiny? Journal of Medicine and Philosophy 35:299-312

human lives/preserving human health alongside dignity, religious and moral concerns, long-term consequences, and patient autonomy. Ultimately, for any bioethical principle to be applied to cadaveric organ procurement it needs to recognise the limitations imposed by the human condition and the complex desires and values that make up human nature. It may be that such a principle will be unwieldy, messy, and frustrating, much like human life, but only a bioethical principle that resembles human life in these ways can best inform decision-making about health, life, and death.

4.1 Introduction

The current ethical framework for the transplantation of vital organs requires that donors are determined to be dead prior to organ procurement, this is known as the DDR. During the last two chapters, I have reviewed the ethical theories and medical practices that are currently being implemented in organ donation programs and how these practices are influencing the diagnosis of death. I have also put forward the argument that these current practices although often argued to be consistent with the DDR, when in fact, violate it.

The latest research that I reviewed for the death chapter suggests that so-called brain-dead donors, although drastically compromised neurologically, remain fully alive, while being maintained on life support. As for those who are treated as dead under circulatory criteria, it is clear that those criteria are not robust enough in terms of time waited to ensure that they have irreversibly lost either circulatory or brain function. I have reached this conclusion based on research that has shown there was a return of circulation which was not detected until 20 minutes after resuscitation was abandoned.[274] There is also a paper by Rodriguez et al.[275] that reported three out of 48 patients who were entered into an uncontrolled non-heart-beating donation protocol had a return of spontaneous circulation during the transfer to a transplant centre, one of whom went on to make a good neurological recovery.

If people are de facto potentially alive then there is clearly a moral issue with treating them as dead – it conflicts with the emphasis on the worth or sanctity of life and widely held notions of human dignity or worth on which these are based. We ought therefore to start with the position that procurement of organs should only proceed based on ethico-legal criteria applicable to the living, - excluding, in particular, the removal of organs or parts of organs that are essential to life or wellbeing. The question is would this scenario be

[274] Wolfgang H Maleck, Swen N Piper, Johannes Triem, Joachim Boldt, Franz U Zittel, *Unexpected return of spontaneous circulation after cessation of resuscitation (Lazarus phenomenon)*, Resuscitation, 1998; 39: 125-8
[275] Alonso Mateos-Rodríguez, Luis Pardillos-Ferrer, José María Navalpotro-Pascual, Carlos Barba-Alonso, María Eugenia Martin-Maldonado, Amado Andrés-Belmonte Kidney transplant function using organs from non-heart-beating donors maintained by mechanical chest compressions, Resuscitation 2010 81(7):904-7

endorsed by the medical community and the general public? The answer is it would have to be accepted within current medical and ethical boundaries. Although this has the potential to effectively reduce or put an end to life-enhancing/saving transplantation operations which may be unpopular in the medical community, popularity is not the issue at hand it is considering what is right.

Existing systems for so-called cadaveric organ procurement throughout the developed world typically describe themselves as consent-based. However, there are systems that allow organs to be extracted for transplantation in the absence of anyone having objected. These so-called opt-out systems lack the necessary ingredient of agreement that is central to an ethically and semantically credible notion of consent. For example, the UK's approach to organ donation has historically been based on an altruistic and voluntary act,[276] and has depended heavily upon public goodwill, but this is beginning to change. Since 2015[277] there has been a gradual introduction of opt-out systems throughout the UK, which means that all adults agree to become organ donors when they die unless they have made it known that they do not wish to donate.[278] With this in mind, it is especially important that the public accepts the medical diagnosis of death, for example, that brainstem death is not an 'early' diagnosis of death and that in the case of controlled DCDs, treatment will only be withdrawn or withheld if it is deemed futile and not in the patients best interests, not because they would make a suitable organ donor.

As discussed in the chapter on death, in England and Wales there is no statutory definition of death, there is nonetheless judicial precedent which defers to medical guidelines.[279] Is there an argument for potential change in this area, should there be a legal definition, and would it help? This approach is quite different compared with other nations, for example in the United States there is legislation in place in the form of The Uniform Determination of

[276]Cynthia Kapoor, C., *The removal of organs from cadavers: a utilitarian perspective*, UCL Jurisprudence Review,1994 1:104-117

[277] The legislation for Wales is now 'deemed consent' since December 2015, England's law changed on the 20th May 2020 and Scotland's law changed on the 26th March 2021

[278] https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-england/

[279] *Re A. A Child*. 2015. EWHC 443 (Fam)

Death Act (UDDA) 1980, of which many states have adopted it. Under section one of the act, states that "an individual who has sustained either irreversible cessation of circulatory and respiratory function, or irreversible cessation of all functions of the entire brain, including the brainstem, is dead."[280] So does this mean that there are in actuality two types of death, as is sometimes thought by people?[281] The answer is no, when we are dealing with a concept that refers to a state that exists or does not, it is intrinsically something singular and objective in nature. Disputes and uncertainties around it are largely simply disputes and uncertainties over what that objective nature is.

One of the concerns I have with the diagnosis of death in England and Wales is that, if brainstem death is seen by the courts[282] and the medical profession as the definitive criterion for diagnosing death then how is DCDD legally permitted? Is what the medical profession and courts trying to say is that death is not dependent on whether circulation can be restarted as this is not the determining factor. The determining factor is whether after the period waited the brain can still function or not but the way in which the medical community determines this waiting period seems to be the arbitrator and dependent on which country you are in. The problems that can be encountered using this surmising approach were highlighted in the death chapter, where the appropriate amount of time to wait before the declaration of death and the retrieval of organs was discussed. If there could be an agreement on an appropriate time, it would have to consider empirical data that not only indicates some people recover circulatory function but there is also evidence to show that they have brain function too. Of course, there is also the issue that not every country supports a DCDD program, for example, Germany does not have a program as it is illegal.[283] In Norway, a preliminary cDCDD protocol was temporarily suspended in 2017, due

[280] Uniform Determination of Death Act (UDDA) 1980
[281] James L Bernat, (ed) in *Ethical Issues in Neurology*, 243-281 (Butterworth Heinmann, Boston, USA, 2002)
[282] Lord Lane C.J. in *R v Malcherek* [1981] 2 All ER 422; *Airedale NHS Trust v Bland* [1993] AC 789
[283] Beatriz Domı´nguez-Gil, Bernadette Haase-Kromwijk, Hendrik Van Leiden, James Neuberger, Leen Coene, Philippe Morel, Antoine Corinne, Ferdinand Muehlbacher, Pavel Brezovsky, Alessandro Nanni Costa, Rafail Rozental and Rafael Matesanz, Current situation of donation after circulatory death in European countries. Transplant International 2011 24(7):676–686. h

to disputes among health professionals.[284] An issue a raised in the fact that physicians from different Norwegian hospitals were unable to agree on when patients should be considered dead, and how death should be correctly diagnosed in cDCDD protocols.[285]

I also have concerns that the current system in place within England and the rest of the UK purports to protect and respect the donor's dignity/autonomy yet, there appears to be no flexibility when issues regarding religious views or personal beliefs are raised. As it stands now if a patient is declared brain stem dead, then medics can remove life support, regardless of previously known views such as religious, or personal beliefs even though these form the basis of the best interest test. Throughout the chapter on death, I demonstrated that not only is there still controversy over testing and diagnosing death but also that there is a need to have a higher standard and more credible approach to the subject one that is more conservative in its approach to protect. If this cannot/will not happen, then perhaps a compromise should be a more flexible approach to protect people at their most vulnerable. Should death be viewed as more of an objective concept, every person tends to have an opinion on how they view death be it guided by religion, society, or cultural beliefs and these should be allowed to form the basis of any decisions taken when it comes to death.

Given that England and Wales are multicultural societies it would make sense for them to adopt such an approach to death. It would offer reassurance to the person involved that their views and opinions will be considered when the time comes, and in turn, it could potentially also help a donor system. After all, this flexibility is not a radical idea as other countries allow for religious views, for example, New Jersey and New York State in the US and Japan.

[284]Mar Lomero , Dale Gardiner , Elisabeth Coll , Bernadette Haase-Kromwijk , Francesco Procaccio , Franz Immer , Lyalya Gabbasova , Corine Antoine , Janis Jushinskis , Nessa Lynch, Stein Foss , Catarina Bolotinha, Tamar Ashkenazi, Luc Colenbie, Andreas Zuckermann , Milos Adamec, Jarosław Czerwinski, Sonata Karciauskaite, Helena Strom, Marta Lopez- Fraga, Beatriz Dominguez-Gil Donation after circulatory death today: An updated overview of the European landscape. Transplant International 2020 33 (1):76–88.
[285] Emil J. Nielsen Busch, Marius T. Mjaaland Does Controlled Donation after Circulatory Death Violate the Dead Donor Rule? The American Journal of Bioethics 2022 23(2):4-11

Japan's history with organ transplantation has been a difficult one mainly due to the country's unique views towards life, death, ethics, and religion. The four main religious beliefs in Japan Shinto, Taoist, Confucian, and Buddhist led to a social consensus that organ transplantation devalues life, as well as the afterlife.[286] This strong negativity meant that it was not until 1997 that the country introduced its first Organ Transplant Law.[287] The legislation contained more stringent regulations compared with other countries to reflect the country's strict religious beliefs. The law allowed for a potential donor to be declared brain dead only if "...the donor expressed in writing before death his/her intent to agree to donate his/her organs and agree to be submitted to an authorized brain death declaration, and his/her family members (spouse, parents, children, grandparents, grandchildren, and live-in family members) did not object to the donation."[288] Only when these two strict conditions are met will a brain-dead patient be considered legally dead for the purposes of an organ transplant.[289] The reason for this ability to refuse or accept a brain death-based standard was because there was a disagreement between the lower diet and the upper diet of the Japanese parliament. The lower approved a measure that would legalise the determination of death by brain-based standards. Although the bill was rejected by the upper diet, this resulted in a compromise being reached between the two diets, and a resolution was passed in June 1997 which allowed for those who accepted brain-death determination and those who rejected it.

Since its introduction a review of the legalisation took place in 2010 this resulted in some changes, the main one being that even if an individual's intention is unclear, donation of their organs is now possible, under family consent. A change in age restrictions also means that donation of organs after brain death by children under the age of 15 is now possible.[290] This flexible approach taken by Japan shows that it is possible to have two separate approaches to death to reflect the current thinking of a country's population. It

[286] John Robert McConnell, III, The ambiguity about death in Japan: an ethical implication for organ procurement, Journal of Medical Ethics 1999;25:322-324
[287] The Enactment of the Organ Transplantation Law, and the revised Organ Transplant Act, https://www.jotnw.or.jp/en/04/ (accessed 2nd December 2022)
[288] ibid
[289] Emily Jackson, *Medical Law: Text, Cases and Materials*, Oxford University Press, 2nd Edition 2010
[290] n 287

may require more of an effort to police it, but should that really be a reason not to consider the thoughts and wishes of the public as a whole?

4.2 Aims

This chapter aims to answer the question is there a case for the reform of the so-called system of cadaveric procurement of organs for transplantation. In doing this I will reflect on the outcomes of my research, which suggests that potential organ donors are not yet dead at the time of organ procurement. I will argue that the potential organ donor should have their rights protected in the same way as the conscious person. In an ideal world, any suggested procurement system should include a universal consensus on the definition of death that can ethically and morally allow organ donation programs to carry on. As it is this is unlikely to happen, I will conclude that any reforms should be based on libertarian and dignitarian/worth ethical thinking, with religious/cultural views of the community the legislation is meant to serve. To finish off the thesis I will question why the current transplant laws in England have undergone major changes to an opt-out system[291] without considering the problems posed by this thesis.

4.3 How should Post-mortem Donation be set up?

There is no getting away from the fact that with any system that a country sets up the central theme that they push is the limiting factor when it comes to organ transplantation, which is the availability of suitable donors and organs. Therefore, it is the first thing that is mentioned in any publicity, and it was the main driving force behind the UK setting up the UK Organ Donation Taskforce in 2006. Although it has since been disbanded by the UK Coalition Government in 2011, the task force remit was to identify barriers to organ donation and recommend actions needed to increase organ donation and procurement.

[291] Organ Donation (Deemed Consent) Act 2019, the so called 'Max and Keira's Law

Throughout the transplant community, there are three systems to which potential organ donors can be recruited, presumed consent (deemed/opt-out), under this system of organ donation following death a patient is automatically considered a donor unless they have specifically registered their wish not willing to donate. However, in some countries with a presumed consent law, doctors will still ask permission from relatives, this is known as a 'soft' opt-out system. 'Informed' consent (opt-in) is a voluntary system whereby the potential donor registers their intention to donate before death. This system can also allow for the relatives to give permission at the time of death, usually in the knowledge that the potential donor had expressed a wish to become a donor. Finally, there is the required request system, this can be seen in the USA, where the physicians in charge of potential donors are required to ensure that someone speaks to the family about organ donation.[292]

Every country that practices organ donation has its own variation on a system, be it an opt-in or opt-out system, and each country legislates for their preferred option which they think will increase the amount of donations. For example, in 1997 Brazil changed its donation laws to a hard opt-out system[293] with the aim to increase organ donation rates and to reduce the amount of organ trafficking. This change evoked much criticism even before it was implemented because under the proposed legislation the Brazilian government made every citizen an organ donor after death unless there was a personal documented objection against donation. The criticism of the legislation came from medical organisations, such as the Brazilian Medical Association and the Federal Council of Medicine. Most doctors who were involved in treatment were also unwilling to remove organs without family consent, even if the law demanded them to do so. Due to this pressure, the Brazilian government relented and abolished presumed consent in 2000. The main issues cited for Brazil's problems and eventual abandonment of presumed consent were down to i) lack of ample discussion about organ donation, especially about the concept of brain death, which had caused fear in some of the population that organs would be removed before they were clinically dead; ii) hesitation of surgeons to remove organs without family authorisation; iii)

[292] https://www.eurotransplant.org/about-eurotransplant/legislation/
[293] D.O.U. No. 9.434, de 4 de fevereiro de 1997, D.O. 1997

as most poor Brazilians do not have personal identification (ID or driver license), it meant they had no way of objecting to donation while alive.[294]

Colombia introduced its own hard opt-out legislation on 4 August 2016.[295] Like the law introduced in Brazil, it provides that all citizens over 18 years of age will be considered as potential donors at the time of death unless they had registered their opposition during their lifetime. If a person had given permission for organ donation, then their family cannot legally reverse their consent to donate.

Colombia's law and Brazil's abolished law can be described as hard opt-out systems as family members are generally given little if any input to the decision to donate organs if the deceased patient has not left any instructions. An example of a soft opt-out system can be seen in the Netherlands' new donation law which came into force in July 2020. The Netherlands' so-called no-objection system means that every unregistered citizen in the Netherlands will receive a letter asking them to make a decision on organ donation. They could choose to become an organ donor, to become a non-donor, or to leave the decision to next of kin (same options as the current opt-in system). When they fail to respond, they receive a reminder six weeks later. When still no decision is made, they will automatically be registered in the donor registry with a no-objection registration.[296]

In stark contrast to Colombia's law and Brazil's abolished law, New Zealand does not have a national register for recording people's consent to being an organ donor. Instead, the information on a driver's licence is the closest thing they have to a register. But having "Donor" on a person's licence does not itself count as giving informed consent to organ

[294] Giácomo Balbinotto Neto, Everton Nunes da Silva, Ana Katarina Campelo, The Impact of Presumed Consent Law on Organ Donation: An Empirical Analysis from Quantile Regression for Longitudinal Data, Working Paper of Public Health nr. 3/2012

[295] Act1805 2016 http://es.presidencia.gov.co/normativa/normativa/LEY%201805%20DEL%2004%20DE%20AGOSTO%20DE%202016.pdf

[296]Nederlandse Transplantatie Stichting (NTS) https://www.transplantatiestichting.nl/page/frequently-asked-questions

donation, it is used as an indication to medical staff that the person is a potential donor. From that, they will ask the family if they knew if their relative had clearly given or refused consent, apart from the indication on their driver's licence. This process is also applied in the reverse situation, saying no to being a donor when you apply for your licence or renewal does not count as an informed objection, so family members will be asked for an opinion. The New Zealand Human Tissue Act 2008 also allows a doctor to decide not to act on consent given by the deceased, and doctors have usually always used this freedom to choose not to go ahead with organ donation if the family opposes or is distressed about it.[297]

In 2007 the then Labour Government asked the Taskforce to undertake a review of opt-out and consider the potential impact of such a system in the UK. The resulting report[298] recommended that an opt-out system should not be introduced in the UK at that time. The Taskforce concluded that there was no evidence to suggest that an opt-out system would deliver significant increases in the number of donated organs, but it would instead undermine the concept of donation as a gift and might erode trust in NHS professionals and the Government.[299] This stance has since changed with the recent introduction of opt-out systems in Wales, England, and in Scotland on 26th March 2021.

Throughout, the next sections I will put forward arguments as to why this should have not happened, while there are still many other problems surrounding procurement systems that have seemed to have been overlooked. I will consider issues that I feel should have been addressed before implementing a new system, including but not limited to, consent, pre-/post-mortem intervention, religious/social views, limiting the type of donation, removal of the DDR, reducing the reliance on organ donation and possible consider stopping transplants altogether.

[297] New Zealand's Human Tissue Act 2008, ss 14, 16–18, 31(2)(a)
[298] The Potential Impact of an Opt-Out System for Organ Donation in the UK: An Independent Report from the Organ Donation Taskforce, 2008 at 34 [The Potential Impact]
[299] ibid

4.3.1 Changes to consent

The role of consent concerning the procurement of organs for transplant is much disputed. This is partly because the ends that consent is seen as serving are themselves disputed. A utilitarian, for example, will treat consent as a functional tool, to be protected to the extent that protecting it serves the common good. By contrast, a libertarian or dignitarian will treat it as one of the means of supporting and maintaining dignity/respect for the individual.

The latter vision is more consistent with European ideals of democracy and human rights and with the rhetoric of donation – a term that implies a real choice to give something up. However, whilst transplant law tends to refer both to donation and to consent one cannot escape the impression that it is prepared to sacrifice robust respect for these to the end of attempting to maximise use.

The terminology of donation and consent implies a considered, informed, positive, choice of giving, yet standards for post-mortem extraction of organs for transplantation fall short of this. Current systems typically describe themselves as consent-based but, they are not based on an ethically and semantically credible notion of it. Some allow organs to be extracted for transplantation in the absence of anyone having objected (so-called opt-out systems) and others allow them to be extracted when the person giving is not the person with whom the material belongs but a next of kin. Furthermore, in the limited circumstances that the extraction is premised on the decision of the person from whom the material comes or a proxy (s)he has nominated, that decision is rarely what one might describe as informed. Only a small proportion of those who are considering becoming a donor are aware of the implications that flow from this. In particular, the potential post and pre-mortem interventions and even specific definitions of death that they might be subject to in order to best facilitate the use of their material. It is not that information about these matters is specifically covered up so much as the fact that the donor card signing and other systems that operate to ‘secure consent’ do not include information about them.

One of the key arguments made against the use of presumed consent is the concern that presumed consent is in fact not consent at all and that consent would no longer be involved in the process of organ acquisition. This situation could then have the potential to create a procurement system that is unclear and open to ambiguity. Garwood-Gowers has argued that there is no such thing as 'presumed consent' in philosophical or legal terms, consent is either implicit or explicit or it does not exist at all.[300] In a later publication, Garwood-Gowers states that the continuing use of the term presumed consent is allowing the public to be deceived into believing that their autonomy is being respected and therefore making them more amenable to an opt-out system.[301] McLachlan on the subject stated that: "To say that it can reasonably be presumed that we consent to donate our organs if we do not specifically say that we do not consent is absurd. It is a deceitful piece of sophistry. There might be a good utilitarian case for having an opt-out rather than an opt-in system of organ donation. However, this would mean that there is a case for using our organs even in the absence of our consent. If consent matters in this area, then only the explicit consent of the people concerned can justify the use of their organs after their deaths. If consent does not matter and the use of their organs can be justified without it, then consent does not matter. We should not appeal to the bogus notion of presumed consent."[302]

There is also the argument that it could be interpreted those organs that are taken under a presumed consent law are no longer gifts or donations in the true sense of the word, they have been 'taken' from the dead. This could lead to some problems with religious groups and leaders who have long said that organ donations are seen as acts of giving a gift which is permissible under some religious texts.

[300] Austen Garwood-Gowers, 'Extraction and use of body materials for transplantation and research purposes: The impact of the Human Rights Act 1998', in Austen Garwood-Gowers, John Tingle and T. Lewis (eds.), Healthcare Law: The Impact of the Human Rights Act 1998 (London: Cavendish Publishing, 2001) 295 at 310.
[301] Austen Garwood-Gowers, Time to Address the Problem of Post-Mortem Procurement of Organs for Transplantation Occurring without Proper Pre-mortem Consent, European Journal of Health Law 20 (2013) 383-40
[302] Hugh McLachlan, 'Presumed consent is no consent at all' at https://www.bmj.com/rapid-response/2011/11/01/presumed-consent-no-consent-all (Accessed 12th July 2021)

There is also the continuing issue of no/lack of information given to potential donors or families about organ preservation techniques or diagnosis of death. For example, in England with the introduction of presumed consent in 2020 there is no reference to DBD or any other pre-mortem measures such as canulisation, where an intravenous tube is used to give fluids to the patient to ensure that organ quality is maintained. The potential donor is also unlikely to know that several post-mortem measures can take place after death in order to preserve organs. This of course is nothing new as it is a continuation from previous systems and again raises the question should potential organ donors be told of these risks? Could the ruling in Montgomery[303] apply, would a reasonable patient consider the fact that there are still uncertainties surrounding the diagnosis of death a material risk when considering organ donation? If so, then the doctor is under a duty to take reasonable care to ensure that the patient is aware before they make their decision to donate.

Others have argued that people would feel pressured into donating organs and not opting out because this would be seen as socially unacceptable. This theory can be seen in England, where 80% of people in England said when asked that they were willing to or would consider donating some or all of their organs, yet only 37% have recorded their decision on the Organ Donor Register.[304] These statistics potentially show that what people say in public for the show is completely different from what they do when the time comes.

Many opponents of presumed consent see hardly any difference from conscription, and the fact that you can simply register your objection still does not make it right as it assumes that the public knows this fact. This is a big assumption, and it would be wrong to refer to the usual every citizen is supposed to know the law, especially given the circumstances in which the new legislation was introduced.[305] There needs to be a more concerted effort from the

[303] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

[304] The New Approach to Organ and Tissue Donation in England - Government Response to public consultation, The Department of Health and Social Care, 5th August 2018. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731913/govt-response-organ-donation-consent.pdf

[305] The Organ Donation (Deemed Consent) Act 2019 was introduced into England in 2020 during the Covid-19 pandemic.

government and NHS to take steps to provide the public with the relevant information in a way that makes it easily accessible before the time comes to make the decision. Treating people as having given consent to donating their organs when they have been kept in the dark about the implications of doing so, is inconsistent with respecting their worth and with the normative emphasis that health and human rights law place on informed consent to medical intervention.[306]

The main arguments for having a presumed consent system in place are that it will:

1. It will have greater effect on the wishes of the now-deceased person (potential organ donor)
2. It will remove the burden of decision-making from the recently bereaved relatives, except for parents of young children
3. It will increase the pool of potential organ donors and in turn the number of organs available for transplantation.

Shaw[307] has argued that the move to deemed consent could actually benefit people who do not want to donate their organs *because* it forces them to opt-out. He states that under the old system, many such people probably assumed that their organs would not be taken if they did not opt-in, but that is not correct.[308] Under the new opt-out system, those who register a refusal to donate will effectively prevent their families from doing this. Thus, objectors may benefit from being forced to take action. Spital and Taylor put forward a case for entirely removing the need for consent for the routine recovery of transplantable cadaveric organs.[309] They claimed that a presumed consent system is more ethical than

[306] Austen Garwood-Gowers, *Medical Use of Human Beings: Respect as a Basis for Critique of Discourse, Law and Practice*, Taylor & Francis Group, 2019.
[307] David M Shaw, The side effects of deemed consent: changing defaults in organ donation. *Journal of medical ethics* 2019*,* 45(7), pp. 435.
[308] As stated in the introduction, in cases where there is no evidence under 'opt in' in England, Scotland and Northern Ireland, families can consent to donation.
[309] Aaron Spital, James Stacey Taylor, Routine recovery of cadaveric organs for transplantation: consistent, fair and lifesaving. Clinical Journal of the American Society of Nephrology 2007; 2: 300-303

explicit consent as routine removal of organs allows for equity and avoids added stress on grieving relatives.

The idea behind consent is that it is put in place to prevent a person from being used to an end. A libertarian vision of consent implies that individuals should control what happens to their bodies after death – such that they are left free from its use in the transplant context unless they have either made a positive decision to donate or granted the power to do so to another.

A dignitarian vision must contemplate that there are certain actions upon the body are unacceptable even with consent but in other respects are likely to mirror the libertarian vision. Whilst the dignitarian would indeed contemplate making decisions for those who cannot make them for themselves this would only be to the end of providing necessary protection. If a person has not decided about donation before death, there is no necessity served by speculating on what they might have wanted to happen to their body in a context where it can simply be left alone.

These ethical philosophies recognise the fact there is an inherent worth in protecting the body, they also fit with how organ procurement is described – the rhetoric of donation and gifting – which implies a real choice to 'offer something up' rather than something being taken. Current transplant laws tend to refer both to donation and to consent, but no system be it either opt-in/out matches up to either the libertarian or dignitarian standard.

One of the key issues with consent is the fact that it can legally take many forms,[310] but surely the basic semantic core of consent is agreement and in order for this the potential donor must have all the information they require to make an 'informed' choice. For England, Wales, and Northern Ireland, The Human Tissue Authority (HTA) states that for

[310] This fact was discussed by Professor David Price in David Price, Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework, Cambridge University Press, 2010

consent to be valid, the person should understand what the activity involves and, where appropriate, what the risks are. When seeking consent, healthcare professionals or other suitably experienced people should ensure that it is appropriate for the intended purpose.[311] None of this happened when all potential donors had to previous do under the old legislation was sign a donor card or add the option to their driving licence or Boots Advantage Card.[312]

The HTA had also stated that it believed that presumed consent for organ transplantation might undermine the current provisions for fully informed consent in the 2004 Act.[313] But this stance has seemed to have recently changed in Wales where the Welsh Government implemented an opt-out system in 2015,[314] whereby a person's consent to donation will be deemed to have been given unless they objected during their lifetime. A similar system was introduced in England in May 2020[315] and Scotland introduced changes to their law in March 2021.[316] But even with these changes the information provided on the Organ Donation UK[317] website still appears to be designed to convince people to donate. It's almost as if it has been set up as an advertising website, selling the virtues of organ donation, with little information clearly given as to what must happen in order to facilitate the procedure. This is not just restricted to the UK, a research group in the US published a study stating a similar problem. Woien *et al,* wrote: "Our findings showed that the disclosure on OPO websites and in online consent forms lacked pertinent information required for informed enrolment for deceased organ donation…The websites predominantly

[311] Human Tissue Authority, Code of Practice 1 Consent: the fundamental principle, para 32 http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?FaArea1=customwidgets.content_view_1&cit_id=662&cit_parent_cit_id=652

[312] The Boots Advantage Card is a loyalty card scheme ran by Boots throughout the UK, a similar scheme is also running throughout the Republic of Ireland (ROI)

[313] Human Tissue Authority News release, 'Statement on Chief Medical Officer's announcement', 24th July 2007

[314] Human Transplantation (Wales) Act 2013 https://www.legislation.gov.uk/anaw/2013/5/contents/enacted

[315] Organ Donation (Deemed Consent) Act 2019 https://www.legislation.gov.uk/ukpga/2019/7/contents

[316] The Human Tissue (Authorisation) (Scotland) Act 2019 is due to be introduced March 2021 https://beta.parliament.scot/bills-and-laws/bills/human-tissue-authorisation-scotland-bill

[317] https://www.organdonation.nhs.uk/

provide positive reinforcement and promotional information rather than the transparent disclosure of the organ donation process."[318]

Consent is a concept that is fundamentally important in medicine, it is used in assessing the legitimacy of medical procedures and will allow medics to carry out their work without the fear that the patient will claim that the procedure constituted a battery under civil law[319] or an offence under criminal law.[320] For consent to be valid for a medical procedure, it must be made voluntarily by a competent,[321] informed individual and the act must not contravene public policy. For all tenses and purposes, it appears that these requirements are not fulfilled with the new opt-out system or the system that it replaced.

For example, at the time of consenting to donation, little information about the process is given to potential donors. Many people at the time of consenting have given little thought to what organ donation means, and what it involves. Most have no idea that their organs may be taken in circumstances in which their relatives may not be completely sure that they are dead. Little is done to explain to people what is involved in diagnosing death by the different criteria or the differences of opinion that exist about such diagnosis. Few realise that organ donation may mean saying goodbye to loved ones while their heart is still beating, and artificial ventilation continues. Few seem to expect donation after death to involve the concept of a 'beating heart cadaver'. Furthermore, before potential donors have been identified General Medical Council (GMC) guidelines and the Organ Donation and Transplantation (OTD) NHS allow for a delay in withdrawal of treatment to carry out an assessment for donation. Their guidelines stipulate that "provided that delay is in the patient's overall best interests' life-sustaining treatments should not be withdrawn or limited until the patient's wishes around organ donation have been explored and the clinical

[318]Sandra Woien, Mohamed Y Rady, Joseph L Verheijde, Joan McGregor, Organ Procurement Organisations Internet Enrolment for Organ Donation: Abandoning Informed Consent, BMC Medical Ethics, 7 (2006):14
[319] For example, Tort of trespass to the person
[320] For example, the Offences Against the Persons Act 1861
[321] In line with the requirements of the Mental Capacity Act (MCA) 2005

potential for the patient to donate has been assessed in accordance with legal and professional guidance."[322,323]

In addition to delaying withdrawal of treatment, many potential donors or families do not realise that there may be some so-called minimum steps taken to facilitate organ donation. These minimum steps can be both pre-/post-mortem. In an editorial in the British Medical Journal (BMJ), consultants in intensive care note that stabilisation of a patient identified as a donor would probably involve the insertion of multiple cannulas for drug and fluid infusions to maintain circulation, tracheal intubation for mechanical ventilation, and sedation to allow the patient to tolerate these interventions.[324] To my mind these are definitely not minimum steps and have rightly been criticised since they tend to offer no direct benefit to the patient, any benefit there maybe will be seen by the recipient therefore, any intervention that is carried out once it is decided that treatment is futile could be perceived as an assault, especially as there is no specific informed consent for it. There is also the risk that some interventions may subject the patient to needless pain or even hasten death,[325] an example of this can be seen with the increased chances of internal bleeding due to heparinisation.

One way to overcome this problem could be to implement a more open and informative approach to the consent process. Yet when this suggestion is put forward one can detect some fear amongst clinicians and policymakers that informing people about these practices pre-mortem and encouraging them to make choices might put them off. However, there is an element of double thinking going on in this regard as clinicians and policymakers are also generally quite happy with concluding that various practices are generally going to be in the best interests of donor. The subject of pre-mortem treatment does create a dilemma for not only the medical professionals who have to deal with it in practice but also for the legal

[322] DCD consensus meeting report, available from https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1360/donation-after-circulatory-death-dcd_consensus_2010.pdf (accessed 01.05.2021)
[323] GMC guidance on treatment and care towards end-of-life https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/treatment-and-care-towards-the-end-of-life
[324] Peter Watkinson, Stuart McKechnie, Dominic Wilkinson, Jonathan Salmon, Duncan Young, Actively delaying death to increase organ donation. British Medical Journal. 2012 Feb 17;344: e1179.
[325] Dale Gardiner, Robert Sparrow, *Not yet dead: Controlled Non-Heart-Beating Organ Donation, Consent, and the Dead Donor Rule*, Cambridge Quarterly of Healthcare Ethics, 2010 19:17-26

and ethical commentators; some have taken the stance that professionals should not be asked to provide medications that are not primarily for the benefit of the patient.[326] Others argue that pre-mortem intervention does offer benefits not only to the patient if they wish to be a donor, to the relatives who are left behind.[327]

Whilst reviewing the current organ donation systems it becomes clear that most of them clash with libertarian and dignitarian systems quite sharply. Consent to organ donation should be freely given based on acceptable, truthful, and balanced information and not obtained by language designed to manipulate both medic and patient, even though this is encouraged. The National Institute for Health Care Excellence (NICE) guidance on this subject suggests the use of manipulative language in trying to gain consent from patients and relatives, advising clinicians to use positive ways to describe donation. Under section 1.1.21 of the guidelines it states that when approaching those close to the patient;[328]

- Discuss with them that donation is a usual part of end-of-life care
- Use open-ended questions – for example, 'How do you think your relative would feel about organ donation?'
- Use positive ways to describe organ donation, especially when patients are on the NHS organ donor register or they have expressed a wish to donate during their lifetime - for example 'by becoming a donor your relative has a chance to save and transform the lives of many others'
- Avoid the use of apologetic or negative language (for example 'I am asking you because it is policy' or 'I am sorry to have to ask you')

[326] Morris D Bell, *Non-Heart-Beating Organ Donation: Old Procurement Strategy New Ethical Problems*, Journal of Medical Ethics, 2003:29 176-181; Dale Gardiner, Robert Sparrow, *Not yet dead: Controlled Non-Heart-Beating Organ Donation, Consent, and the Dead Donor Rule*, Cambridge Quarterly of Healthcare Ethics, 2010 19:17-26

[327] John Coggan, Margaret Brazier, Paul Murphy, David Price, Muireann Quigley, Best Interests and Potential Organ Donors, British Medical Journal, 14th June 2008, Vol. 336; *Increasing the supply of donor organs within the European Union*, European Union Committee Report, Published by the Authority of the House of Lords, Volume 1: Report 2nd July 2008; Robert Veatch, *Transplantation Ethics*, (Georgetown University Press, Washington, DC 2000) at 20

[328] https://www.nice.org.uk/guidance/cg135/chapter/1-Recommendations#approach-to-those-close-to-the-patient2:344:e1179

Respect for patients' or their relative's autonomy and dignity is now fundamental to medical ethics both of which are undermined using this manipulative language. This coupled with limited information about deceased organ donation, and no information about ante-mortem interventions to facilitate organ donation makes most donation systems far from being an informed consent process. This is certainly true when opt-out systems or deemed consent systems are considered. It is almost as if these systems rely on the fact that most of the public tends not to want to think about their death. This means that they do not register their objections, which the system in turn deems as consent. This lack of informed consent from the beginning means that any pre-mortem intervention to a patient in order to facilitate organ donation the lack of direct benefit merely, as far as common law jurisdictions are concerned, makes it more difficult to justify the intervention as in fact lawful - but such interventions can be lawful even in some circumstances when performed on incapable adults or incompetent children. For example, if it is known that the patient wishes to be considered as a potential organ donor then this wish should become an integral part of the patient's care in their last days and hours.[329] Interventions specifically designed to facilitate organ donation tend to be performed on someone who is thought to be close to death and would normally be in a coma hence not capable or (in the case of minors) competent to consent.

4.3.2 Pre-/Post-mortem Intervention

Linking in with informed consent is the issue of pre-/post-mortem intervention techniques, all of which offer no direct medical benefit to the organ donor. As discussed in the previous section, the lack of informed consent at the beginning of the organ donation process means that any pre-mortem intervention to a patient in order to facilitate organ donation, plus the lack of direct benefit to the donor, should make it difficult to justify the intervention as lawful. When we are talking about interventions the range is vast, from minor adjustments to treatments, through to placing a donor on Extracorporeal Support (ECS). The following paragraphs will describe some techniques that are used in some organ procurement

[329] Principle 2 stated by the UK Donation Ethics Committee (UKDEC) in *An ethical Framework for Controlled Organ Donation After Circulatory Death*, 2011

programs throughout the world. I will then consider if the present consenting process is not enough to allow for the intervention, and what adjustments would need to be implemented to allow for the intervention.

The first intervention that I will consider was abandoned in the UK before it really took off, Elective Ventilation (EV). EV or the 'Exeter Protocol' was first published in 1990, the method of the protocol was to identify potential patients, for the purpose of organ-preserving ventilation. The procedure was described by David Price as follows: "[Elective Ventilation] protocols target patients in deep irreversible coma and believed to be dying imminently of intracranial haemorrhage. Such patients are transferred with the consent of relatives to intensive care units so that artificial ventilation can be initiated as soon as respiratory arrest occurs, thus preserving the organs until brain death can be established."[330]

Subject to consent, the protocol involved intubation and invasive ventilation after the patient's terminal breath, either on the ward or following transfer to the intensive care unit (ICU). It was argued that ventilation was being initiated at the point when the patient died. Organ donation would follow once death had been confirmed by neurological criteria.

The publication of the protocol in the Lancet[331] led to considerable debate. Some clinicians objected because it was impossible to know for certain that the patient had taken their last breath and that without ventilation they would imminently be shown to have died. It was also suggested that there was a risk of putting the patient into a Persistent Vegetative State (PVS) and that it was unlawful as family members have no power to consent under English law. In 1994 the Department of Health (DH) advised that the practice was unlawful[332] as EV, being non-therapeutic, would not be 'for the patient's own benefit'. In the face of this

[330] David Price, Contemporary transplantation initiatives: where's the harm in them? *Journal of Law and Medical Ethics* 1996; 24:139–49

[331] Terry G Feest Hany N Riad, Charles H Collins, Michael G S Golby, Anthony J S Nicholls, SN Hamad, Protocol for increasing organ donation after cerebrovascular deaths in a district general hospital. *Lancet.* 1990 May 12;335(8698):1133–1135.

[332] Acute Services Policy Unit, Identification of Potential Donors of Organs for Transplantation, NHS Executive HSG (94), 41, 1994

advice, elective ventilation was inevitably abandoned though, its original proponents argued,[333] and continue to argue, that its practice could safely and lawfully have been developed across the UK.

As with everything, over time opinions and views change, recently the British Medical Association (BMA) has called for a debate on this issue in the face of a chronic shortage in the availability of organs for transplantation.[334] In its report on the current state of organ donation, the BMA said the following about EV: "Elective ventilation is not an easy option, but it has been shown to increase donation rates and to facilitate the wishes of a group of patients who want to donate and would otherwise be unable to do so. The BMA is not calling for the law to be changed to permit EV but believes this may be an issue that would benefit from debate both to assess the clinical, legal, and ethical issues raised and to assess public opinion about its use."[335]

In 2016 the UK Donation Ethics Committee (UKDEC) was in the process of completing its work on non-therapeutic elective ventilation (NTEV) before government funding was pulled. In their discussion paper, they offered five recommendations that would need to be considered before NTEV could be considered in the UK:[336] "If, following consideration of the law, the clinical potential, and the wider professional and public response, proposals were made for the use of NTEV, then ethical principles such as those in the UKDEC generic guidance on nontherapeutic interventions should be used to make case-by-case decisions on its use."[337]

To proceed anywhere with EV firstly the medical and legal community will need to overhaul the consent process so that it is informed consent. Potential donors will need to have all

[333] Hany Riad, Anthony Nicholls An ethical debate: elective ventilation of potential organ donors. British Medical Journal 1995; 310:714
[334] Building on progress: Where next for organ donation policy in the UK? British Medical Association, February 2012. https://www.bma.org.uk/media/3729/bma-organ-donation-building-on-progress-feb-2012.pdf
[335] ibid
[336] https://www.aomrc.org.uk/wp-content/uploads/2016/07/Nontherapeutic_elective_ventilation_0416-2.pdf
[337] Recommendation 5 in re-examination on NTEV https://www.aomrc.org.uk/wp-content/uploads/2016/07/Nontherapeutic_elective_ventilation_0416-2.pdf

the relevant information in advance of any decision-making so that they have time to discuss with relatives and ask any questions they may have. This of course would have to take place before organ donation would be an issue for the potential donor, the process could be initiated once a person starts to consider the idea of becoming an organ donor, and the decision could be reviewed regularly so that the information held on that person is up to date. Another way that could potentially allow for EV to take place is with the use of the 'best interest' test.

It was believed that the patient's best interest was solely encompassing procedures that are to be medically advantageous, but best interest must now be defined not just in medical terms, but in terms relative to the values of the patient in question. The Mental Capacity Act (MCA) 2005 states that there are several factors to consider when assessing a person's best interests,[338] including a) the person's known wishes and feelings, in particular, any relevant written statements; b) the beliefs or values that would be likely to influence the person's decision if they had the capacity to make it; c) any other factors they would be likely to consider if they were able to do so; d) the views of the person's family, friends and anyone involved in their care as appropriate as to what would be in the person's best interests; and e) anyone named by the person to be consulted about such decisions.[339] EV for the purpose of organ donation, could be argued to be in the best interest of a patient who has expressed a desire to be a donor under the MCA 2005. For this to be realised there needs to be a change in the consenting process so that there is access to up-to-date information on the patient when the time comes to fulfil their wish to become an organ donor.

The idea of EV does not appear to be ethically objectionable in all nations. For example, in the US, if a patient has expressed a desire to be an organ donor and subsequently suffers a critical brain injury with family consent, mechanical ventilation would be allowed to continue until brain death. In the US this procedure is called "following a patient's wishes,"

[338] S.4 Mental Capacity Act 2005
[339] Legal issues relevant to non-heart beating organ donation, Department of Health, 20th November 2009

rather than elective ventilation.[340] In 2000, the University of Michigan (UM), started a research program that combined their transplant program and their Extracorporeal support (ECS) program. In combining the two programs they came up with a method of in situ conditioning of abdominal organs in circumstances of controlled DCDD, when the family requested organ donation.[341] During the procedure, cannulas are placed in the femoral vessels, and heparin is administered to prevent clots from forming in organs. A thoracic balloon was also placed using a cannula during the perfusion to prevent both coronary artery flow and any residual brain flow, and the body temperature was maintained at 37°C throughout the procedure.[342]

One of the main differences between this procedure and the Exeter Protocol is the use of a thoracic balloon. The aim behind the thoracic balloon is to decrease the chances of cardiac reanimation and cerebral reperfusion and, therefore the chances of the patient falling into a PVS. The research group results suggest that if normothermic ECS protocols are widely applied, then this could result in more donor organs, especially when the procedure is applied to DCDD in uncontrolled conditions.[343]

Three large transplant centres in Spain (La Coruña, Madrid, and Barcelona) have also been studying normothermic ECS for several years in animals and patients. The group from Madrid has been using normothermic ECS for uncontrolled DCDD since 2005, while the group from Barcelona has widely studied ECS in DCDD in porcine models and identified the benefits of normothermic preconditioning of hepatic grafts (liver).[344] Norway is now looking at reintroducing ECS after the results of a pilot study that was originally accepted by the

[340] Michael Monette, The ethics of elective ventilation, Canadian Medical Association Journal. 2012 Nov 6; 184(16): E841–E842.
[341] Alvaro Rojas-Peña, Lauren E. Sall, Mark T. Gravel, Elaine G. Cooley, Shawn J. Pelletier, Robert H. Bartlett, Jeffrey Punch, Donation After Circulatory Determination of Death, Transplantation: August 15, 2014 - Volume 98 - Issue 3 - p 328-334
[342] ibid
[343] ibid
[344] Juan Carlos García-Valdecasas, Jeanine Tabet, Ricardo Valero, Pilar Taurá, Ramón Rull, Félix García, Elena Montserrat, Francisco X. González, Jaume Ordi, Joan Beltran, Miguel A. López-Boado, Ramón Deulofeu, Joaquín Angás, Andrés Cifuentes, José Visa, Liver conditioning after cardiac arrest: the use of normothermic recirculation in an experimental animal model. *Transplant International* 1998; 11: 424.

Regional Ethical Committee and started in December 2009. The concept is now under scrutiny and being evaluated by a government-appointed official body before a national implementation may take place.[345]

In some DCD protocols in the US, intravenous heparin is administered after a decision is made to withdraw life support and after 'consent' is given for organ donation, but it is administered before death is declared.[346] Heparin is an anticoagulant and is used in DCD protocols to prevent clotting within the organs that are to be transplanted. This intervention is said to improve the long-term survival of the transplanted organ by reducing the risk of thrombi impeding the circulation to the organ after reperfusion. Advocates of heparin use state that the omission of it would have a negative effect on the impact of organ recovery and it could potentially hinder the acceptance of recovered organs for transplantation. However, its use is still seen as controversial firstly because the consent process in which consent was sought for organ donation is far removed from informed. Secondly, the question is ethical to administer drugs before death to potential organ donors if those drugs are not primarily for the patient's benefit, not is this an issue but there are also some suggestions that heparin can pose a risk of causing or hastening the death of DCD donors.

[345] Stein Foss, Espen Nordheim, Dag W Sørensen, Torgunn B Syversen, Karsten Midtvedt, Anders Åsberg, Thorleif Dahl, Per A Bakkan, Aksel E Foss, Odd R Geiran, Arnt E Fiane, and Pal-Dag Line, (2018) First Scandinavian Protocol for Controlled Donation After Circulatory Death Using Normothermic Regional Perfusion. *Transplantation direct*, *4*(7), e366.

[346] Institute of Medicine. Non-Heart-Beating Organ Transplantation. Practice and Protocols. Washington, DC: National Academy Press; 2000.

4.3.3 Religious and social views

This section intends to highlight the issues regarding religious/social views and death that are currently being experienced within the UK, this is an extensive area of research and could in itself be a full chapter, but for this thesis it will concentrate on the idea that the UK should adopt a policy similar to other countries.

Currently, in the UK, there are no provisions under the law requiring accommodation of and respect for residents' religious rights and commitments when secular conceptions of death based on medical codes and practices conflict with a traditional concept well-grounded in religious and cultural values and practices. Everyone should have the fundamental right not to be involved in medical procedures that are contrary to their personal beliefs, and the right of health professionals and others to conscientious objection must be protected. They must not be made to suffer disadvantage because they have a conscientious objection to a procedure. So why does it appear that the medical/legal community views death differently? From a religious perspective death is seen as the separation of the soul from the body, the means used for determining death by loss of brain function if they are going to be used should positively exclude the possibility that some brain function may continue. Within the UK the neurological testing process for diagnosing death is the brainstem test, therefore this test does not establish loss of all function of the brain. There is also the risk that the actual test may in fact cause further damage leading to the death of the patient.

Some religious scholars have suggested that the apnoea test should not be used if there is any chance that it may cause damage to the brain; other tests such as the brain perfusion tests are preferable because they are not harmful and they produce an image that helps to explain the situation to the family, healthcare personnel and others. The use of imaging to identify a lack of blood flow to the brain would help to prevent confusion by providing evidence (images) showing loss of circulation to the brain and greater certainty. It is also a more certain test than the apnoea test, which is a test only for whether the person can breathe spontaneously, the latter being a brain stem function. If adequate tests that positively exclude the possibility that some brain function may continue have been

undertaken, then it is morally acceptable to diagnose death by the loss of all functions of the brain.

From a family perspective, potential donors and their families can seek support from their religious advocate who might advise them that in our pluralist society, there are different views and different practices about death by the brain criterion. This in turn could lead to conflict with the medical team especially if they refuse to allow tests to be carried out to diagnose brainstem death. There are strong viewpoints on this issue some of which state that families have a right to insist that the apnoea test not be done because it is not of therapeutic benefit and may be harmful, and that the diagnosis of death by the brain criterion should involve a less invasive technique such as imaging of blood flow to the brain to ensure that that there was indeed loss of all brain function. [347]

Religious views and the conflict they can have with the 2008 Academy of Medical Royal Colleges Codes of Practice definition of diagnosis and confirmation of death have been discussed in end-of-life cases. In Re A (A Child)[348] the judge acknowledged that the concept of the 'breath of life' had an important spiritual significance to those who follow the monotheistic faiths of Judaism, Christianity, and Islam. He accepted that devout Muslim parents would see their baby as still being alive while he was still on the ventilator, but he concluded that the life support had to be switched off. The recent case of Archie Battersbee highlighted whether or not more consideration should be given to religious views. During the hearing, Archie's mother explained that Archie had become a catholic after taking up Mix Martial Arts (MMA) fighting, as many fighters are religious. She claimed that Archie had discussed the fact that he did not agree with a neurological diagnosis as it did not line up with his religious viewpoint. Although, briefly considered it was felt that the comments made were coming from a desperate parent trying to cling to hope.

[347] Nicholas Tonti-Filippini, Religious and secular death: A parting of the ways, Bioethics Volume 26 Number 8 2012 pp 410–421
[348] *Re A (A Child)* [2015] EWHC 463 (fam)

One way to try and encourage the courts to take into account religious views when considering end-of-life cases could be to argue that Article 9 Freedom of Thought, Conscience and Religion of the ECHR is being violated. Article 9 applies to religious beliefs and other philosophical beliefs not based upon religious faiths. A good example of its application is Polat v Austria[349] where performing a post-mortem without fully informing the parents of the extent of the post-mortem was considered a breach because it was against the applicant's interests in burying their son in accordance with their religious beliefs. beliefs. Article 9 is not an absolute right but the Court found that it had been violated in this instance because d the domestic authorities had not struck a fair balance between the competing interests at stake and hence could not justify the breach as necessary in a democratic society for the protection of one of the interests laid out in the second part of the Article. Even though it is not absolute, there is potential scope for Article 9 to be interpreted in ways that limit how standards for the determination of death are shaped.

Is it not about time that the UK and other jurisdictions in a similar position start to implement some legislation that makes an effort to accommodate and respect residents' religious rights and commitments when secular conceptions of death based on medical codes and practices conflict with a traditional concept well-grounded in religious and cultural values and practices? No society is monolithic and having an autonomic approach shows that there is a difference, it offers protection to both minor/dominant religions/cultures as patients can make decisions based on their own individuality rather than being subject to one diagnosis that fits all. A publication on this issue by Choong *et al*[350] argues that the legal system should adopt a more compassionate approach to death determination that is respectful of cultural and religious belief systems in a pluralistic society like the UK.

[349] Polat v Austria Application No 12886/16, Merits, 20 July 2021; ECtHR,
[350] Kartina A Choong, Mohamed Y Rady, 'Re A (A Child) and the United Kingdom Code of Practice for the Diagnosis and Confirmation of Death: Should a Secular Construct of Death Override Religious Values in a Pluralistic Society?' HEC Forum (2018) 30:71–89

Although, Choong puts forward a strong case for reform based on religious/cultural beliefs this too could have the potential to lead to issues. If you had a country or region with a dominant religion/cultural belief there is a chance that their diagnosis of death would be based on their concepts and therefore there is the potential to alienate a minority religion/cultural belief.

To avoid this conflict with Article 9 Freedom of Thought, Conscience, and Religion, I suggest that a more suitable approach to death would be that of biological death approach as this can be based on dignity/worth which is inherently associated with the sanctity of life. By taking a biological death approach, as it recognises that the human body can still function when there are issues with organs until there is a destruction of cells in major organs, would satisfy Article 9. For those who wish to be considered as organ donors, I am fully aware that a biological approach to death is incompatible with organ donation. I will argue that by taking a special autonomy approach it would give them the chance to consent once they are fully aware of what is involved. Again, this too has the potential to satisfy Article 9.

4.3.4 Removal of the Dead Donor Rule (DDR)

What is clear despite what some commentators would have us believe is the fact there are still unanswered questions about death and how it is diagnosed, and it is not conceded to the past. These are indeed still very real and have serious consequences after all, being declared dead leads to actions (such as organ donation, embalming, burning, or burial) that would be incompatible with the functional interests one has if still alive. But is there a point where we can say that a potential organ donor is near enough to death to allow the removal of organs before being diagnosed as dead? For this to happen there needs to be the abandonment of the dead donor rule (DDR).

The DDR is an informal rule that has guided the practice of organ transplantation since its beginning. It requires that a person must be dead before their organs are taken, it offers protection to a patient which is inherently associated with the sanctity of life, and is the

central part of the moral framework underlying organ procurement. The debate on the DDR is challenging because it involves views about a wide range of issues, including whether and when patients are appropriately declared dead, the validity of the doctrine of double effect, and the moral difference between or equivalence of active euthanasia and withdrawal of life-sustaining treatment.

So, do you abandon the DDR after all it does appear that most organ donation protocols are only paying lip service to it. For instance, brain-dead organ donors are viewed as the ideal source of transplantable organs, however, it is still being debated within the discourse as to whether brain death is the same as biological death. This makes the situation unclear, are organs that are removed from brain death patients consistent with the DDR, which states that organ removal must not cause death? Some scholars feel that the DDR is being ignored by current transplant policies, for example, some have argued that 'brain death' is inconsistent with a scientific understanding of death, which is defined in terms of the basic biological concepts of homeostasis and the resistance of entropy.[351] Others have called for the abandonment of the DDR, these scholars have argued that since brain-dead patients are irreversibly comatose, they do not have any interests that can be either satisfied or frustrated, and thus, cannot be harmed by organ removal even though it causes death.[352] John Robertson who coined the term, made the case over two decades ago that such changes are ethically undesirable, arguing that even if a utilitarian case can be made against the DDR, "The dead donor rule is a centrepiece of the social order's commitment to respect for persons and human life."[353]

A study was carried out by Nair-Collins[354] to evaluate the public's opinion about organ removal if explicitly described as causing the death of a donor in irreversible apnoeic

[351]Alan Shewmon, 'The brain and somatic integration: insights into the standard biological rationale for equating "brain death" with death.' Journal of Medicine and Philosophy 2001;26(5):457–78.
[352] Franklin G Miller, Robert D Truog, Death, dying, and organ transplantation: reconstructing medical ethics at the end of life. New York: Oxford University Press, 2011.
[353] John A. Robertson, "The Dead Donor Rule," *Hastings Centre Report* 29, no. 6 (1999): 6–14, at 6.
[354] Michael Nair-Collins, Sydney R Green, Angelina R Sutin, 'Abandoning the dead donor rule? A national survey of public views on death and organ donation' *Journal of Medical Ethics* 2015; 41:297-302.

coma. What he found was that "71% of the sample agreed that it should be legal for patients to donate organs in the scenario described and 67% agreed that they would want to donate organs in a similar situation. Of the 85% of the sample who agreed that they were willing to donate organs after death, 76% agreed that they would donate in the scenario of irreversible coma with organ removal causing death."[355]

What the paper concluded was that when faced with a scenario explicitly described as violating the dead donor rule, it appeared that the public still supported organ donation. But is this a true reflection of the public thinks, after all in the UK public support for organ donation is said to be around 90%.[356] This figure is considerably inflated compared with the actual number on the organ donor register in 2021. In England it was 38%, in Wales it was 42%, in Northern Ireland it was 49% with Scotland having the highest at 51%.[357] These figures go up slightly when families are actually asked to make a decision regarding organ donation, this increases the consent rate to roughly 60% in the UK,[358] but this is still much lower than the 90% who are said to support organ donation.

Another argument against the DDR is that some feel that procurement programs are only paying lip service to it. It is highly desirable that donation programs continue to procure organs for transplantation. Therefore, it could be suggested that the law/medical profession is only interested in maintaining the DDR with the main purpose of protecting transplant programs, by allowing people to think that the DDR is there to protect them from a declaration that they might be considered dead prematurely. This combined with the growing belief that those from whom we often and possibly typically procure organs are not "really" dead leaves us with a dilemma—either we abandon organ procurement, or we abandon the DDR.

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[355] ibid

[356] BBC. BBC DoNation survey reveals UK are happy to donate their organs but are keeping it to themselves, www.bbc.co.uk/pressoffice/pressreleases/stories/2005/ 08_august/21/donation.shtml (visited 15.02.22)

[357] https://www.statista.com/statistics/520920/individuals-on-the-organ-donor-register-by-country-united-kingdom-uk/ (visited 16.02.22)

[358] David Shaw, Dale Gardiner, Penney Lewis, et al. 'Conscientious objection to deceased organ donation by healthcare professionals.' *Journal of the Intensive Care Society*. 2018;19(1):43-47.

The utilitarian appeal of organ transplantation has led to many procurement programs determined to increase the donor pool. Therefore, the question must be asked if current/future programs are willing to give up on the DDR and how far they are willing to go to procure more organs to potentially save more lives. Can the flexing of the DDR/paying lip service to it, be allowed to continue or is it now time to replace the current protocols with a rigorous consent process and protocols that prevent real harm? This thinking can be linked to an overhaul of the consent system that was discussed in section 3.4.1 of this thesis.

If medicine is supposed to be patient-centred/lead, then is now the time to consider a rethinking of the whole process of organ procurement? By forming a new ethical/legal justification for the removal of vital organs for donation would begin to allow commentators and society to dispense with the "legal fiction" [359] that brain death is the same as the biological death of the entire human being. It will also allow for the adoption of other legal methods grounded in the reality of the complexity inherent when it comes to defining death. This will enable potential donors to be given information that will allow them to decide what they consider are the requirements for death, even if this means a drop in organ transplantations, which if Nair-Collins[360] paper is to be believed would not happen. None of this is new this dilemma has been around since the first inception of brain death and has been reoccurring ever since for example, back in 2004 Truog and Robinson argued that "sometimes the harm of dying is sufficiently small that patients should be allowed to voluntarily accept that harm if it makes organ donation possible."[361] To say that a patient in this situation has died might be stretching the concept clear they have not died they have been killed. But if a patient has consented to donation and understands the implications, why should they not be allowed to donate their organs in certain circumstances before death has been declared?

[359] Robert D Truog, Franklin G Miller, 'Changing the conversation about brain death.' *American Journal of Bioeth*ics 2014;14(8):9-14

[360] Michael Nair-Collins, Sydney R Green, Angelina R Sutin, 'Abandoning the dead donor rule? A national survey of public views on death and organ donation' *Journal of Medical Ethics* 2015; 41:297-302

[361] Robert D Truog, Walter M Robinson, 'Role of brain death and the dead-donor rule in the ethics of organ transplantation,' (2004) 31 Critical Care Medicine 2391-6

This interest in rewriting the rules on organ donation has led to the proposal of an imminent death donation (IDD) program as an additional option for organ donation that may increase the quantity and quality of organs available for transplant.[362] IDD is the removal of organs for donation from living donors immediately before an impending and planned withdrawal of ventilator support is expected to result in the patient's death.[363] In other words, the patient is still alive at the time of organ retrieval is planned so, is this, not just thrift euthanasia[364] under a different name? In their text, Miller and Truog argue that a patient who is on life support cannot be harmed once the decision has been made to remove them from said support. They state that "these patients are not harmed because they have no interests that are set back by procurement of organs before treatment is withdrawn. Specifically, and most importantly, the patient's interests in continued living are not set back by the decision to withdraw life support. The prior plan to withdraw life support crates the moral possibility for a life-saving donation of vital organs to another patient."[365] The issue with this thinking is what happens if their interests are set back by the virtue of an incorrect diagnosis, the inherent uncertainty of medical outcomes, and the possibility of recovery.

They go on to claim that the ethical procurement of vital organs does not require adherence to the DDR. If the decision has been made it has to have been made in isolation, then the procedure will be similar to that already being implemented in organ donation after euthanasia. If not then the former decision to remove life support could be deemed to have been made for the sake of the latter, and this means it can become possible for vulnerable patients to be sacrificed to save the lives of others.

[362] Paul E Morrissey, 'The case for kidney donation before end-of-life care.' American Journal of Bioethics. 2012;12(6):1-8.
[363] Lee Bolton, Ethical Considerations of Imminent Death Donation OPTN/UNOS Ethics Committee. 2016. https://optn.transplant. hrsa.gov/governance/public-comment/ethical-considerations-ofimminent-death-donation/. (Visited 18.02.22)
[364] *Thrift-euthanasia is an intentional act of one or more individuals that directly causes, or knowingly contributes to, the death of another in a manner conducive to the benefit of others,* as in terminal live-organ harvesting and/or terminal vivisection experimentation.
[365] Franklin G Miller, Robert D Truog Death, dying, and organ transplantation: reconstructing medical ethics at the end of life. New York: Oxford University Press, 2011

The problem with current systems in place and going forward is that they are set up with the main aim to maximise the number of potential donors at the expense of the person at the centre of it the potential donor. These people have a vested interest to be viewed as alive until it can confidently be said that they are dead. But what is becoming more apparent is that these interests are deliberately being diluted to meet the needs of procuring organs for transplantation. The shorter the time waited between loss of circulation and declaring a patient to be dead the less the warm ischemic time and thus the more the potential, all other things being equal, for their organs to be in a good state for transplantation.[366] All of which will go on to benefit the recipient, not the donor.

Having the DDR and enforcing it properly will stop this deliberate dilution of donor interests, from its first inception the DDR stated that organ donors must not be killed by and for organ donation. Over the years this has been stretched by some commentators who think that the DDR should state that it requires that vital organs should not be procured before death. The DDR should not be open to interpretation it is the fundamental norm that should be maintained in transplantation ethics. As discussed in the death chapter, the uncertainties that are still apparent with defining, testing, and diagnosing death the protection that is offered by upholding the DDR is even more important. It is a safeguard for those who may be exposed to false positives in whatever tests are used to determine when someone is dead and therefore beyond harm.[367]

4.3.5 Implement preventative measures to reduce the reliance on organ donation

During my research, I have come across many articles on ways to increase the number of viable organs for transplantation. There has been a renewed interest in the old practice of DCDD since the early 1990s because donors from DBDD and living donors could not keep up with the demands for suitable organs for transplantation. Up until then, the DCDD approach fell out of favour due to it being unable to provide a large number of viable organs

[366] Austen Garwood-Gowers, *Medical Use of Human Beings: Respect As a Basis for Critique of Discourse, Law and Practice*, Taylor & Francis Group, 2019

[367] Adam Omelianchuk, Against abandoning the dead donor rule: reply to Smith, *Journal of Medical Ethics* Published Online First: 25 November 2022.

compared with the DBDD criteria, since this criterion essentially permitted surgeons to remove vital organs from patients who remained on mechanical ventilation while their hearts were still beating, allowing the surgeons to effectively remove living organs from a body that was legally dead.[368]

In the UK the main aim of the UK organ task force was to increase the number of organs rather than trying to reduce the need for them. Is it now time to rethink the idea of organ transplantation to see it as a palliative rather than as a curative treatment of end-stage organ disease? There are at least two reasons for this, firstly, there is no guarantee that the transplanted organ will not be rejected. Plus, although transplants are credited for improving the quality of life for the recipient compared with dialysis when you consider the chances of rejection and a lifetime on immunosuppressive drugs which can worsen pre-existing conditions such as diabetes and hypertension this brings into question the curative claim. Another issue that has been at the forefront of the recipient's thoughts is the fact that having a compromised immune system can increase the risk of death from infections. This became a very real prospect during the Covid-19 pandemic when many people who had received a transplant were advised to shield themselves to avoid infection, what many people did not realise at the time was just how long it would last.

So rather than relying on increasing the pool of organ donors, there should be more funds made available for public health education and intervention programs to avert the rapid rise in the incidents of end-stage organ disease. There are lifestyle choices that can increase the risk of future need for an organ transplant many of which are modifiable with education/preventative schemes, such as smoking, alcohol abuse, drug addiction, and obesity. Preventative measures are not just limited to lifestyle changes, there are the implications of societal changes too. For example, monitoring air pollution in densely populated areas and putting in reduction measures when needed could prevent respiratory diseases.

[368] Franklin G Miller, Robert D, *Death, Dying, and Organ Transplantation; Reconstructing Medical Ethics at the End of Life*, 2012, Oxford University Press

At present, there are generally no substitute therapies for transplantation available for end-stage organ failure. Research is continuing but it is not without its controversies, in July 2011, the world was told about a sensational medical breakthrough that had taken place in Stockholm, Sweden. The Italian surgeon Paolo Macchiarini had performed the world's first synthetic organ transplant, replacing a patient's trachea, with a plastic tube. The synthetic 'scaffold' for the new trachea was made in a laboratory in London. It was seeded with stem cells taken from the patient's bone marrow, then placed in a bioreactor, where it rotated in a cell culture media designed to encourage cell growth.

Unfortunately, it became apparent that this medical breakthrough was based on fraudulent claims as five years after Macchiarini's headline-making work out of the nine patients that received the treatment, in Sweden and elsewhere, seven had died. The two still alive had their synthetic tracheas removed and replaced with a trachea from a donor. The investigation, into Macchiarini's work, found that the scientific foundation for the new operation was weak, and condemned the failure to carry out risk analyses before the patients received their operations, or seek the necessary ethical approval and even if there was enough scientific evidence to support the procedure at all. Some experts claim that the entire project of growing human organs, although appealing to popular science journalists, is flawed. A professor of respiratory surgery Dr Pierre Delaere, on the subject, has said that it is impossible for surgeons to establish a new blood supply to a trachea donated or synthetic. Delaere had called Macchiarini's method "one of the biggest lies in medical history because you are doing something impossible from a theoretical point of view."[369]

Bioengineering organs is not the only research that is being considered for plugging the gap between organ donors and the waiting list, xenotransplantation[370] has recently hit the headlines again. Doctors have been trying to use animal organs for decades, with mixed success. In 1984, doctors in California tried to save a baby girl's life by giving her the heart of

[369] Paolo Macchiarini: A surgeon's downfall, By William Kremer, 10 September 2016, https://www.bbc.co.uk/news/magazine-37311038 visited 05.03.2022

[370] Xenotransplantation is defined as any procedure that involves the transplantation, implantation, or infusion into a human recipient of live cells, tissues, or organs from a nonhuman animal source.

a baboon, but she died 21 days later.[371] In 2021, surgeons at New York University Langone Health transplanted kidneys from the genetically modified pigs into two legally dead people with no detectable brain function. It was reported that the organs were not rejected and functioned normally while the deceased recipients were sustained on ventilators, but these initial reports were issued with limited information.[372] For instance, the recipient's own kidneys were left *in situ* and there was no mention as to whether the recipient's two native kidneys (that appear to have been retained) were still functioning well. In one media report, it was stated that the graft maintained a normal serum creatinine, but this cannot be known for certain because the native kidneys may well have contributed significantly to the maintenance of normal serum creatinine.[373]

But can it be ethically justifiable to use these patients, with questions still being asked about brain death is it realistic to say that these patients are dead, and if they are considered dead should the issue of harm be considered? Many philosophers hold that people can be harmed by events that occur after they have died, by so-called posthumous harm. This view is based on an assumption that people can be injured, or the interests that they had while alive could be thwarted, by what happens in the world after they die, especially by events that could have been avoided, and having a pig kidney transplanted after death is certainly avoidable.

The latest step in the xenotransplant 'experiments' was published in January 2022 when 57-year-old male patient David Bennett, received a genetically modified pig's heart. Bennet gave the surgical team a chance to jump straight to a human transplant. He had been on cardiac support for almost two months and could not receive a mechanical heart pump because of an irregular heartbeat. Neither could he receive a human transplant because he had a history of not complying with doctors' treatment instructions. Given that he otherwise

[371] https://www-bmj-com.ezproxy3.lib.le.ac.uk/content/bmj/366/bmj.l4669.full.pdf
[372] Roni Caryn Rabin, In a first, surgeons attached a pig kidney to a human, and it worked. N Y Times. 2021. October 19, 2021.
[373] David K C Cooper, Genetically engineered pig kidney transplantation in a brain-dead human subject. Xenotransplantation. 2021;28: e12718. https://doi.org/10.1111/xen.12718

faced certain death, the researchers got permission from the US Food and Drug Administration (FDA) to give Bennett the genetically modified pig heart. It has been reported that he was doing well three days after the experimental seven-hour treatment.[374] Bennett's health deteriorated, and he died two months after the surgery took place.

Moving forward to March 2024 it was publicly announced that the first patient to receive a genetically modified kidney transplant from a pig had been discharged from hospital.[375] This was quickly followed up with a severely ill 54-year-old woman becoming the second person to receive a kidney transplant from a genetically modified pig.[376] The patient involved was ineligible to receive human organs, because of her advanced disease, she is said to have consented to the procedure because she was eager to gain more time so she could see her grandchildren grow up. These transplant operations were carried out by the same team who carried out the initial trials in brain-dead patients discussed on the previous page.

The surgery is being acclaimed by many as a medical breakthrough that could shorten transplant waiting times and change the lives of patients around the world. But are these patients being used as clinical guinea pigs? Some are questioning if the procedure can be ethically justified. This is an experimental surgery and brings with it huge risks for the patient and one should question if a patient who is facing imminent death can ever really give informed consent for the go-ahead. On the other side of the argument, are these patients not equivalent to the first patients who were involved in organ transplantation in its infancy?

[374] Sara Reardon, First pig-to-human heart transplant: what can scientists learn? Nature 601, 305-306 (2022)
[375] Roni Caryn Rabin, Surgeons Transplant Pig Kidney into a Patient, a Medical Milestone, The New York Times, Published March 21, 2024
https://www.nytimes.com/2024/03/21/health/pig-kidney-organ-transplant.html
[376] Roni Caryn Rabin, Grandmother Becomes Second Patient to Receive Kidney from Gene-Edited Pig, The New York Times, Published April 24, 2024 https://www.nytimes.com/2024/04/24/health/kidney-transplant-pig.html?action=click&pgtype=Article&state=default&module=styln-organ-transplants&variant=show&region=MAIN_CONTENT_1&block=storyline_top_links_recirc

4.3.6 Stop transplant procedures

Is it enough to say that the good that comes from transplantation should outweigh the issues that still surround the process? The answer to this should always be no. The primary concerns of the medical profession and legislators should be to protect and maintain dignity/respect and this should be reflected in any policies made. After all, the patients we are concerned with are in a vulnerable position and deserve to be protected. Based on the research carried out for this thesis it appears that the evidence shows that this is not apparent therefore, current transplant programs should stop. Despite what certain commentators claim about current procurement systems I have shown throughout this thesis that many of them clash with libertarian and dignitarian viewpoints. In doing so they fail to place the idea of respecting the human body during and upon death at the centre of any procurement programs that are set up.

The problem is there does not appear to be any consideration in stopping current practices, this is especially highlighted in the UK since Wales, England, and Scotland have recently introduced major changes to their transplantation laws. None of the changes that have been implemented have considered the ongoing issues discussed in the literature, in fact, it could be argued that the new systems that are in place are worse than the ones the UK originally had.

4.4 Conclusion

A major goal of the national organ transplantation system has always been to maximise the number of organs made available and throughout this chapter, it has been shown that current alternative organ procurement programs being used in different jurisdictions despite what they claim seems to be based on a utilitarian system since they clash with any notions based on libertarian and dignitarian thinking. This fact on its own should be enough to instigate a policy review that has respect for human beings during and after death and should be put at the centre of the system. They also do not address the main issue that potential donors based on the balance of probabilities are in fact not dead at the time of

removal of organs. Put simply, how death is currently diagnosed is not credible, it appears to depend on what the jurisdiction thinks will best serve the need to increase the number of organs available for donation. Surely, there should be some sort of consensus as to a definition of death and means of diagnosis that can be applied to all donation systems, irrespective of which jurisdiction the patient may be in. Or maybe as I suspect death cannot be pinpointed to a specific time and if this cannot be achieved then public policy and common law should make this clear and decide if organ donation should continue in its current format.

4.5 Suggested Alternative System

As suggested by some commenters, the brain death criterion used to diagnose death is a potential fallacy, it has been noted that the Harvard Committee rationale was a "legal utility: that it would free up beds in intensive care units and facilitate organ transplantation."[377] It has also been described as not being a 'biologically plausible definition' but rather 'a social construction not grounded in biological reality'.[378]

Is there an argument that organ donation systems should only rely on a cardiorespiratory criterion, after all, this is traditionally how death was diagnosed before the introduction of ventilators. But as shown in the chapter on death this is not without its critics and problems, first and foremost being the length of time between declaring death and the onset of cessation of heartbeat. As discussed previously, waiting times can vary greatly from 75 seconds in Denver,[379] 5 minutes in the UK to 20 minutes in Italy. There are some countries that do not permit DCDD, an example of this can be seen with Germany where DCDD is illegal, presumably because their legal system and medical/ethical community are uncertain that these patients are dead. How can there be such a big difference in times, surely for

[377] D Alan Shewmon, 2009, Brain death: Can it be resuscitated? Asian bioethics review, 1 (1), 17-28
[378] Robert D Truog, and Franklin G., 2014 Changing the conversion about brain death, The American Journal of Bioethics, 14 (8), 9-14
[379] In 2008 doctors from Denver reported on three controversial cases of heart transplantation from new-born infants. Transplant surgeons waited only a relatively short period after the donor's heart had stopped (75 seconds) before starting the organ retrieval process.

there to be credibility in a test there must be uniformity, which in the case of the cardiorespiratory criteria there needs to be a universal agreement on the requirement on the so-called ‘no touch’ time and this must be consistent with broader norms concerning medical decision-making, including requiring it to be informed.

Going forward to give credibility to diagnostic tests for death there needs to be uniformity and better clarification not only to the potential organ donor but to the general public as a whole as issues with diagnosing death are not just restricted to organ donation. If there are real concerns with current practices, which based on evidence throughout this thesis there is, what should be done? Over the next few paragraphs, I will put forward a suggested alternative to what the UK has in place now. This will be based on my personal opinion which I will back up with evidence from the research carried out to complete this thesis.

A starting point for reform would be to change how the medical community currently views patients' and relatives’ opinions on death. What is clear and becoming more so as time goes on is the fact that the concept of death, definition, and testing are not aligned, and this area of medicine is not settled like some would want us to think. Medicine is a relatively fast-moving area of research, yet when it comes to defining something as important as death, we still rely on techniques that were developed nearly 70 years ago under dubious circumstances. To rectify this there needs to be an open approach to explaining how death is defined, this should include an explanation that there are still some uncertainties and as with everything, research is moving forward and that what the medical community believes to be right now may change. Information should be available to potential donors about the pros and cons of both brainstem death and cardiorespiratory criteria. There is the argument that the public overall does not need to know everything and the scholars who are insisting on change should just accept this, but at the very least surely, they should be aware of the basic principles of brain stem and cardiorespiratory criterion.

The central idea that there needs to be an increase in the supply of organs also requires change. This thinking is constantly at the centre of all policies that have been implemented, for example despite what was said at the time and since the Harvard Committee deliberations discussed developments in organ donation and the UK Organ Donation Taskforce in 2006 set the remit to identify barriers to organ donation and recommend actions needed to increase organ donation and procurement. This constant driving force has not gone unnoticed and some feel that this approach is starting to have an impact on patients, as was raised by Suhre when discussing the McMath case who stated; "It's hard to deny that organ donation is at the forefront in the USA the main concerns in reports following the McMath case was the potentially devastating impact the case may have on organ transplantation rather than on the devastating effect an entrenched purely medical approach to death can have on patients and families who, for religious or personal reasons, do not accept brain death as a concept or have reasons to mistrust the health care system as a whole."[380]

A simple way to make a significant change would be to accommodate for religious views and personal choices to be considered over the method of diagnosis of death. Zink points out; "Multiple and sometimes competing definitions are permitted, because we so exist in a world where individuals understanding creates different (and sometimes competing) world views', brain death may be acceptable for some families, and not others."[381]

The recent case of Archie Battersbee[382] is an example of when families do not accept a brain death diagnosis. During the initial ruling from the Family Court, it was declared that it was not in the third respondent's (Archie) best interests for him to continue medical treatment in the form of medical ventilation and the ancillary care that accompanies the ventilation.[383] The family won the right to appeal this ruling as the Appeal Judges allowed the case to be

[380] Wendy Suhre, Gill A. Van Norman, Ethical Issue in Organ Transplantation at End of Life, Anaesthesiology Clinics, 2020-03-01, Volume 38, Issue 1, Pages 231-246
[381] Sheldon Zink, Death and donation: a reply to Koppelman. American Journal of Bioethics 2003; 3: pp. 29-30
[382] *Dance & Battersbee (respondents/appellants) v Bart's Health NHS Trust (applicant/respondent)* Court of Appeal Civil Division Court 71 30th June 2022
[383] *Bart's Health NHS Trust v Dance and Others* [2022] EWHC 1435 (Fam)

reheard at the high court. During the hearing, Archie's legal team had argued that evidence given at the original hearing had not shown "beyond reasonable doubt" that Archie was dead but had based this decision on the balance of probabilities.

The family felt that Archie's case was the first to be based on an MRI scan and not on the traditional brain stem tests, which were not performed. Archie's legal team argued that the medical expert opinion presented in Court was clear in that the whole concept of "brain death" is now discredited, and in any event, Archie cannot be reliably diagnosed as brain dead. It was also argued that the original judge did not give enough consideration to Archie's best interests based on religious grounds. Although best interests are founded within the MCA 2005 therefore would not apply in Archie's case,[384] the Welfare Principle (which is similar in meaning) under Section 1(2B) (3) of The Children Act 1989 would. It stipulates that the Courts should have regard in particular to:

> (a) The ascertainable wishes and feelings of the child concerned (considered in the light of his age and understanding);
>
> (b) His physical, emotional and educational needs;
>
> (c) The likely effect on him of any change in his circumstances;

Therefore, in ascertaining Archie's wishes and feelings the Courts should have given more consideration to religious views and emotional needs. His mother said that he had stated that he did not agree with a neurological diagnosis as it did not line up with his religious viewpoint. Of course, this may have just been a comment from a desperate parent trying to cling to hope, even so, it should have been given more consideration. As for the likely effects on him,[385] the fact that there was never a reliable diagnosis of brainstem death as the test was not carried out, this decision would have a major change in his circumstances, and he would go from being seen as alive to dead. With something as crucial as a life and

[384] The Mental Capacity Act 2005 applies to a person 16 years and over
[385] Section 1(2B) (3) (c) of The Children Act 1989

death decision how can it be made without the basic requirements, in this case, a brainstem test? Are we really to believe that this was the best decision for the welfare of Archie?

So how do I envision a new system, I will be basing it on libertarian/dignitarian thinking. Initially, I would make a simple change by reverting to an opt-in system, once this is achieved, I would then look at implementing a more stringent system that will make it a legal requirement to register an opinion on death. The default for death would be biological death, as this is the only credible way to determine death. This of course is not conclusive for organ donation therefore if a patient wishes to be considered as an organ donor, they can be told about an alternative approach to death which will enable this. It is at this point the patient will be told about a neurological approach i.e., brainstem death or loss of circulation. They will be told of the uncertainties as discussed in the death chapter that still exist with these definitions and they will be given the option to accept one or both in order to be an organ donor, or if they are unhappy with what they are told they can change their mind and not be a donor. By informing potential organ donors of the material risks this will satisfy the requirements set out in the Montgomery case[386] which would then bring consenting for organ donation in line with normal medical treatment. It would ensure that the medic involved disclosed the fact that there are still unresolved issues with the diagnosis of death.

To implement this, there would have to be a way of notifying the public to do this I would suggest a public notification on a similar system currently being used in The Netherlands, with their so-called no-objection system. But there would be a significant difference, where The Netherlands takes a no response to be no objection to organ donation, the system that I am suggesting would not have this as a default, instead the no response default would be seen as an objection to register. This can then be reviewed regularly to make sure that the register is up to date. The framework of this system will incorporate several topics that have been discussed throughout this thesis to create a centralised record of refusals and

[386] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

agreements pertaining to potential concerns of diagnosis (be it on religious/social or any reason), and pre/post-mortem practices.

With regards to the ECHRs, it would be compliant with Article 8 Right to Private Life which also protects the notion of personal autonomy. In Pretty v UK[387] declared that the notion of personal autonomy is an important principle underlying the interpretation of its guarantee. Article 9 Freedom of Thought, Conscience, and Religion there would be no conflicts as my suggestion takes an autonomic approach and does not favour one religion over another as can sometimes be the case. It will allow for freedom of thought as a decision on diagnosis can be for any reason that aligns with their own personal viewpoints, with biological death as the default approach if no decision has been registered.

For this to happen there needs to be a combined effort from the medical, legal, and ethical community, as well as involving religious leaders and community leaders. Death should be recognised not just as a medical diagnosis; it goes much further and beyond biological/medical terminology. It can have social, spiritual, and religious connotations all of which should be taken into account when dealing with patients and to some extent their relatives.

Of course, when developing a new system as always there are the issues of cost, time, and publicity, all of which are in short supply at the minute. Not to mention the fact that there has just been a recent major overhaul in the UK transplant laws,[388] and it could even be argued, successfully, that many people within England do not even realise this is the change of law as it was implemented during the height of the Covid-19 pandemic.

One clear thing is organ donation and transplantation still present many ethical challenges and dilemmas, both at personal and community levels and even within the medical

[387] *Pretty v The United Kingdom* App no. 2346/02 (ECHR) 29 April 2002 para 61
[388] Wales 2015, England 2020, and Scotland in 2021 will all be following an opt-system.

community. Organ donation continues to raise complex ethical issues that defy simple answers. These include the definition and diagnosis of death, the justification for peri-mortem interventions on the potential organ donor, consent and organ donor research, and the right of the family to overrule donation intentions. Therefore, a balanced ethical account of organ donation must not only include the potential organ donor but also the potential organ recipients, the donor's bereaved family, healthcare providers, and the lay public. As a social act, organ donation is dependent upon public trust and support. Transparent and open discussion of its many successes and lingering problems are important components of this process. This highlights both the persistent difficulty in achieving international consensus for diagnosing death, and under the DDR, the continuing debate as to when it is ethically and legally acceptable to procure vital organs for the purpose of transplantation.

5. Conclusion

When organ donation is discussed in the public arena the main take-home message is that there are not enough donors, not the fact there are still ongoing uncertainties surrounding the determination and pronouncement of death. Whilst I am writing up this thesis the push to increase the number of potential organ donors has increased considerably. In the UK, for example, the total number of patients registered for a transplant has increased (by 47%), so at the end of March 2023 6,959 patients were waiting for a transplant, with a further 3,822[389] temporarily suspended from the transplant list. During this time 439 patients died while waiting for a transplant. This situation will no doubt led to a mammoth effort for those concerned to try and increase the number of potential organ donors, even though as shown throughout this thesis there are still uncertainties surrounding the determination and pronouncement of death.

It became apparent from the early stages of this research that questions surrounding the determination and pronouncement of death are potentially as old as humankind itself. Concerns about being defined as dead when one is not, are very natural and primal, at least in contexts where the consequence of being defined dead is to be subject to action (such as embalming, burning, or burial) that would be incompatible with the functional interests one has if still alive. Over time, with the increased understanding of human anatomy and biological function, death was declared after the passing of time. This ensured that respiratory failure was permanent, which in turn led to terminal cardiac arrest. Equally, prolonged cardiopulmonary failure inevitably led to total, irreversible loss of brain function.

However, with the developments in medical technology in the mid-twentieth century posed exciting opportunities and perplexing challenges. For example, with the invention of mechanical respirators in the 1950s, it became possible for patients who had had such failure to have their cardiopulmonary functioning maintained, and with that the functioning

[389] Summary of donor and transplant activity, in the financial year to 31 March 2023 (accessed 26th April 2024) https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/30028/section-1-summary-of-donor-and-transplant-activity.pdf

of their organs sustained. The question of whether such a patient was alive, or dead started to be asked and debated and the possibility of having a definition, criteria, and tests for death that centred purely on the loss of neurological functioning emerged.

In 1968 the Harvard Medical School ad hoc committee published its landmark report, 'The Definition of Irreversible Coma' which set out to answer the question, is a neurological criterion alone sufficient to establish a legally and ethically defensible definition of death? The committee itself answered affirmatively, proposing irreversible loss of whole brain function as a superior alternative to what it deemed 'obsolete criteria' for death. Since its inception questions have been and still are being asked about the validity of brain death as a standard due to the fact there is a long association between the development of brain death as a diagnosis of death and the practice of organ donation. Since then, death standards have become more dubious as standards have been stretched to accommodate the fact that organ donation has become over-relied in the medical community.

What is now beginning to be apparent is that the transplantation of vital organs though nominally governed by the DDR, involves organ procurement from potentially still-living patients. But should I be surprised by this alienation of the body and apparent lack of dignity; the answer is probably no because every new development in the field of transplantation has been implemented to try and increase the number of viable organs for donation. Yet the medical ethics arena appears not to have faced up to this yet and therefore has not developed an honest ethical rationale for these practices.

Throughout this thesis, I have made one overarching claim, that it is becoming more apparent that the foundations on which organ donation/transplantation were founded (and they were on shaky grounds to begin with) are being stretched beyond their limits. Throughout the discourse for any subject area, there are always going to be discussions and disagreements as to which the best approach to be taken but when it comes to protecting and respecting human worth during the organ donation process this somehow gets

overlooked in favour of increasing the number of organs for donation. Whilst considering the numerous procurement systems that are currently being used, I have put forward the argument for a libertarian/dignitarian approach to protect people's autonomous rights to make decisions for themselves and that ultimately, they are treated with dignity and respect. Yet this approach in terms of death and organ donation seems to be eroding due to the constant lack of supply of donors at a time when the need is greater than ever. As described by Garwood-Gowers, this is leading to a growing tolerance and even embrace of various practices that entail alienation of body-related interests that are both significant and disproportionate to any expected counter-veiling benefits.[390]

It is often stated that autonomy is placed at the centre of organ donation procurement programs yet, for autonomy to be truly respected, requires that a person be sufficiently informed and knowledgeable of a subject to be regarded as autonomous with respect to a particular choice. Beauchamp and Childress, for example, suggest that 'a substantial degree of understanding' is one of three criteria of autonomous action, acting intentionally and without controlling influences being the other two requirements.[391]

As debated during the chapter on death there are currently several significant discussions that are ongoing about how death is defined, diagnosed, and tested for, which for some should not be taking place at all, commentators like Dubois[392] and Caplan[393] have not only suggested that these criticisms are unwarranted but argue that they should be suppressed because of their potential to adversely impact procurement. But could it not have the opposite effect, if there was to be an open review of all current standards that are currently being implemented and it was found that current procedures are fit for purpose then this

[390] Austen Garwood-Gowers, Medical Use of Human Beings- Respect as a Basis for Critique of Discourse, Law and Practice, Taylor & Francis Ltd (2019)
[391] Tom L Beauchamp and James F Childress, Principles of Biomedical Ethics (New York: Oxford University Press, 2001).
[392] James M Dubois, *The Ethics of Creating and Responding to Doubts about Death Criteria,* The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine, Volume 35, Issue 3, 1 June 2010, Pages 365–380
[393] Arthur Caplan, *The case against care for those who are brain dead, https://www.newsday.com/opinion/oped/caplan-the-case-against-care-for-those-who-are-brain-dead-1.6767446,* January 2014 (Accessed 10th May 2018)

would offer reassurance to the public. On the other hand, if it was shown that there was a need to change practices this too may be seen as a good thing as it will show that as an entity the transplant community is willing to review and make changes, if necessary, to protect the dignity of the potential donor.

There are also 'administrational' concerns, should there be a consent process in place for brain-based death pronouncement, and if so then who should give this consent to the patient themselves or their family? This consent would then be used to enable diagnostic tests such as apnoea testing to take place, something which does not happen now. There is also the question of which criteria should be used in measuring brain function loss and whether loss of all functions of the entire brain can be measured with existing criteria sets, is the brain function loss really irreversible and could potential clinician error in applying tests be too great? Most critically, taking on board the above criticisms there needs to be a full review of whether the current brain death concepts of death should be favoured/abandoned over some erosion of a circulatory or even moving to a higher-brain concept.

The issues seen with brain-based death diagnosis are by no means the only problems that are ongoing when it comes to the issue of declaring the death of a patient. In recent years with the advancements in vehicle safety and medical intervention, there has been a fall in brain death patients therefore, a continuing limited number of potential donors, which has led to a resurgence of interest in donation after circulatory death (DCD) as an effective means of expanding the potential donor pool. This in itself has resulted in several problems for example, at the very least there needs to be a standardisation of the time for the no-touch period, to make DCD more credible. There is also the ongoing debate with the terminology 'irreversible cessation', which remains controversial, should irreversible be taken to mean 'not possible to reverse' (permanent) or should it properly equate to 'no intention to reverse' (not necessarily permanent)?[395]

[395] Michael Nair-Collins, Taking science seriously in the debate on death and organ transplantation, Hastings Cent Rep, (2015), pp. 34-48

None of the above problems seem to be going away and in reality, they may never be truly solved, so maybe it is time to take a different approach to death, rather than having standards set by those who only seem to benefit from them, perhaps it is worth considering a more flexible approach to defining and diagnosing death. To achieve this will mean there is a complete overhaul of the current practices, there should be more inference on the diverse makeup of societies to ensure that not only different perspectives on death and organ donation are considered for example some potential donors may wish to donate organs only after cardiorespiratory death but, also on the role of a family may have at the time of death. All these factors add up to create a complexity that needs to be addressed in the open to truly get an understanding of the general public's views on death and organ donation.

It should never be underestimated how the subject of death and the subsequent decisions surrounding organ donation create a very complex and delicate subject area, which should be the case. The human body evokes various beliefs, symbols, sentiments, and emotions as well as various rituals and social practices, all of which play a vital part in death and should be at the forefront of any policy decisions. But, from a rationalistic standpoint, some policies to increase the supply of transplantable organs may appear to be quite defensible but they turn out to be ineffective and perhaps even counterproductive because of inadequate attention to these rich and complex features of human body parts. Therefore, organ donation continues to raise complex ethical issues that defy simple answers, these issues include the definition/diagnosis of death, consent to organ donation, the justification of pre/post-mortem interventions on the potential organ donor, and the potential for family/surrogate involvement. To achieve a balanced ethical account of organ donation any discussions and any resulting decisions must be transparent and open in trying to solve the lingering problems associated with the practice. The requirements for diagnosis of death should not just be restricted to those with the requisite clinical expertise, but the parameters for deciding the social and legal significance of such crucial concepts as death should be engaged in a widespread consultation and examination. The question of a definition of death should be decided not only at a political and legal level but, it should also

be in the general public sphere, by doing this would place this decision where it belongs, at the level of society and not just with the medical profession.

The crux of organ donation is that the decision to donate one's organs is and should always be an altruistic act and the idea that a potential donor can be deemed to consent seems to contradict this very idea. Yet as I have already mentioned this has recently happened in England[396] and Scotland,[397] five and six years after Wales introduced deemed consent back in December 2015. In England under the Organ Donation (Deemed Consent) Act 2019 (DCA 2019),[398] in the absence of a formally recorded objection, any person aged 18 or over who is not in one of the excluded groups[399] is deemed to have consented to donation 'unless a person who stood in a qualifying relationship to the person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned would not have consented'.[400]

This new approach could and should be seen as utilitarian in principle, unclear, and open to ambiguity. Critics of deemed consent have reported that by accepting the absence of objection as permission for donation, undermines the very essence of the ethical principles of informed consent. There is also potentially an issue with how legislation was introduced in England since its introduction there has been little or no coverage through media outlets about the change in law. This raises the question does the general public realise that there has been this change and did the government do enough to bring it to the public's attention? The lack of awareness is problematic not only in respect of individuals who may wish to declare their objections to organ donation but also to those in qualifying relationships who may perceive a duty to serve the deceased interests where applicable.

[396] Organ Donation (Deemed Consent) Act 2019 (DCA 2019) was enacted on 20th May 2020
[397] Human Tissue (Authorisation) (Scotland) Act 2019 was enacted on 26th March 2021
[398] Section 3(6) (6B) Human Tissue Act 2004 (HTA 2004), as amended by section 1(4) DCA 2019
[399] Section 3 HTA 2004 (as enacted)
[400] A person is excluded if they were not ordinarily resident in England for at least 12 months immediately prior to their death or if they had lacked capacity to understand the effect of the DCA 2019 for a significant period before their death. See section 3(9) and 3 (10) HTA 2004, as amended by section 1(5) DCA 2019

Potentially, one of the main reasons behind the lack of information may not be the government/healthcare fault, no one could have predicted that a pandemic would occur just before they amended the law. But the government could have potentially delayed the introduction of the legislation as in Scotland, instead, they chose not to, so there now needs to be a fully accessible campaign to promote the changes to the law, with targeted advertising where the public will see it. After all, with the vast majority of GPs are only just starting to do face-to-face consultations, with phone consultations still being preferred, there is no point in having posters and information leaflets there and placing them in A&E departments or on hospital wards may be seen as too late. This is where the media can play its part, there have been several studies[401] that have shown that media is a primary source of information about organ donation. Although most of this evidence is based on research from the pre-mass-Internet age, therefore the common findings that television has the greatest impact will inevitably be outdated for the millennials although, it could theoretically still apply to an older generation. Nonetheless, these studies are helpful in consistently identifying specific types of communication that tend to have favourable or non-favourable effects on public opinion toward organ donation.[402] Why has there not been a major TV advertising campaign, the government managed to do it for the Covid-19 safety campaign, yet with something as important as a change in the law I have not seen one information advert on the TV and it was only on YouTube, after purposely search for them that I finally saw them.[403] Of the available information on the NHS Blood and Transplant website I find that it is biased, it appears to be designed to convince people to donate, and it is almost as if it has been set up as an advertising website, selling the virtues of organ donation, with little information clearly given as to what would have to happen in order to facilitate the procedure. It could be said that the website is designed to nudge

[401] Catalina Conesa, Antonio Ríos Zambudio, Pablo Ramírez, Manuel Canteras, Maria Mar Rodríguez, Parrilla Paricio, Influence of different sources of information on attitude toward organ donation: a factor analysis. Transplantation Proceedings. 2004;36(5):1245-1248; Rafael Matesanz, Organ donation, transplantation, and mass media. Transplantation Proceedings 2003;35(3):987-989

[402] Susan E Morgan, Tyler R Harrison, Shawn D Long, Walid A Afifi, Michael T Stephenson, Tom Reichert, Family discussions about organ donation: how the media influences opinions about donation decisions. Clinical Transplantation 2005;19(5):674-682.
Catalina Conesa, Antonio Ríos Zambudio, Pablo Ramírez, Manuel Canteras, Maria Mar Rodríguez, Parrillal Paricio, Influence of different sources of information on attitude toward organ donation a factor analysis. Transplantation Proceedings 2004;36(5):1245-1248.

[403] Pass it on TV Advert Dec 2019 https://www.youtube.com/watch?v=DZC26ZKu6M4, Leave them certain May 2019 https://www.youtube.com/watch?v=1LQuOCPCHH8

prospective donors to agree to donate, by almost making them feel guilty if they do not agree to it.

This so-called nudge technique is a new way in which the majority of academic work and policy debate has focused on how best to address the problem of chronic organ shortage. Such debate has primarily concentrated on clarifying which strategies are best used to increase the supply of both living and deceased organ donation. The underpinning of some of this research has been based on the need to get a better understanding of donor motivation which, has recently led to greater reliance to be placed on insights drawn from behavioural sciences research, specifically, with the use of so-called nudges.[404] It has been suggested by Sharif and Moorlock[405] that nudge interventions may be a permissible way of influencing potential donors' and their families' views on organ donation to increase the likelihood of a successful donation. In their 2018 article, they argued that well-designed nudges are not manipulative in a problematic sense within this specific context and that they may lead to what we argue to be the most important wishes being respected.[406] Thaler and Sunstein defend nudging based on the claim that people are predictably irrational and therefore by nudging them towards a certain viewpoint can 'improve' people's decisions.[407] Jeremy Waldron calls nudging "an affront to human dignity (…) in the sense of self-respect, an individual's awareness of their worth as a chooser."[408]

The use of nudges can be seen within England's transplant community, the mere fact that the DCA 2019 is also known as the 'Max and Kiera's'[409] law plays not only on the potential donor's consciousness but also the relatives who may be asked about donation and their relative's views. The NHS Blood and Transplant website has a page dedicated to Kiera's

[404] Richard Thaler, Cass Sunstein, Nudge: Improving Decisions about Health, Wealth and Happiness, Penguin Books, 2009
[405] Adnan Sharif, Greg Moorlock, 'Influencing relatives to respect donor autonomy: Should we nudge families to consent to organ donation?' Bioethics, 2018-03, Vol.32 (3), p.155-163
[406] ibid
[407] Thaler (n 403)
[408] Jeremy Waldron 2014. "It's All for Your Own Good." The New York Review of Books, October 9
[409] https://www.organdonation.nhs.uk/helping-you-to-decide/real-life-stories/families-who-donated-their-loved-ones-organs-andor-tissue/keiras-story-max-and-keiras-law/

story on how her family consented to donate her organs, and how one of the recipients Max and his family, have campaigned for deemed consent. There is also a big green tick so that you can register to be a donor. I do find this ironic as the HTA 2004 which stipulated the need for consent[410] was enacted after a public inquiry into the retention of children's organs without consent by medics during the 1980s and 1990s. Yet now the government is using children to promote the removal of organs through deemed consent even though it is very unlikely to help children, because children cannot have consent deemed under the new system; it will still be required from their parents (and children cannot normally receive hearts from adults). Consequently, the default for child donors and recipients remains the same and any benefit to the paediatric population will only happen in the long term, if deemed consent improves attitudes to donation overall and more parents start to donate their child's organs.

This is not the only way in which nudges are used, throughout the website you are constantly bombarded with information selling the virtues of organ donation, all of which are designed with the main aim of increasing the potential numbers of organs for donation. Not at any point is it mentioned that there are still ongoing discussions about the validity of the definition/diagnosis of death, nor is it mentioned the possible pre/post-mortem interventions that may have to occur to facilitate the donation process.

If the above is still unsatisfactory, then the question must be asked what the alternative is. As discussed in the alternative systems chapter, there is no real prospect of there being a tissue-engineered solution anytime soon, this has been further hindered by the recent scandal involving the Italian surgeon Paolo Macchiarini. In 2020 the Italian surgeon was officially indicted for aggravated assault in Sweden, over three deadly plastic trachea transplants performed at the hospital of the Karolinska Institutet (KI). This is after he was handed a 16-month prison sentence in Italy for forging documents and abuse of office,

[410] Before the change that happened after the introduction of the DCA 2019

where he was found guilty of faking research relating to dangerous and largely discredited tracheal transplants.[411]

More recently there have been attempts to use xenotransplantation,[412]as discussed in the alternative system chapter, doctors have been trying to use animal organs for decades, with mixed success with the use of xenotransplantation hitting the headlines again.[413,414] the latest attempt involved a patient who was unsuitable for the transplant list, so his medics applied to the US Food and Drug Administration (FDA) on compassionate grounds for permission to use a genetically modified pig's heart. The heart had ten genetic changes that prevented the organ from being rejected, with four pig genes deleted and six human genes added.[415] The patient survived for two months before dying, an investigation into the death suggested that the patient died because the heart had a pig virus which attacked the heart tissue. The research stated that "it was likely that the viral infection may have been why the pig heart failed, rather than the patient's immune system rejecting the organ…There is no evidence that the virus caused an infection in the patient or infected any tissues or organs beyond the heart."[416] How and why do we still find ourselves discussing issues that were supposed sorted out nearly sixty years ago, the simple answer to this is that the public was hoodwinked in the beginning and still is. Can it be said that it was a coincidence that brain-death criteria were developed at a similar pace as organ transplant procedures? Even if this is not true, the alternative reason behind the development of brain-death criteria, reduced medical costs, and increased bed capacity is not any better. Both these reasons are not publicly promoted for obvious reasons, but should this be the case, surely the fact that

[411] Disgraced tracheal transplant surgeon is handed 16-month prison sentence in Italy, BMJ 2019;367: l6676 https://www.bmj.com/content/367/bmj.l6676

[412] Xenotransplantation is defined as any procedure that involves the transplantation, implantation, or infusion into a human recipient of live cells, tissues, or organs from a nonhuman animal source.

[413] David K C Cooper, Genetically engineered pig kidney transplantation in a brain-dead human subject. Xenotransplantation. 2021;28: e12718. https://doi.org/10.1111/xen.12718

[414] Roni Caryn Rabin, In a first, surgeons attached a pig kidney to a human, and it worked. New York Times. 2021. October 19, 2021.

[415] Michael Le Page, Man who received pig heart transplant has died after pig virus found, New Scientist, 6th May 2022 https://www.newscientist.com/article/2319108-man-who-received-pig-heart-transplant-has-died-after-pig-virus-found/#ixzz7TFtFUF39

[416] ibid

there are still grey areas surrounding the subject should be open to allow potential donors to make informed choices.

Consequently, for the system to move forward it must become more transparent, a new system should be based on honesty it should be made clear that there is still a grey area. Initially, consent should revert to informed consent. The public should be made aware of the differences in diagnosis, the tests involved, and the uncertainties discussed in this thesis. One of the main issues with the current procurement systems is that nothing is explained, medical procedures that are performed at the end of life on donors to preserve organs for transplantation, the criterion used to determine death, and the surgical procedures performed to procure organs are not disclosed. Without full disclosure of relevant information, individuals are not allowed the opportunity to make a fully informed decision. The interventions used to orchestrate a planned time, place, and method of death to secure the procurement of transplantable organs can artificially manipulate the dying process violate the physical integrity of the body are generally harmful at the end of life[417]

It is becoming more apparent that there is no credible rationale as to why the brain-dead criteria emerged. With new research starting to show that brain-dead donors, although drastically compromised neurologically[418] remain fully alive then the starting approach in assessing a patient should be to protect that person. A person who is severely compromised should be protected under Article 10 of the United Nations Convention on the Rights of Persons with Disabilities which reaffirms the interest rights to life of every human being and takes all measures to ensure its effective enjoyment by persons with disabilities on equal basis with others. We cannot say with certainty what the borderline between life and death is, therefore with this absence of certainty, we should lean over backward towards the side of possible life. Therefore, the patient ought to be treated as alive and as such is entitled to

[417] Mohamed Y Rady, Joseph L Verheijde, Campaigning for organ donation at mosques, HEC forum, 2016, Vol.28 (3), p.193-204

[418] Brain dead patients retain some brain function and more importantly they retain the ability function, in the form of circulation, respiration, metabolism, wound healing, fighting infection, going through puberty, and gestating a foetus

respect for that worth in the same way as any other living person.[419] If the living are protected from intentional and direct invasions of their bodily security by trespass laws and the like which are actionable, there is no convincing reason why this should not be the same when it comes to the rights of the living concerning what happens to their body after death.[420]

The current problems with diagnosis/definitions of death are not limited to brain-based criterion, the practice of donation after cardiorespiratory death is also on rocky grounds. The credibility of adhering to the DDR has been brought into question since one can be certain that circulation has irreversibly ceased within a few minutes after asystole. It seems that current practices on diagnosing death are based on the balance of probabilities and most of the time it almost seems as if the starting point is that the patient is dead until it is proven otherwise[421] this is wrong. Surely the starting point when considering the diagnosis of death should be the patient is living until it can be proven for make sure that patients are actually dead? This would be more compatible with the Article 2 right to life. We should ensure that life is protected especially as we are talking about the most vulnerable of society. When you consider this along with the fact that there is a growing concern that so-called cadaveric donors are not dead but are being declared dead in order to increase organ procurement. That is why I am calling for an open and fresh debate on so-called cadaveric donors which will give people the opportunity to discuss the issues highlighted in this thesis. It will also be a chance to try and answer the question, of whether would it be acceptable to remove organs from patients whose prognosis is death, and hence the removal of organs would be a contributing cause of death.

There is a limit to what a person can consent to, consent provides an objective reason for allowing a person to make choices that might involve consenting to harm, but consent is not

[419] Hans Jonas, *Philosophical essays: from ancient creed to technological man*. Englewood Cliffs, NJ: Prentice-Hall; 1974.
[420] Austen Garwood-Gowers, Ch 25 pg. 375-398 Autonomy and Human Rights in Health Care, 2008.
[421] The recent case of Archie Battersbee highlighted this when he was declared brain-stem dead based on probabilities and without the standard tests being carried out.

absolute. Consent protects personal autonomy, but it does not allow a person to degrade or destroy the human dignity of the consenting party.[422] In theory, organ donation comes under this, during the death chapter I considered the fact that based on the balance of probabilities an organ donor is not dead at the time of procurement. Therefore, by consenting to the donation they are consenting to cause intentional harm to themselves which should raise the question of why this is allowed, the only acceptable answer is that the act of organ procurement must be deemed to be 'in the public interest' and not against public policy.[423]

This situation could become acceptable if it was clearly explained to the public, there may be a drop in donor numbers but at least the ones that do would be fully aware of what they were signing up to. At the moment it feels like the medical/legal/ethical arena is allowing organ donation to take place from patients who they cannot say for certain are dead without consent. I cannot see any circumstance where implied consent, which has now been implemented,[424] can be accepted in this situation. It is bad enough that there is a chance that potential donors are unaware of the changes, especially in England, but even if they are, there is no guarantee that they know/understand the process and what is involved. Leading to the question of how any of this can be seen as valid consent.

While there are still these uncertainties, I cannot see how current procurement systems can justifiably continue, currently, organ donations are taking place without the informed consent of the donor. At the very least for the continuation of donation, the system should revert to an opt-in system. Although, not perfect, at least the potential donor had to actively join the donor list rather than being on it by default because they have not registered an objection. For a long-term solution, there needs to be a more flexible and

[422] Attorney General's Ref (No 6 of 1980); *R v Brown* [I9921 2 All ER 552 (CA); [I9931 2 All ER 75 (HL)
[423] Attorney General's Ref (No 6 of 1980), allows consent to harm for good reason such as a surgical procedure and the fact that organ donation is seen to be in the public interest might be an explanation as to why it is allowed even though there are still uncertainties
[424] An Opt-out system or implied consent is now implemented in England, Scotland, and Wales. In Northern Ireland from spring 2023, the law around organ and tissue donation in Northern Ireland will move to an opt-out system.

joined-up approach to how the medical/ethical/legal system deals with death. The approach should consider the patient's needs, and these should be a reflection on how that person lived their life it needs to include the patient's view be they spiritual, religious, or some other connotation. The idea of death needs to be normalised again, it is not just a medical term, it is part of life, and as such should be influenced by how the person led their life. For example, forcing relatives to accept a neurological diagnosis as a definition of death when this directly contravenes the patient's views could be stopped like that in New York State[425] and New Jersey.[426] Not only could this have a benefit in the organ donor sense, but it could also be applied to patients/relatives in general who are faced with end-of-life decisions. If the information is known beforehand and the current systems in the UK are changed then there may less families having to go to court to fight for their relatives' rights.

This could be said to be a libertarian view as it holds the idea that what is best for an individual should be decided by the person in question, but I would not see it as an anarchist libertarian view,[427] as there still needs to be some governmental consideration necessary for the sole purpose of protecting the rights of the people, which seems to be lacking with current procedures in place.

Putting aside the ongoing issues with death there is also the issue that some of the public in England are unaware of the recent changes to the HTA 2004 so are unaware that they are

[425] Section 400.16 - Determination of death (3) a procedure for the reasonable accommodation of the individual's religious or moral objection to the determination as expressed by the individual, or by the next of kin or another person closest to the individual.

[426] HEALTH AND VITAL STATISTICS Section 26:6A-5 - Death not declared in violation of individual's religious beliefs 26:6A-5. Death not declared in violation of individual's religious beliefs
The death of an individual shall not be declared upon the basis of neurological criteria pursuant to sections 3 and 4 of this act when the licensed physician authorized to declare death, has reason to believe, on the basis of information in the individual's available medical records, or information provided by a member of the individual's family or any other person knowledgeable about the individual's personal religious beliefs that such a declaration would violate the personal religious beliefs of the individual. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardio-respiratory criteria pursuant to section 2 of this act.

[427] An anarchist favours no governmental constraints at all. Their thinking assumes that any rules and laws are unnecessary because in the absence of government, individuals will naturally form self-governing social bonds and rules.

now seen as potential organ donors. With the introduction of the DCA 2019[428] in England every person over the age of eighteen[429] is deemed to have consented to organ donation if they have not registered an objection. How can this be right, as humans we have a right to control what happens to our bodies, which means that others do not have an automatic right to any of our body parts, no matter how great their need, even after death. Taking a utilitarian approach to organ procurement such as seen with the introduction of the DCA 2019 could increase the pool of potential organs which in turn would be of enormous benefit to patients awaiting a transplant, permitting such harm to donors cannot be justified morally, despite the great benefits that may obtain.

In this field of debate and research, there needs to be a continuing challenge to the utilitarian principle of using one person to serve a greater good, not only because it is morally justifiable to defend dignity, autonomy, and freedom of choice, but, also because as shown in this thesis there is still uncertainty over the diagnosing of death, even if there are those in the area unwilling to accept this.

[428] Organ Donation (Deemed Consent) Act 2019

[429] There are exceptions, an adult who has died and who had not been ordinarily resident in England for a period of at least 12 months immediately before dying, or an adult who has died and who for a significant period before dying lacked capacity to understand the effect of subsection are exempted.

Form for the Diagnosis of Death using Neurological Criteria {long version}

This form is consistent with and should be used in conjunction with, the AoMRC (2008) *A Code of Practice for the Diagnosis and Confirmation of Death* and has been endorsed for use by the following institutions: Intensive Care Society and the Faculty of Intensive Care Medicine.

HOSPITAL ADDRESSOGRAPH or

Surname
First Name
Date of Birth
NHS / CHI Number

Objective of Care

- To diagnose and confirm the death of a mechanically ventilated, severely brain injured patient in coma, using neurological criteria.

Academy of the Medical Royal Colleges Definition of Human Death (2008).[1]

"Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe. The irreversible cessation of brain-stem function whether induced by intra-cranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore irreversible cessation of the integrative function of the brain-stem equates with the death of the individual and allows the medical practitioner to diagnose death."

Context

- National professional guidance advocates the confirmation of death using neurological criteria wherever this seems a likely diagnosis and regardless of the likelihood of organ donation.[2]
- UK General Medical Council (GMC) guidance on end of life care (2010) states that national procedures for identifying potential organ donors should be followed and, in appropriate cases, the specialist nurse for organ donation (SN-OD) should be notified.[3] NICE guidance recommends that the specialist nurse for organ donation (SN-OD) should be notified at the point when the clinical team declare the intention to perform brain-stem death tests.[4]

  Date and time of referral to SN-OD:

- Whilst most patients will already be in an Intensive Care Unit (ICU) when the diagnosis is suspected, some patients may be in other areas, e.g. the Emergency Department. On such occasions it is legitimate, if considered necessary, to transfer a patient to the ICU for the diagnosis to be made.

- For many clinicians the diagnosis and confirmation of death using neurological criteria, will be a relatively infrequent task and may be complicated by uncertainties regarding the nature of the primary diagnosis, irreversibility and the availability of suitably experienced personnel. Updated guidance on the diagnosis and confirmation of death by neurological criteria was published by the Academy of the Medical Royal Colleges in 2008.[1] A series of helpful education videos are available https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donation-after-brainstem-death/diagnosing-death-using-neurological-criteria/.

The Patient's Close Family and Friends

Should be made aware that the purpose of testing is to confirm if the patient's death has already occurred. If given an opportunity to witness the neurological examination, they should be prepared for the possibility of spinal reflexes and their relevance, as far as the diagnosis of death by neurological criteria is concerned. Whether the patient's close family and friends witness the clinical examination or not, the patient's need for dignity, privacy and spiritual support, remain paramount.

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

Preparation

1. Evidence of Irreversible Brain Damage of known Aetiology

Case records, past medical history including possibly contacting the GP, relevant imaging.

2. Exclusion of Reversible Causes of Coma and Apnoea

Standard ICU cardio-respiratory monitoring (to ensure haemodynamic stability), medication chart and history, blood and urine drug assay results (where relevant), drug antagonists (e.g. flumazenil, naloxone), peripheral nerve stimulator, recent serum glucose and biochemistry, thermometer, patient warming device.

3. Tests for Absence of Brain-Stem Function

Brain-stem reflexes

Bright light source; small gauze sterile swabs, otoscope with disposable ear pieces, 50 ml luer lock syringe and disposable quill, ice-cold water; a spatula, Yankauer sucker or laryngoscope, endotracheal suction catheters.

Apnoea test

Haemodynamic monitoring (continuous ECG, invasive arterial pressure), arterial blood gas analysis including blood gas syringes x4, pulse oximetry and end-tidal CO_2 monitoring, means of delivering oxygen to the trachea by bulk flow (e.g. Mapleson C circuit which allows CPAP or endotracheal suction catheter and oxygen tubing).

Examining Doctors

Guidance

1. The diagnosis of death by neurological criteria should be made by at least two medical practitioners. Both medical practitioners should have been registered with the General Medical Council (or equivalent Professional Body) for more than five years and be competent in the assessment of a patient who may be deceased following the irreversible cessation of brain-stem function and competent in the conduct and interpretation of the brain-stem examination. At least one of the doctors must be a consultant. See below for special guidance in children.
2. Those carrying out the tests must not have, or be perceived to have, any clinical conflict of interest and neither doctor should be a member of the transplant team. Clinical Leads for Organ Donation can carry out testing and are likely to have significant expertise.
3. Testing should be undertaken by the nominated doctors acting together and must always be performed on two occasions. A complete set of tests should be performed on each occasion, i.e., a total of two sets of tests will be performed. Typically, Doctor One may perform the tests while Doctor Two observes; this would constitute the first set. Roles may be reversed for the second set. The tests, in particular the apnoea test, are therefore performed only twice in total.
4. Where required, four different medical practitioners can make the diagnosis **provided each pair fulfils the requirements.**

Validity of neurological criteria to diagnose death in children.

- **Older than 2 months:** guidance as per adult testing forms. Recommended paediatric form available.
- **Between thirty seven weeks corrected gestation (post menstrual) age to 2 months of age post term:** use the RCPCH Guidance available at www.rcpch.ac.uk. Form available.
- **Infants less than 37 weeks corrected gestation (post menstrual) age:** the concept of 'brain-stem death' is inappropriate for infants in this age group.

In addition to the usual requirement (as given above) that one of the examining doctors is a consultant, additionally in children, one of the doctors should normally be a paediatrician or should have experience with children and one of the doctors should not be primarily involved in the child's care.

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

Evidence of Irreversible Brain Damage of known Aetiology

Primary Diagnosis:

Evidence of Irreversible Brain Damage of known Aetiology:

Diagnostic caution is advised in the following 'Red Flag' patient groups. Consider the need to delay testing and/or perform ancillary investigations. For advice in difficult circumstances contact the local or regional Clinical Lead for Organ Donation or the regional neuro-intensive care unit.

1. Testing **less than 6 hours** of the loss of the last brain-stem reflex
2. Testing **less than 24 hours** of the loss of the last brain-stem reflex, where aetiology primarily anoxic damage
3. **Hypothermia** 24 hour observation period following re-warming to normothermia recommended
4. Patients with any **neuromuscular disorders**
5. **Steroids** given in space occupying lesions such as abscesses
6. Prolonged **fentanyl** infusions
7. Aetiology **primarily** located to the **brain-stem or posterior fossa**
8. Therapeutic **decompressive craniectomy**

Red Flag Present? **Yes / No**

If YES, document how the **Red Flag** was mitigated:

Guidance

1. The patient must have a Glasgow Coma Score of 3 and be mechanically ventilated with apnoea.
2. There should be no doubt that the patient's condition is due to irreversible brain damage of known aetiology.
3. It remains the duty of the two doctors carrying out the testing to be satisfied with the aetiology, the exclusion of all potentially reversible causes, the clinical tests of brain-stem function and of any ancillary investigations; so that each doctor may independently confirm death following irreversible cessation of brain-stem function.
4. It may take a period of continued clinical observation and investigation (e.g. neuroimaging or neurophysiological evidence) to be confident of the irreversible nature of the prognosis. The timing of the tests should be appropriate for the reassurance of all those directly concerned. If in doubt, wait and seek advice.
5. It is recommended that there is a minimum of twenty-four hours, of continued clinical observation, in patients where anoxic damage, following cardiorespiratory arrest, is the aetiology of the brain injury. If prior treatment of the patient has included induced hypothermia, it is recommended that there is a minimum of twenty-four hours, of continued clinical observation, following re-warming to normothermia. See above for 'Red Flag' patient groups.
6. Stabilisation of the patient prior to testing, especially support of the cardiovascular system, is a prerequisite to testing. Mean Arterial Pressure should be consistently greater than 60mmHg and appropriate fluid resuscitation administered. This almost invariably requires the use of inotropes / vasopressors via central venous access.
7. Diabetes insipidus can develop rapidly and should be suspected in patients with a high urine output (typically greater than 100 mls/hr) and rising Na^+. Matched urinary and plasma electrolytes and osmolality may assist in the diagnosis. Treatment with desmopressin, 1-2 mcg boluses, is usually sufficient for treatment but repeated doses or vasopressin infusion may be required. Serum sodium should ideally be maintained between 140-160mmol/L.

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

Exclusion of Reversible Causes of Coma and Apnoea

Guidance
Attempts should be made to maintain relatively normal cardiovascular and respiratory physiological parameters in the preceding hours prior to testing.
This may not be possible and does not necessarily preclude testing.

The key question the two doctors must exclude is the possibility that cardiovascular and respiratory instability is the cause of the observed coma and apnoea.
The answer should be no.

	1st Test		2nd Test	
Mean arterial pressure at time of testing? Should be consistently greater than 60mmHg prior to testing.	mmHg		mmHg	
$PaCO_2$ at time of testing? A goal of normocarbia ($PaCO_2$ less than 6.0 kPa), *if possible*, is recommended in the preceding hours prior to testing. See below for *starting $PaCO_2$ in the apnoea test.*	kPa		kPa	
PaO_2 at time of testing? Hypoxia (PaO_2 less than 10 kPa) should be avoided *if possible.*	kPa		kPa	
Arterial pH/$[H^+]$ at time of testing? Acidaemia and alkalaemia should be avoided, *if possible*, aiming for a relatively normal pH 7.35 –7.45 / $[H^+]$ 45-35 nmols/L.	pH/$[H^+]$=		pH/$[H^+]$=	
Is the coma or apnoea due to ongoing cardiorespiratory instability? **(To diagnose death using neurological criteria, ALL answers should be NO)**	**Dr One** **Yes / No**	**Dr Two** **Yes / No**	**Dr One** **Yes / No**	**Dr Two** **Yes / No**

Guidance
It remains the duty of the two doctors carrying out the testing to be satisfied that sufficient time has elapsed to ensure that any remaining drug effect is non-contributory to the unconsciousness and loss of brain-stem reflexes. The patient should therefore not have received any drugs that might still be contributing to the unconsciousness, apnoea and loss of brain-stem reflexes (narcotics, hypnotics, sedatives or tranquillisers); nor should they have any residual effect from any neuromuscular blocking agents (atracurium, vecuronium or suxamethonium). This will be based on an assessment of the medications the patient has received and from knowledge of the pharmacokinetics of these agents. Renal or hepatic failure may prolong metabolism / excretion of these drugs.
Consider: dose, duration, drug clearance, need for antagonist / drug levels. See also above for 'Red Flag' patient groups.

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

	1st Test		2nd Test	
Where there is any doubt, specific drug levels should be measured (midazolam should be less than less than 10mcg/L, thiopentone less than 5mg/L).	Drug levels (if measured):		Drug levels (if measured):	
Antagonists such as flumazenil, naloxone and neostigmine may be used but there is no specific pharmacological data for predicting the dose effect of these antagonists.	Drug antagonists (if used):		Drug antagonists (if used):	
Residual neuromuscular blockade can be tested for, if felt necessary, by peripheral nerve stimulation.	Train of Four (if measured):		Train of Four (if measured):	
Is the coma or apnoea due to depressant drugs? **(To diagnose death using neurological criteria, ALL answers should be NO)**	**Dr One Yes / No**	**Dr Two Yes / No**	**Dr One Yes / No**	**Dr Two Yes / No**
Body temperature at time of testing? If core temperature is less than or equal to 34°C testing cannot be carried out.		°C		°C
Serum sodium (Na^+) at time of testing? Serum sodium should be between 115-160mmol/L. Rapid rises or falls in Na^+ should be avoided.		mmol/L		mmol/L
Serum potassium (K^+) at time of testing? Serum potassium should be greater than 2mmol/L.		mmol/L		mmol/L
Serum phosphate (PO_4^{3-}) at time of testing? Serum phosphate should not be greater than 3.0mmol/L or less than 0.5mmol/L.		mmol/L		mmol/L
Serum magnesium ($Mg2^+$) at time of testing? Serum magnesium should not be greater than 3.0mmol/L or less than 0.5mmol/L.		mmol/L		mmol/L
Blood glucose at time of testing? Blood glucose should be between 3.0-20.0 mmol/L and should be tested prior to each test.		mmol/L		mmol/L
If there is any clinical reason to expect endocrine disturbances hormonal assays should be undertaken.	Hormone level (if measured):		Hormone level (if measured):	
Is the coma or apnoea due to a metabolic or endocrine disorder? **(To diagnose death using neurological criteria, ALL answers should be NO)**	**Dr One Yes / No**	**Dr Two Yes / No**	**Dr One Yes / No**	**Dr Two Yes / No**

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

Guidance
It remains the duty of the two doctors carrying out the testing to be satisfied that the only explanation for the respiratory failure is due to the irreversible cessation of brain-stem function. A train of four examination, using a peripheral nerve stimulator, may be required. See above for 'Red Flag' patient groups.

	Test 1		Test 2	
Is the apnoea due to neuromuscular blocking agents, other drugs or a non brain-stem cause (*eg.* cervical injury, any neuromuscular weakness)? (ALL answers should be NO)	**Dr One Yes / No**	**Dr Two Yes / No**	**Dr One Yes / No**	**Dr Two Yes / No**

Tests for Absence of Brain-Stem Function

Guidance: A complete set of tests should be performed on each occasion, i.e., a total of two sets of tests will be performed. Doctor One may perform the tests while Doctor Two observes; this would constitute the first set. Roles may be reversed for the second set. The tests, in particular the apnoea test, are therefore performed only twice in total.

	Test 1		Test 2	
	Dr One Examining	**Dr Two** Observing	**Dr One** Observing	**Dr Two** Examining
Do the pupils react to light? The pupils are fixed and do not respond to sharp changes in the intensity of incident light. Cranial nerves II, III.	**Yes / No**	**Yes / No**	**Yes / No**	**Yes / No**
Is there any eyelid movement when each cornea is touched in turn? Corneal reflex - Cranial nerves V,VII. The use of sterile gauze is recommended.	**Yes / No**	**Yes / No**	**Yes / No**	**Yes / No**
Is there any eye movement seen during or following the slow injection of at least 50mls ice cold water over 1 minute into each ear with the head flexed at 30°? Each ear drum should be clearly visualised before the test. Vestibulo-ocular reflex - Cranial nerves III VI VIII.	**Yes / No**	**Yes / No**	**Yes / No**	**Yes / No**
Is the gag reflex present? Use a spatula or Yankauer sucker or laryngoscope to stimulate the posterior pharynx. Cranial Nerves IX, X.	**Yes / No**	**Yes / No**	**Yes / No**	**Yes / No**
Is the cough reflex response present when a suction catheter is passed down the trachea to the carina? Cranial Nerves IX, X.	**Yes / No**	**Yes / No**	**Yes / No**	**Yes / No**
Is there any motor response in a cranial nerve or somatic distribution when supraorbital pressure is applied? Cranial Nerves V,VII. Reflex limb and trunk movements (spinal reflexes) can be present.	**Yes / No**	**Yes / No**	**Yes / No**	**Yes / No**

Brain-Stem Reflexes

To diagnose death using neurological criteria, ALL answers should be NO

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

Tests for Absence of Brain-Stem Function

Preparation for the Apnoea Test

- Oxygenation and cardiovascular stability should be maintained through each apnoea test. Pre-oxygenate FiO_2 1.0.
- Allow $PaCO_2$ to rise to at least 6.0 kPa by reducing the minute ventilation prior to commencing the apnoea test. End tidal carbon dioxide can be used to guide the starting of each apnoea test but should not replace the pre and post arterial $PaCO_2$.
- Cardiac pulsation may be sufficient to trigger supportive breaths if the patient remains connected to the mechanical ventilator and on a spontaneous breathing mode. Performing the apnoea test whilst remaining on mechanical ventilation is not recommended.

Guidance

- Use a CPAP circuit (eg Mapleson C).

Apnoea Test (the apnoea test is performed only twice in total)

	1st Test		2nd Test	
Arterial Blood Gas PRE apnoea test: Confirm **$PaCO_2$ is at least 6.0 kPa** but not substantially greater. In patients with chronic CO_2 retention, or those who have received intravenous bicarbonate, it recommended that $PaCO_2$ is allowed to rise to above 6.5 kPa.	Starting $PaCO_2$: kPa Should be greater than or equal to 6.0 kPa		Starting $PaCO_2$: kPa Should be greater than or equal to 6.0 kPa	
PRE Arterial Blood Gas pH/[H^+]: Confirm **pH less than 7.4** or **[H^+] greater than 40 nmol/L.**	pH/[H+]= pH should be less than 7.4 / [H+] should be greater than 40nmol/L		pH/[H+]= pH should be less than 7.4 / [H+] should be greater than 40nmol/L	
Start time: Time when apnoea test was commenced.	hr : min (24 hour clock)		hr : min (24 hour clock)	
Arterial Blood Gas POST apnoea test: Ensure the **$PaCO_2$ has increased by greater than 0.5 kPa.**	Stopping $PaCO_2$: kPa Should have increased by greater than 0.5		Stopping $PaCO_2$: kPa Should have increased by greater than 0.5	
Stop time: Time when apnoea test was ceased.	hr : min (24 hour clock) *Perform lung recruitment*		hr : min (24 hour clock) *Perform lung recruitment*	
Was there any spontaneous respiration during a minimum of 5 (five) minutes continuous observation following disconnection from the ventilator? **(To diagnose death using neurological criteria, ALL answers should be NO)**	**Dr One** **Yes / No**	**Dr Two** **Yes / No**	**Dr One** **Yes / No**	**Dr Two** **Yes / No**

Considerable atelectasis develops in the apnoeic period. At the conclusion of the apnoea test, manual recruitment manoeuvres should be carried out before resuming mechanical ventilation.

Form for the Diagnosis of Death using Neurological Criteria
{long version}

Ancillary Investigations Used to Confirm the Diagnosis

Guidance
Ancillary investigations are **NOT** required for the diagnosis and confirmation of death using neurological criteria.
They may be useful however, where neurological examination is not possible (eg. extensive facio-maxillary injuries, residual sedation and some cases of paediatric hypoxic brain injury), where a primary metabolic or pharmacological derangement cannot be ruled out or in cases of high cervical cord injury, or where spontaneous or reflex movements in the patient generate uncertainty over the diagnosis. In such cases a confirmatory test may reduce any element of uncertainty and possibly foreshorten any period of observation prior to formal testing of brain-stem reflexes.
Any ancillary or confirmatory investigation should be considered **ADDITIONAL** to the fullest clinical testing and examination (as outlined above) carried out to the best of the two doctors capabilities in the given circumstances.
The utility of any additional investigation is for the testing doctors to decide and they should seek further professional opinion from other specialities and other expert centres, where appropriate.
Some possible ancillary investigations are:

- Clinical
  - Rotation of the head to either side should not produce any eye movement (absent doll's eyes response). This should NOT be performed if there is suspected or known cervical spine injury.
  - Administration of 2mg atropine should not lead to an increased heart rate (more than 3%).
- Neurophysiological demonstration of loss of bioelectrical activity in the brain (EEG, evoked potentials).
- Radiological demonstration of absent cerebral blood flow or brain tissue perfusion (CT angiography, 4 vessel angiography, transcranial doppler).

The interpretation of ancillary investigations is complex and their availability usually restricted to neurological centres.

Helpful references on ancillary testing

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2. Young & Lee (2004) "A critique of Ancillary Tests for Brain Death." *Neurocritical Care;* 1:499-508.
3. Heran, Heran & Shemie (2008) "A review of ancillary tests in evaluating brain death." *Can J Neurol Sci*; 35:409–19.

	1st Test		2nd Test	
Is there a need for any ancillary investigations?	Dr One Yes / No	Dr Two Yes / No	Dr One Yes / No	Dr Two Yes / No
If yes please outline the results of these investigations:				

Form for the Diagnosis of Death using Neurological Criteria {long version}

Patient Name: **NHS / CHI Number:**

Document any required Clinical Variance from AoMRC (2008) Guidance

Completion of Diagnosis				
	Test 1		Test 2	
Are you satisfied that death has been confirmed following the irreversible cessation of brain-stem-function?	**Dr One** **Yes / No**	**Dr Two** **Yes / No**	**Dr One** **Yes / No**	**Dr Two** **Yes / No**
Legal time of death is when the 1st Test indicates death due to the absence of brain-stem reflexes. Death is confirmed following the 2nd Test.	**Date:** **Time:** Dr One *Name* *Grade* *GMC* *Signature* Dr Two *Name* *Grade* *GMC* *Signature*		**Date:** **Time:** Dr One *Name* *Grade* *GMC* *Signature* Dr Two *Name* *Grade* *GMC* *Signature*	

References & Resources

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2. Report from the Organ Donation Taskforce (2008) "Organs for Transplant" www.dh.gov.uk
3. GMC (2010) "Treatment and care towards the end of life." www.gmc-uk.org
4. NICE (2011) "Organ Donation for Transplantation" http://guidance.nice.org.uk/CG135
5. Gardiner D, Shemie S, Manara A & Opdam H (2012) "International perspective on the diagnosis of death" BJA 108 Suppl 1:i14-28. BJA 108 Suppl 1:i14-28.
6. A series of helpful education videos are available: https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donation-after-brainstem-death/diagnosing-death-using-neurological-criteria/.

Form authorship and feedback

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Form for the Diagnosis of Death using Neurological Criteria {long version}

Attach Arterial Blood Gases

Additional NOTES

Cases:

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Bart's Health NHS Trust v Dance and Others [2022] EWHC 1435 (Fam)

Bolam v Friern Hospital Management Committee [1957] 1 WLR 582

Bolitho v City and Hackney Health Authority [1997] 4 All ER 771

Dance & Battersbee (respondents/appellants) v Bart's Health NHS Trust (applicant/respondent) Court of Appeal Civil Division Court 71 30th June 2022

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Polat v Austria Application No 12886/16, Merits, 20 July 2021; ECtHR,

Pretty v The United Kingdom App no. 2346/02 (ECHR)

Sidaway v Bethlem Royal Hospital Governors [1985] AC 871

R v Malcherek and Steel [1981] 2 All ER 422

Re A [1992] 3 Med LR 303

Re A (A Child) (withdrawal of life support) [2015] EWHC 443 (Fam)

Re T (Adult: Refusal of Treatment) [1993] Family Law 93

Winkfield v. Children's Hospital Oakland et al. Case No: C 13-5993 In: California Northern District Court Oakland Division

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